Optimising Physiotherapy Assessment of Trauma Patients in the Acute Hospital Setting

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Submitted in total fulfilment of the requirements of the Degree of

Master of Applied Science

April 2020

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Abstract

Traumatic injury is a global public health problem, with ongoing impact on health and quality of life for many of those who survive. There is increasing understanding of longer-term outcomes for survivors, however little is known about early recovery in the acute hospital setting. Physiotherapists are key team members involved in the assessment and early rehabilitation of trauma patients in acute care, with the aim of improving physical and functional outcomes. However, the roles and responsibilities of physiotherapists in acute trauma care are not well defined, and the impact of physiotherapy interventions is inconsistently measured and poorly understood. The aim of this thesis was to improve the understanding of physiotherapy for adult trauma patients in the acute setting and explore the measurement of physical outcomes. This involved a benchmarking survey, systematic review and prospective study to test key clinimetric properties of four outcome measures.

A benchmarking survey (n= 25, 92% response rate) showed that there is great variation in physiotherapy service delivery across Australian and New Zealand adult major trauma services, with minimal use of any routine outcome measures. A systematic review (n=37 included papers reporting on six instruments) highlighted how little evidence exists regarding the clinimetric properties of outcome measures related to mobility and physical function in acute trauma patients. In a prospective study (n=100 participants), four measures of mobility and physical function demonstrated excellent reliability, validity and responsiveness, but differed in feasibility and floor/ceiling effects.

This research provides physiotherapists working in acute trauma care with new information regarding the clinimetric properties and clinical relevance of outcome

measures related to mobility and physical function. This may facilitate routine measurement of outcomes, allow more comprehensive benchmarking and collaboration, enhance understanding of the impact of physiotherapy interventions and ultimately improve short and long-term patient outcomes for those who experience trauma.

Statement of Authorship

"This thesis includes work by the author that has been published or accepted for publication as described in the text. Except where reference is made in the text of the thesis, this thesis contains no other material published elsewhere or extracted in whole or in part from a thesis accepted for the award of any other degree or diploma. No other person's work has been used without due acknowledgment in the main text of the thesis. This thesis has not been submitted for the award of any degree or diploma in any other tertiary institution."

29th March 2020

SCOP

Publications during Enrolment

The thesis includes three original papers: two published and one submitted for publication, all of which included co-authors.

- Calthorpe S, Kimmel LA, Webb MJ and Holland AE. A benchmarking project of physiotherapy in Australian and New Zealand adult major trauma services. New Zealand Journal of Physiotherapy 2016,44(3):148-156. DOI: 10.15619/NZJP/44.3.04
- Calthorpe S, Kimmel LA, Webb MJ, Gabbe BJ and Holland AE. Measurement of mobility and physical function in hospitalised trauma patients: A systematic review of instruments and their measurement properties. Trauma 2020, Vol. 22(1) pp 7–17. DOI: https://doi.org/10.1177/1460408619879326
- Calthorpe S, Kimmel LA, Fitzgerald M, Webb MJ and Holland AE. The Reliability, Validity, Feasibility and Responsiveness of Measures for Assessing Mobility and Physical Function in Patients following Traumatic Injury in the Acute Hospital Setting: A Prospective Study. Submitted to Physical Therapy Journal 29/03/20

My contribution to the work is described prior to each chapter they are presented in.

Acknowledgements

To Professor Anne Holland. We met unexpectedly during a randomised controlled trial which inadvertently kick started my research career! Since then you have become my main supervisor and more importantly, you have been a constant support and true inspiration. Thank you for always being able to explain things so I could understand them, and for your prompt advice and feedback. Nothing ever seemed too much trouble. I am so grateful for everything you have done for me.

To the "Alfred angels" duo and original trauma physiotherapists Melissa Webb and Lara Kimmel (who also took on the co-supervisor role). Thank you for welcoming me into your team 11 years ago and for all your support since both professionally and beyond. You taught me so much and your passion to improve trauma patient care never fades. I could never have achieved this without your constant guidance.

Thank you to the physiotherapy department at The Alfred Hospital for being so flexible in covering my caseload and for the many coffees and words of support when required. In particular, thank you to my ICU stream leaders Carol Hodgson and Scott Bradley, ever inspiring and supportive. And to my postgraduate research gang Claire, Kate, Jac and Ben, even our brief corridor conversations and moral support always meant so much.

Mum and Dad, you have always encouraged me to achieve as much as I can in life, which is partly how I have ended up on the other side of the world completing this degree! Thanks for all your support, despite the many miles between us...please know I think of you often and miss you always.

And most importantly to my husband Anthony. Who knows why I never considered doing this before we had the boys (?!) but thank you for your patience and support throughout. I could never have done it without you being such an amazing and capable dad. And to my boys Peter and Henry, I hope one day this achievement makes you proud and thanks for understanding as I missed out on family time to focus on this. Your ever-smiling faces and hugs on my return have always made it worthwhile.

This work was supported by an Australian Government Research Training Program Scholarship.

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List of abbreviations

ACIF- Acute Care Index of Function

AIS- Abbreviated Injury Scale

AMPAC "6 Clicks"- Activity Measure for Post-Acute Care "6 Clicks" Short Forms

COSMIN- COnsensus-based Standards for the selection of health Measurement

INstruments

DVT- Deep vein thrombosis

EMP- Early mobility protocol

FIM- Functional Independence Measure

ISS- Injury Severity Score

IQR- Interquartile range

ICU- Intensive Care Unit

ICC- Interclass correlation coefficient

LOS- Length of stay

MTS- Major Trauma Service

mILOA- modified Iowa Level of Assistance Score

PE- Pulmonary embolus

PM&R- Physical Medicine and Rehabilitation Physician

RR- Risk ratios

SCI- Spinal Cord Injury

SD- Standard deviation

TBI- Traumatic Brain Injury

US- United States of America

UK- United Kingdom

Chapter 1: Introduction

Background

Definition of trauma and injury

"Trauma" describes the disease entity relating to physical injury of the body [1] and may include fractures, soft tissue or vascular injuries, contusions, organ injury and the secondary complications relating to these. Injuries may range from minor to life-threatening, and for those with physical trauma, psychological sequalae may also be experienced [2].

Across the world, the main causes of trauma include violence against others or oneself; road traffic crashes and falls [3]. The injury occurs as a direct result of forces from outside of the body, which are either blunt (such as with a motor vehicle accident, fall or crush injury), or penetrating (such as a knife or gunshot injury) [2]. It is usually described according to the body region of injury, and whether it occurs in isolation or in combination with other injuries. Examples of common isolated injury groups include spinal cord injury, traumatic brain injury, orthopaedic injury (broken bones and/or muscle/ ligament injury) and chest trauma (including fractures ribs, pulmonary contusion and pneumothorax/haemothorax). For medical and research purposes, the severity of injury is also defined by calculating an injury severity score (ISS), based on the abbreviated injury scale (AIS) classification for each injury. An ISS of >12 is defined as major trauma in Australia and New Zealand [4] and >15 as major trauma in England and Wales [5, 6] and the United States of America (US) [7, 8], with scores lower than these often described as minor trauma. Those with injury

to more than one body region may also be described as a multitrauma or polytrauma patient, but exact consensus on these definitions does not exist in the literature [9]. This thesis will mainly focus on adults (defined as ≥18 years) following traumatic injury, describing those admitted to hospital as trauma patients (encompassing major/ multi and minor trauma unless otherwise stated). Patients following isolated fractured neck of femur were not the focus of the work in this thesis as they often have a different clinical course and demographic characteristics, and are frequently excluded [10].

Burden of trauma and injury

Traumatic injury is a global public health problem. Every six seconds someone in the world dies as a result of an injury, equating to five million deaths/year or 9% of the world's total deaths [3]. It has a particular impact on young people, accounting for more than 25% of deaths for people aged 15-29 years [3]. These numbers are predicted to rise by 2030, as road traffic injuries and falls increase as leading causes of death [3]. Australian specific data reveals a similar picture, with injury related deaths accounting for just over 8% of all deaths (or 13,000 people) in 2016-17. Deaths from injury are highest in younger people, accounting for over 60% of deaths in 15-24 year olds and 40% in 25-44 year olds (due to suicide, accidental poisoning and land transport accidents) [11]. There were also over 460,000 hospitalisations for injury in 2016-17, of which 41% were due to falls, followed by road traffic accidents (12%) [12]. Gross disparity in mortality exists between low- and higher-income countries which may relate to the severity of an injury, but also other factors such as access to health care services. For example, mortality from life-threatening but survivable injury may vary from 36% in a low income setting to just 6% in a high income setting [13].

Deaths only represent a small fraction of those injured, as tens of millions more suffer non-fatal injuries, responsible for 6% of all years lived with temporary or permanent disability [3]. These figures show that deaths represent only the tip of an "injury pyramid" (a graphical representation of the burden of injury), where for every death, more are hospitalised and countless more again attend emergency departments [14], with ever increasing numbers [15]. Their care consumes a significant amount of public funding, with estimations in the region of US\$518 billion/year globally for road traffic injury related healthcare costs alone [16].

For those who survive injury, the impact on health and quality of life is increasingly recognised across the recovery trajectory. At six months after severe injury, various longitudinal cohort studies (n= 376 to 1962 patients) have revealed ongoing physical limitations (in 27-62% of patients); anxiety and depression (20-43%); pain and discomfort (52%); self-care issues (27-37%) and being unable to return to work (41-50%) [17-20]. These symptoms and issues have been found to persist in a proportion of patients at 12 months [18, 21, 22]; 24-36 months [18, 23, 24]; 4 years [25]; 5 years [26]; 6 years [27] and even 12 years after injury [28]. With this increasing awareness, some even advocate for traumatic injury to be recognised as a chronic disease in a proportion of cases [18]. A recent scoping study found that the number of publications relating to patient reported outcomes in trauma was 28 times higher in 2015 than in 1985 [29], demonstrating the increasing recognition of the impact of trauma on the lives of those who experience it. While the impacts on physical, psychosocial and emotional wellbeing have been clearly demonstrated in research literature, these factors are often not routinely measured for individual patients in clinical practice. The work in this thesis aims to address some of these gaps in practice with a focus on the acute hospital setting.

Systems of trauma care worldwide

Development of the infrastructure, resources and policies to better manage and care for patients after traumatic injury began in the military setting in the US over 70 years ago. These principles of care evolved to the civilian setting after the publication of the report "Accidental Death and Disability – The Neglected Disease of Modern Society" [30], which stimulated research and provided evidence that some deaths were preventable with better medical care [31]. This led to the American College of Surgeons establishing criteria for the designation of trauma centres (from level I to level IV) and defined systems of care [1]. The systems are based around regional, coordinated networks of definitive care facilities that can provide the spectrum of care for all injured patients. Over time, the criteria have been refined and evolved into modern consensus-based recommendations and guidelines [32, 33], which have been the reference standard for the development of numerous trauma systems around the world, including Australia.

Since the driving force behind these systems was reducing mortality, monitoring mortality as a way to measure improvements was essential. As a result, it is now well recognised that the implementation of trauma systems of care in higher income countries has reduced mortality over time [34-41]. A recent systematic review and meta-analysis concluded trauma systems may take up to 10 years to fully mature, over which time the mortality reduction may be as high as 30% [42]. As these mature systems continue to evolve it is possible there may be some further reduction in mortality, but it is predicted to be small as absolute numbers of preventable deaths are low [43]. There is therefore a need to broaden the focus of system measurement towards quality of survival [43, 44], both in the short and longer-term. This would enable further understanding of the burden of

injury, allow benchmarking of practice across systems and facilitate the investigation of interventions aimed at improving function and quality of life for survivors.

There is some evidence that overall physical function outcomes may be improved in mature trauma systems, even though patients now survive severe injuries that would have previously resulted in death. Two large US studies using registry data (from the National Trauma Databank) found that patients who had sustained severe injuries (n=12,254) had significantly better odds of improved mobility and function at acute hospital discharge with less severe disability if managed at a major trauma service (incidence 20.3%), compared to a non-major trauma service (incidence 33.8%; adjusted odds ratio 0.54; 95% confidence interval 0.44-0.68) [45], and a higher likelihood of total independence at discharge (n=474,024) [46]. Another two studies reported functional outcomes at 12 months after injury. One study from Australia found lower odds of a better functional outcome in major trauma patients managed at non-major trauma services (adjusted odds ratio 0.82; 95% confidence interval 0.69-0.97) compared with major trauma services (p=0.021) [47]. A study from the US found that those with severe highenergy lower-limb trauma had significantly better physical function at 12 months if managed at a major trauma compared with a non-major trauma service (p<0.001) [48]. The reasons for these findings are unknown, but may relate to the expertise within surgical specialities and rehabilitation teams [48], as well as dedicated trauma allied health teams [47]. Despite these interesting results all published more than 12 years ago, little additional work has been done to understand the functional outcomes of patients following trauma. It should also be noted that the US National Trauma Databank has not collected any functional outcomes at hospital discharge since 2007. The work in this thesis will help contribute new

information to address some of these gaps by exploring how patient outcomes should be measured in clinical practice to better understand early recovery.

The Australian context

The work contained in this thesis was undertaken at the Alfred Hospital, a major trauma service in the state of Victoria, Australia. Australia has a close collaboration with New Zealand with regards to trauma patient care, both having trauma systems based on the previously described US trauma system principles, with management of patients across the spectrum of injury severity by networks of hospitals. Those with known or suspected severe injury are managed at major trauma centres (all level I equivalent, and designated as an adult and/or paediatric centre), with well-defined and developed retrieval patterns to expedite transfer to the nearest appropriate centre [49]. Trauma patient admission to the acute hospital may be for less than 24 hours to a few days, or even many months. It may include general ward based observational care only, to surgical intervention and even an Intensive Care Unit (ICU) stay if further life-supporting therapy is required. Some patients return home directly from the acute hospital, whilst others may require ongoing inpatient rehabilitation or longer-term care. In 2017-18, adult major trauma patients (ISS >12) managed at Australian and New Zealand major trauma centres had a mortality rate of 9.9%; median acute hospital length of stay of seven days, with 36% requiring an Intensive Care Unit admission (for a median of 3.7 days). After discharge from the acute hospital, 62% of patients returned home, whilst 24% required ongoing inpatient rehabilitation [50]. In Australia and New Zealand hospitals, physiotherapists are usually members of a broader allied health team providing care for patients in the acute setting. Physiotherapists perform a thorough assessment and can deliver interventions

targeting cardiorespiratory, musculoskeletal and neurological systems [51], with a focus on improving mobility and physical function. Trauma patients perceive physiotherapists as pivotal in commencing early rehabilitation processes, providing expert knowledge, advice, exercises, reassurance and encouragement, whilst also promoting coping strategies to facilitate recovery [52, 53].

Despite this, little is known about the roles and responsibilities of physiotherapists within adult major trauma centres in Australia and New Zealand. This is in contrast to other medical/ surgical specialities [54] and nursing [55, 56], where their roles in trauma care have been extensively documented. To address this gap, a survey to benchmark physiotherapy practice, roles and responsibilities was designed and distributed to all adult major trauma centres in Australia and New Zealand. This project is reported in Chapter 2 of the thesis.

Trauma patient rehabilitation in the acute hospital setting

Rehabilitation is the care required when a person is experiencing limitations of everyday functioning that may be due a health disorder (such as an acute or chronic disease), ageing or injury [57]. It is a process of assessment, treatment and management by which individuals (and their family/ carers) are supported to achieve their maximum potential for physical, cognitive, social and psychological function, participation in society and quality of living [58]. It usually includes interventions provided by rehabilitation professionals such as physiotherapists, occupational therapists, psychologists and rehabilitation medicine doctors.

Rehabilitation was recognised as a global health priority by the World Health Organization in 2017, as it is seen as key to tackling critical emerging health trends and global demographics (such as an ageing population and rising rates of

chronic disease), yet is often underdeveloped, under-resourced and undervalued [59]. In acute hospitals settings the integration, access to, and models of rehabilitation vary worldwide from non-existent to well-integrated outreach and shared care teams [60, 61]. However for trauma patients in acute care, rehabilitation services are often not well-developed or studied, given the historical focus of acute trauma care has emphasised saving lives and achieving medical stability. Exceptions may exist in some countries, and the UK trauma system is an example where the British Society of Rehabilitation Medicine has been included in the development, ensuring the inclusion of rehabilitation as a critical component of the acute care pathway, including the completion of a "rehabilitation prescription" within 24-48 hours of acute hospital admission with traumatic injury [62]. Clearly defined rehabilitation pathways also exist in the UK, including hyper-acute rehabilitation services (dedicated rehabilitation beds located in acute care settings) which have most commonly been investigated in patients with traumatic brain injury [63-66]. However, consistency of access and provision of rehabilitation across the UK is still limited [67], particularly for those groups outside of the commonly defined "specialist" rehabilitation cohorts (including patients following Spinal Cord Injury, limb amputations and Traumatic Brain Injury).

Rehabilitation for patients in intensive care (including trauma patients) is increasingly accepted as a core element of good care, with meta-analysis of clinical trials suggesting improved patient outcomes and reduced mortality [68]. There has also been increasing interest in the role of early rehabilitation for patients following trauma in the acute hospital ward setting, but the evidence base is not well developed [69, 70]. There are seven recent studies (in the last 10 years) describing early rehabilitation in patients following trauma outside of the

intensive care setting, which are summarised in Table One. These mostly tested various interventions including earlier mobilisation rather than bedrest; more intensive physiotherapy; earlier input by specialist multi-disciplinary rehabilitation teams and physical medicine and rehabilitation specialist input. The measurement of the effects varied from patient related outcomes (such as the level of assistance required to complete daily activities and number of in-hospital complications), to hospital length of stay and health system costs. Overall, these studies show that trauma patient mobility may improve more quickly with early mobility or more intensive physiotherapy; or be no different with early multidisciplinary rehabilitation teams and physical medicine and rehabilitation specialist input. Acute hospital length of stay is usually reduced (ranging from 0.7 days to 3 days fewer in hospital) and where statistical significance is not reached, a cost saving per patient may be observed (when calculated). However, only three of the studies are level II randomised controlled trials (according to the National Health and Medical Research Council grading system [71]), with the remainder only level III, due to retrospective study design and small sample sizes. Only two of the studies included any measure of patient mobility and physical function using two different measurement instruments, which further restricts the ability to compare these outcomes across studies. The measurement of mobility and physical function in trauma patients will therefore be explored in detail in the following section.

Table 1: Studies including early mobility or rehabilitation in trauma patients

Study author and year published	Type of Study	Patient population, numbers and study characteristics	Outcome/s	Results	Considerations for interpretation/ Level of Evidence
Kimmel 2012	Single-centre, randomised controlled trial	Isolated ankle fractures requiring surgical intervention admitted to a MTS 2 groups: 1) Control group (bedrest with limb elevation until day 2 post-operatively) n=53 2) Intervention group (early mobilisation day 1 post-op) n=51	Hospital LOS and surgical wound condition at 10-14 days post-op	Reduced hospital LOS in intervention group (2.3 days vs. 3 days; p<0.0001) with no increase in wound complications	Single-centre Level II
Calthorpe 2014	Single-centre, randomised controlled trial	Adult trauma patients admitted to a MTS 2 groups: 1) Control group (usual physiotherapy care once/day) n=44 2) Intervention group (more physiotherapy intervention aiming 3 times/day) n=43	Mobility score (Modified lowa Level of Assistance score, 0-36) at day 3: Modified lowa Level of Assistance score at day 5:	Better in the intervention group: median 7 points (1-15) vs. 10 points (4-19); p=0.02 Better in the intervention group: median 7.5 points (2-15) vs. 16 points (4-24); p=0.04	Single-centre Level II
Wu 2016	Retrospective cohort study using linked trauma registry data	Adult major trauma patients (ISS >12) with injuries related to road trauma	Acute hospital LOS Admission to rehabilitation and discharge FIM scores:	No statistically significant difference between the 2 groups	Retrospective study Level III-3

		requiring inpatient rehabilitation (excluding SCI and TBI) n=249 2 groups: 1) Those who received rehabilitation at associated "inhouse" rehabilitation service 2) Those who received rehabilitation at an external rehabilitation service (not linked to treating trauma hospital)	Rehabilitation LOS: Cost calculations for benefit of "in-house" rehabilitation:	Shorter "in-house" rehabilitation LOS (30 days vs. 40 days); p=0.02 Cost saving of AU\$8220/ patient not transferred to an external rehabilitation facility	
Wang 2017	Single centre, prospective observational study	Blunt solid organ injuries (liver, spleen and kidney) managed initially without surgical or angiographic intervention 1) Early ambulation <24 hours n= 36 2) Late ambulation >24 hours n= 43	Complications: (subsequent blood transfusions, percutaneous or operative interventions) ICU LOS: Hospital LOS:	No statistically significant difference between the 2 groups Longer ICU LOS in late ambulation group: median 3 days (2-3) vs. median 0 days (0-2); p=0.001 Longer LOS in late	Small sample size Clinically important differences between the 2 groups for injury severity, initial haemoglobin and organ injury grading (all worse in late ambulation group) Level III-2
			Tiospital EOO.	ambulation group: median 5 days (4-7)	

				vs. median 2 days (1-3); p<0.001	
Wu	Multi-centre,	Adult trauma	Hospital LOS,	No statistically	Trial ceased for
2017	randomised controlled trial	patients with injuries related to road trauma with expected LOS >5 days. 2 groups: 1) Control group (usual care) 2) Intervention group (early rehabilitation from an "in-reach" multi-disciplinary	physical function and psychological status	significant difference between the 2 groups for all measures	financial reasons so sample size not reached (214/250) Variability in experience of rehabilitation team staff Trial protocol only retrospectively registered Level II
T-1-1	Detre constitue cons	rehabilitation team)		Dadward in EMD	NI- in an and in
Teichman 2018	Retrospective pre- and post- study	All non-operatively managed liver or spleen injuries admitted to MTS 2 groups:	Length of bed rest Hospital LOS and	Reduced in EMP (3.46 days vs. 4.53 days); p=0.005	No increase in failure of non-operative management in EMP group
		1) Usual care minimum of 3 days bedrest prior to ambulation	ICU LOS:	significant difference between the 2 groups	Level III-3
		n= 77 2) After EMP introduction n= 107	In-hospital costs:	Reduced costs in EMP group related to reduced LOS (\$7077/ patient); p=0.0001	
Robinson 2019	Retrospective pre- and post- study	Adult major trauma patients (ISS >15) admitted to MTS 2 groups: 1) Prior to implementation of a physical medicine	Acute care LOS, 30- day readmission rates, frequency of potentially preventable complications and discharge destination	No statistically significant difference between the 2 groups for all measures	Single site, retrospective study with small sample size Sub-group analyses did have some statistically significant findings

and rehabilitation (PM&R) service n= 274 2) Following implementation of a PM&R service	Level III-3
n=76	

LOS- length of stay; ICU- Intensive Care Unit; ISS- Injury Severity Score; 95% CI- 95% Confidence Interval; RR- Risk Ratios; MTS-Major Trauma Service; PE- Pulmonary Embolus; DVT- Deep Vein Thrombosis; SCI- Spinal Cord Injury; TBI- Traumatic Brain Injury; EMP- Early Mobility Protocol; PM&R- Physical Medicine and Rehabilitation physician;

Measuring outcome after traumatic injury

Trauma system performance is frequently monitored by a trauma registry that collects information about patients hospitalised after injury. Trauma registries commonly include various pre-hospital and in-hospital process measures, mortality, length of stay and discharge destination, although the specifics vary worldwide [72]. Their function serves several purposes, including quality improvement, injury prevention, clinical research and policy development [73]. Only one registry (The Victorian State Trauma Registry, Australia) routinely collects any patient related outcomes beyond mortality [72], through telephone interviews and completion of measures relating to function, pain, health related quality of life and return to work, at six, 12 and 24-months after injury [74]. Despite the lack of routine collection by many trauma registries, the longer-term consequences of injury (from 6 months after injury and beyond) have been well explored in many research studies as previously described, whereas much less information exists relating to the earlier stages of trauma patient recovery in the acute hospital setting.

Given the recognised longer-term consequences of traumatic injury, it is important to understand this early phase of recovery and identify factors which may affect longer term outcomes and may be modifiable through specific interventions. Although some studies have captured patient disability and function at acute hospital discharge, [45, 46, 75-78], and other data may be extracted from previous interventional studies [79, 80], considerable gaps still exist. In many of these studies, generic measures of health and quality of life have been applied (as opposed to disease, injury process or body region specific measures), to ensure applicability to this heterogeneous group (eg. the Medical Outcome Study

Short Form Health Survey and European Quality of Life measure). Alongside these more generic measures, disciplines involved in specialist trauma patient care (such as speech pathologists, psychologists or physiotherapists) may use specific outcome measurement instruments which focus on important aspects of their treatments [81, 82]. Trauma physiotherapy in the acute hospital setting commonly focuses on interventions to improve mobility and physical function. Since there is no consensus on the optimal physiotherapy outcome measure for use in this patient group and setting [72, 81, 83], we completed a systematic review of published studies that included outcome measure instruments covering mobility and physical function, reported in Chapter Three.

Assessment of the clinimetric properties of health outcome measurement instruments

When considering instruments to measure health outcomes, consensus-based guidelines exist to assist appropriate selection [84]. Once the construct to be measured and patient cohort have been defined, consideration must be given to what is known about the instrument/s with regards to several important clinimetric properties. Relevant properties include reliability [85], validity [85, 86], responsiveness [87], feasibility [84] and floor/ceiling effects [88] which are all defined in Table 2 below.

Table 2: Definitions of clinimetric properties of health outcome measures

Measurement Property	Definition	Examples of Metrics
Reliability [85]	The extent to which repeated measurements in patients who have not changed, yield consistent results	Intraclass correlation coefficient (ICC)
Intra-rater reliability	How consistently the same person (or rater) administers and scores an outcome measure instrument (assuming no real change has occurred in the patient between sessions)	Weighted Kappa
Inter-rater reliability	How well 2 (or more) raters agree in the way they administer and score an outcome measure instrument (assuming no real change has occurred in the patient between sessions)	
Validity [85, 86]	The degree to which an outcome measure instrument, measures what it purports to measure	Correlation with gold standard measure
Content validity	The degree to which an outcome measure instrument includes all the items necessary to represent the concept being measured	
Criterion validity	The validity is tested by comparing it with the results of an identified gold standard measurement instrument. If it measures what it intends to, the results should agree with the results of the gold standard measure	
Construct validity	The ability of an outcome measure instrument to measure the underlying concept of interest to the clinician/ researcher	
Known-groups validity	A type of construct validity where the outcome measure instrument is used in groups known to be different in the construct of interest, so the scores should different if this is the case	
Predictive validity	The ability of an outcome measure instrument at one timepoint, to predict outcome of a gold standard measure at another timepoint	Correlation coefficients

Responsiveness [87]	The ability of an outcome measure instrument to measure clinical change over time	Effect Size (ES) Standard Error of Measurement (SEM) Minimal Detectable Change at the 95% confidence interval (MDC95)
Feasibility [84]	The ease of application of the measure in its intended	
Floor and ceiling effects [88]	The proportion of patients scoring the worst (floor) and best (ceiling) possible scores of the outcome measure instrument.	% of cohort (present if calculated as > 15%)

An optimal mobility and physical function measure for use by physiotherapists in the acute hospital would need to be broadly applicable to the range of patients treated by physiotherapists in this setting, across a range of injury types and severity. It needs to capture relevant aspects of mobility and physical function such as the ability to get up out of bed, get dressed, stand, shower, walk and climb stairs, as well as the degree of assistance required to complete these activities. To be feasible for use by physiotherapists in an acute setting it must be relatively quick and easy to administer, with minimal costs or equipment involved (due to busy patient caseloads and few extra resources available). As different physiotherapists often treat each patient, it needs to give a similar answer irrespective of who completes the score and it must be able to detect patient changes in these domains over the course of the hospital admission. If the measure is to be used to track longer-term patient recovery, it would be important it did not have any floor or ceiling effects during the acute care episode.

When considering the clinimetric properties reported in previous research, assessment of the methodological quality of the study is an important step. This is because lower quality studies have a higher risk of bias, which needs to be considered when interpreting and drawing conclusions from results. The COnsensus-based Standards for the selection of health Measurement Instruments (COSMIN) checklist was chosen for this thesis to systematically assess the methodological quality of studies included in the systematic review reported in Chapter Three [89]. The COSMIN checklist was developed after an international Delphi study reached consensus on how measurement properties should be defined and evaluated, collating the information into an evidence-based list to assist outcome measure instrument assessment and selection [90].

Although the original focus was on health-related patient-reported outcomes, the checklist is also relevant for other kinds of measurement instruments, such as the clinician assessed/reported instruments examined in this thesis [91]. The use of the COSMIN checklist first requires identification of which measurement property/ies were reported in the study (for instance reliability or responsiveness). The relevant section/s of the checklist is then completed to generate an overall methodological quality score (poor, fair, good and excellent), based on the lowest rating item ("worst score counts") [89].

As the understanding and measurement of mobility and physical function in acute trauma patients remains in its infancy, the clinimetric properties of many of the instruments have not been comprehensively assessed in published literature.

Therefore, a prospective study was designed to further investigate the key clinimetric properties of four different outcome measures in trauma patients in the acute setting, informed by the results of the systematic review. This prospective study is detailed in Chapter Four.

Aims of thesis

The overall aim of this thesis was to optimise physiotherapy assessment of trauma patients in the acute hospital setting. The specific aims were to:

- Describe the current role and responsibilities of physiotherapists in Australian and New Zealand Major Trauma Services
- Understand the clinimetric properties of mobility and physical function outcome measures previously used in published literature in trauma patients

3) Investigate and document the feasibility, validity, reliability and responsiveness of four mobility and physical function measures in acute hospitalised trauma patients.

Thesis overview

Chapter Two presents a benchmarking paper which describes the roles and responsibilities of physiotherapists in adult major trauma services in Australia and New Zealand (published in the New Zealand Journal of Physiotherapy, November 2016).

Chapter Three is a systematic review of outcome measures previously used in literature in trauma patients, highlighting gaps in evidence for their use (published in Trauma, January 2020).

Chapter Four is a prospective study exploring the clinimetric properties of four outcome measures in trauma patient in the acute hospital setting (under review, Physical Therapy Journal).

Chapter Two: Benchmarking project

Declaration for thesis Chapter Two, which was published in the New Zealand Journal of Physiotherapy in 2016:

Calthorpe S, Kimmel LA, Webb MJ and Holland AE. A benchmarking project of physiotherapy in Australian and New Zealand adult major trauma services. New Zealand Journal of Physiotherapy 2016,44(3):148-156. DOI:

10.15619/NZJP/44.3.04

The nature and extent of my contribution to the work in Chapter Two was the following:

Nature of contribution	Extent of contribution
Principle author responsible for the concept, design, distribution of the surveys, collation of responses,	
statistical analysis, manuscript development and writing.	80%

The following co-authors contributed to the work. There are no student coauthors.

Name	Nature of contribution
Lara A Kimmel	Assisted with concept, design, statistical analysis, manuscript development and writing.
Melissa J Webb	Assisted with concept, design, manuscript development and writing.
Anne E Holland	Assisted with concept, design, statistical analysis, manuscript development and writing.

The undersigned hereby certify that the above declaration correctly reflects the nature and extent of the candidate's and co-authors' contributions to this work.

Candidate's Signature: School Date: 29/03/2020

Main Supervisor's Signature: Date: 29/03/2020

A benchmarking project of physiotherapy in Australian and New Zealand adult major trauma services

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ABSTRACT

Traumatic injury places a great burden on individuals and society. As mortality plateaus in mature trauma systems, there is an increasing shift towards understanding patients' morbidity and functional outcomes. Physiotherapy plays a key role in recovery after traumatic injury, but little is currently known about its role in the acute hospital setting for trauma patients. This study aimed to document physiotherapy service structure and practice in adult major trauma services (MTS) across Australia and New Zealand.

A survey was distributed electronically to physiotherapists working within designated MTS (n=25), achieving a 92% response rate (n=23). Physiotherapy service delivery, expertise and availability varied greatly. Only seven sites (30%) had a dedicated trauma physiotherapist with this showing a trend towards an association with major trauma admissions (provided by the Australian Trauma Registry; p=0.07). Only eight (35%) had blanket referral systems for physiotherapy review, which was significantly associated with having a dedicated specialised physiotherapist (p =0.015). Most ran a five day/week service for all patients with priority cover over the weekends (78% n=18). Future research should explore the benefits of specialised trauma physiotherapy roles in optimising patient outcomes in order to standardise this across all trauma centres in Australia and New Zealand.

Calthorpe S, Kimmel L, Webb M, Holland A (2016) A Benchmarking Project of Physiotherapy in Australian and New Zealand Adult Major Trauma Services. New Zealand Journal of Physiotherapy 44(3): 148-156. doi:

10.15619/NZJP/44.3.04 Key words: Physiotherapy, Wounds and injuries, Physical therapy modalities, Multiple trauma, Benchmarking.

INTRODUCTION

Traumatic injury is the most common cause of death in those aged less than 45 years in Australia and New Zealand (NZ) and the fourth highest regardless of age (Australian Institute of Health and Welfare 2014, Ministry of Health New Zealand 2006, 2015). Organised systems of trauma care that exist in both countries have been shown to reduce mortality (Ashley et al 2015, Cameron et al 2008, Gabbe et al 2011) and central to this system design is the categorisation of hospitals to provide designated levels of trauma care (from Level I to Level IV). Requirements for Level I trauma centres include defined hospital infrastructure such as a helipad landing site and access to emergency operating theatres 24 hours a day, as well as specified healthcare professionals. The professionals included are pre-

hospital, specialist medical and nursing staff, with little mention of allied health or rehabilitation team members such as physiotherapy. Most designated Australian and

[]]]]NZ major trauma services (MTS) fulfil Level I or II criteria.

As these systems mature, there is an increasing shift towards measuring the quality of life for survivors and their morbidity over time (Cameron et al 2006). Care at MTS has been shown to improve functional outcomes (Gabbe et al 2016, MacKenzie et al 2008, Nirula and Brasel 2006), but the reasons for this

are unknown. It has been suggested that this may, in part, relate to greater clinical expertise, experience and staffing levels within allied health (Gabbe et al 2012),

whose interventions are specifically focused on this aspect of patient recovery.

Physiotherapists are an integral part of the trauma team. Their input is primarily concerned with the resolution or reduction of impairments and disabilities and the promotion of mobility, functional ability and quality of life through examination, evaluation, diagnosis, and physical intervention (Calthorpe et al 2014). Previous research has shown early physiotherapy intervention can improve early function after hip fracture (Kimmel et al 2016a) or admission following trauma (Calthorpe et al 2014). It has also been shown to reduce hospital length of stay (LOS) (Calthorpe et al 2014; Kimmel et al 2012; Kimmel et al 2016a). Early functional mobility was measured using the modified Iowa level of assistance score (mILOA), which has been shown to be reliable and valid in an acute hospital population (Kimmel et al 2016b). The implications of this emerging evidence relating to trauma care and health care systems could be profound. With a modest investment in acute inpatient physiotherapy services, it may be possible to reduce overall costs and improve patient outcomes. However, it is important to engage physiotherapists working within MTS to participate in comparative benchmarking work as a step towards understanding optimal physiotherapy service delivery before commencing clinical practice benchmarking (Ellis 2006).

In Australia and NZ, little is currently known about the structure of physiotherapy services to trauma patients. In Canada, comparative work found great variability of physiotherapy service structure within their MTS but key findings included a five day a week full physiotherapy service to trauma patients with priority-only coverage at weekends. Additionally, the majority worked within a separate physiotherapy department structure, where management decisions and quality assurance focused on the best interests of the physiotherapy department as a whole rather than necessarily being patient or unit specific (Fisher et al 2012).

The primary purpose of this study was to document current physiotherapy service structure and practice in the adult MTS across Australia and NZ. Additionally we aimed to ascertain what factors are associated with the amount and type of physiotherapy intervention to trauma patients.

METHODS

A purpose-designed survey was undertaken to collect information regarding the characteristics of physiotherapy service provision at MTS in Australia and New Zealand. This information was matched, where available, with quantitative information describing MTS admission numbers, LOS and discharge destination. The project was approved by the Alfred Research and Ethics committee as a low risk project (579/14).

The Australian adult MTS were identified through the inaugural report published by the Australian Trauma Registry (Alfred Health 2014) and the NZ adult MTS from a publication regarding their systems (Paice 2007). Twenty-five sites were identified in total; 19 in Australia and six in NZ.

Since no validated tool existed for benchmarking trauma physiotherapy services, a survey was designed using 16 open and closed ended questions. This was divided into three sections: trauma service model of care, trauma physiotherapy service provision and patient scenarios. The scenarios were included to help better understand the assessments and interventions physiotherapists complete with specific patient groups. These scenarios reflected the diverse nature of trauma patients from young to older adults, with varying severity of injury and pre-existing comorbidities. All involved at least two separate injuries and respondents were asked what input they would give to the patient on a defined day in their hospital stay. The initial version was pilot-tested by two senior physiotherapists who worked in Australian adult MTS and one physiotherapist who worked in a Victorian metropolitan trauma service. Based on their feedback, the survey was altered and finalised (Appendix).

The physiotherapy managers were contacted via email and requested to provide the contact details for the most senior physiotherapist who managed the trauma patients at their institution. The survey was distributed electronically via SurveyMonkey (SurveyMonkey Inc.) and included a cover letter inviting participation. Participants were informed that completion of the survey would indicate their consent. Where required, reminder emails for non-responders were distributed.

To receive the most accurate information with regards to major trauma patient admissions, LOS and discharge destination at each MTS, the Australian Trauma Registry (ATR) was used. This registry was developed as part of the Australian Trauma Quality Improvement Program (AusTQIP), a collaboration of the 26 designated Australian MTS (adult and paediatric), with the aim to provide an evidence base for trauma quality improvement and development of performance indicators. The ATR included the bi-national minimum dataset (BMDS) developed by the collaborative Australian and New Zealand National Trauma Registry Consortium (Palmer et al 2013). Although NZ were involved in the development of the BMDS, NZ MTS data were not included in the ATR. Request to access the data items listed using the ATR data access policy was undertaken with permission received in writing from the ATR manager. Data items extracted were: major trauma patient admission numbers, acute hospital length of stay and discharge destination for the period 2010-2012. Provided data were coded but were reidentifiable to allow them to be linked to the survey information where possible.

Statistical Analysis

Survey results and ATR data items (where available) were combined together into a spreadsheet. Numerical data were analysed using SPSS version 22.0 for Windows (IBM Chicago, IL). Continuous data were presented as means and standard deviations or medians and interquartile ranges for data not normally distributed. To explore any relationships between major trauma patient admission numbers, LOS and discharge destination with trauma unit and physiotherapy service structure, either an

independent samples t-test or a nonparametric Mann-Whitney U test was performed. To explore relationships between trauma and physiotherapy service structure, a Chi-squared test was performed. Open-ended responses were grouped according to themes and the responses to case scenarios were reported as percentages.

RESULTS

Twenty five questionnaires were distributed with a response rate of 92% (n=23). Of these, 18 were from Australia and five from NZ. For the ATR data items requested, 70% (n=16/23) had complete data available, one site had incomplete data and two sites had not contributed any data to the ATR at the time of the study. Overall, complete survey and ATR data were available from 15 of the 25 sites (60%). All available data were used for the analysis.

Table 1 summarises the responses to key questions regarding trauma unit and physiotherapy service. Only five (22%) of the 23 respondents worked in a hospital with a dedicated trauma bedcard; that is, the ability to admit a trauma patient and continue their care throughout their acute hospital stay until discharge. In all other MTS, trauma patients were admitted under subspecialty units such as Neurosurgery, Orthopaedics and General Surgery. Of these sites without a dedicated trauma bedcard, three described a "trauma service" that helped coordinate all trauma patients' care across the hospital. Seven of the 23 sites (30%) had a dedicated trauma physiotherapist defined as being either allocated to the trauma unit or identified as the key physiotherapist who managed trauma patients.

Table 1: Trauma service and physiotherapy service characteristics

Characteristic	Number of MTS n=23(%)
Dedicated trauma bedcard	5 (22)
Dedicated trauma physiotherapist	7 (30)
Blanket referral* for physiotherapy review	8 (35)
Out of business hours physiotherapy service	3 (13)
On-call physiotherapy service	8 (35)
Weekend physiotherapy service for prioritised patients only	18 (78)
Weekend physiotherapy service for all patients	5 (22)

Notes: MTS, Major trauma service.

Of those sites with a trauma bedcard, 60% (n=3/5) also had a dedicated trauma physiotherapist, whereas of

those sites without a trauma bedcard (n=18/23), only 22% (n=4/18) had a dedicated trauma physiotherapist (p=0.10). Of those sites with a dedicated trauma physiotherapist (n=7/23), five (71%) physiotherapists were full-time senior specialists supported by mainly rotating seniors and juniors, many of whom worked within trauma in a part-time capacity only. These specialist trauma physiotherapists reviewed trauma patients in various locations across the hospital including: the emergency department (ED), intensive care unit (ICU), wards and outpatient clinic. At the other 16 sites without a dedicated trauma physiotherapist, trauma patients were seen by an array of other specialised and rotational physiotherapists of varying levels of seniority, including but not limited to ICU, cardiothoracic, plastics, orthopaedics, neurosurgery, ED, burns, general surgery, spinal and rehabilitation.

The 2012 ATR data revealed a wide range of major trauma patient admission numbers across Australian MTS with a median of 342 admissions per year (n=17 sites, IQR 177-385 admissions) and a mean length of stay of 9.3 days (n=17, SD 1.9 days). On average, the percentage of major trauma patients discharged home was 52% (n=16, SD 10.2) and to rehabilitation was 31% (n=16, SD 9.7). Sites with greater numbers of major trauma patient admissions tended to be more likely to have a dedicated trauma physiotherapist (median 541 vs 240 admissions, p=0.07). Similarly those with greater admission numbers tended to be more likely to have a dedicated trauma bedcard (median 774 vs 314 admissions, p=0.13).

Only 35% (n=8/23) of respondents reported their site had a blanket referral for physiotherapy review of trauma patients. This involved a systematic review of all trauma admissions by a physiotherapist to establish current needs, identify any potential problems and implement an early therapy regime as required. Those sites with a dedicated trauma physiotherapist (n=7/23) were significantly more likely to have a blanket referral for physiotherapy review (p=0.02). All sites (n=23) provided a physiotherapy service to trauma patients from Monday-Friday during business hours (8am -4.30pm), with three sites also providing extended later hours coverage until around 8pm every weekday only. Eight sites (35%) also provided an "oncall" service. This service was identified as being for high risk patients with a deteriorating respiratory issue where further physiotherapy input would be beneficial out of usual business hours. This service was available to all patients within the MTS hospital, not just trauma patients. One site also included discharges and priority casting within their "on-call" service. One further site reported no structured "oncall" system, but identified they did provide an out of hours service on a needs basis for a defined group of cervical/upper thoracic spinal cord injured patients. With regards to weekend physiotherapy service provision, five sites (22%) provided a full business

^{*}Blanket referral is where all trauma patients are seen (referral not needed)

hours service, with all other sites providing a reduced/ prioritised service only.

Only three sites (13%) reported collecting any standardised outcome measures for physiotherapy interventions. These included the burns specific health scale or BSHS (Blades et al 1982); the modified lowa level of assistance score or mILOA

(Kimmel et al 2016b) and the de Morton Mobility Index (de Morton et al 2008). Time points for administering these measures to trauma patients varied.

Trauma physiotherapy specific clinical guidelines, assessment tools, pathways and competencies were used within 48% (n=11/23) of the sites. Of the respondents, 74% (n=17/23) reported they run trauma specific education sessions for physiotherapy staff, usually as part of their physiotherapy department inservice training. One site also reported they run an annual trauma lecture series and basic trauma day for physiotherapists available to both internal and external staff. Some physiotherapists also attended trauma team education sessions, along with other trauma activities as detailed in table two.

Table 2: Physiotherapy attendance at trauma team activities

Trauma team activity	Number of MTS where physiotherapists attends n=22 (%)
Handovers	10 (45)
Ward rounds	9 (41)
Unit meetings	12 (55)
Unit audits	3 (14)
X-ray meetings	7 (32)
Education sessions	12 (55)
No attendance at any activities	3 (14)

Notes: MTS, Major trauma service.

Just over a quarter of respondents (n=6/23) reported their physiotherapy staff were involved in research related to trauma patients, although 87% (n=20/23) were interested in being part of future collaborative physiotherapy research. There was also keen interest in being part of a trauma network aimed at supporting and sharing knowledge and skills for those working with trauma patients (91%, n=21/23).

Patient Scenarios

Responses to the four patient case studies are detailed in table three, with full details of each case listed in the survey (Appendix). At all but one site, all patient cases would have been seen by physiotherapy on a weekday, but weekend input varied case by case from being seen at only 52% up to 100% of sites. There was consensus around some assessments and interventions performed, particularly with regards to musculoskeletal

assessment and mobilisation, exercises and discharge planning which were completed by at least 87% of physiotherapists across the cases. Other assessments and intervention appeared to be more varied. Several physiotherapists reported that their intervention would depend on physical assessment findings. Time spent on all activities varied greatly (range 0 minutes - 25 minutes).

DISCUSSION

This study shows that there is a great variation of physiotherapy service delivery, expertise and availability within Australian and NZ adult MTS. Sites with more major trauma admissions tended to be more likely to have a dedicated trauma physiotherapist. Specific case scenarios also highlighted the varied assessment and intervention trauma patients receive across the different sites. Physiotherapists' participation in trauma team activities, trauma specific education and trauma related research also differed, although interest in collaborative research work and a supportive trauma network was high.

The variability in service provision described in this study is similar to that found in 2012 within Canadian MTS (Fisher et al 2012). These authors' research focused on models of service delivery in relation to specific hospital management structures and physiotherapy patient caseload numbers, particularly examining how the state of Ontario compared to the rest of Canada. However, comparison can be made around physiotherapy service delivery. In Canada, 89% (n=17/19) of their MTS ran a physiotherapy service five days/week with cover to priority patients only over the weekend which was similar to our finding of 78% (n=18/23) of sites providing this structure of service delivery. Further details of the physiotherapy service delivery in Canada with regards to referral process and specialisation however were not examined, so broader comparisons are limited.

In the absence of any established guidelines around optimal physiotherapy service delivery within MTS, it is not surprising that services varied across sites. Only the sites with a blanket referral for physiotherapy review (35% of sites) ensured that all trauma patients would have a physiotherapy assessment. Elsewhere, input relied on a referral, or was dependent on patient admission location or medical team allocation. Combined with the fact that a full physiotherapy service only occurred on weekdays and not weekends at the majority of sites (n=18/23, 78%), it is likely that physiotherapy input for patients would often be inconsistent, even within each individual MTS. One initiative that has been shown to increase physiotherapy referral rates and reduce time to physiotherapy assessment in an Australian MTS is the addition of a trauma case manager to the trauma team (Curtis et al 2006). However, it could be argued that even this referral process is not as effective as a blanket physiotherapy referral given only 55% of all trauma patients in that study received any physiotherapy and not until a median time point of 1.5 days into their hospital stay (Curtis et al 2006). Given early and more intensive physiotherapy has been shown to improve

functional independence (Calthorpe et al 2014, Khan et al 2012) and reduce length of stay (Kimmel et al 2012, Pendleton et al 2007), a more consistent approach to referrals and staffing may improve patient and organisational outcomes. Despite the presence of an admitting trauma bedcard being regarded as essential in MTS care (Royal Australasian College of Surgeons 2014), only 22% of centres fulfilled this criterion. A potential flow on effect of not having a trauma bedcard or admitting service is that trauma patients may not always be cared for in a specialist trauma ward or unit, but rather be "outliers" on other specialist wards where nursing and allied health staff may be unfamiliar with their management and access to their medical team may be less frequent (Civil 2005).

Table 3: Patient scenarios

team service structure. Of particular note is that physiotherapists attended ward rounds at less than 50% of the sites, despite research that shows their participation in this activity can reduce trauma patient hospital length of stay (Dutton et al 2003).

Only three respondents reported using any objective measures of treatment outcome with their patients. This may be due to the paucity of evidence around the best outcome measure for use in this diverse population. Recently the mILOA has been shown to be responsive, reliable and valid in patients following trauma in the acute setting (Calthorpe et al 2014, Kimmel et al 2016b). Additionally, the Functional Independence Score (FIM) motor subscore at acute hospital discharge has been shown to be a predictor of 6 month functional outcome

Case Scenario	Physiotherapy input weekday/weekend n (%)	Neurological assessment n (%)	Musculoskeletal assessment n (%)	Respiratory assessment n (%)		Mobilisation n (%)	Respiratory intervention n (%)	Discharge planning n (%)
Case 1	22 (96) / 15 (65)	18 (78)	21(91)	13 (57)	16 (70)	22 (96)	8 (35)	22 (96)
Case 2	23 (100) / 21(91)	11 (48)	22 (96)	23 (100)	21 (91)	23 (100)	23 (100)	21 (91)
Case 3	23 (100) / 12 (52)	8 (35)	23 (100)	11 (48)	23 (100)	23 (100)	6 (26)	21 (94)
Case 4	23 (100) / 23 (100)	6 (26)	20 (87)	23 (100)	20 (87)	23 (100)	23 (100)	20 (87)

Note: All percentages calculated from the n = 23 responses.

Case 1: 75 year old female two days post fall with C6 and wrist fracture just cleared to mobilise.

Case 2: 25 year old male post motor vehicle accident, day one post laparotomy and ankle fixation with eight fractured ribs and smoking history. Case 3: 50 year old female four days post motorbike accident with left femoral nail and fixation of L3 fracture who has so far managed only to sit out of bed.

Case 4: 80 year old male three days post fall at home with right pubic rami and five fractured ribs with flail and intercostal catheter with secretion retention and increasing oxygen requirements

Sub-optimal nursing care has been demonstrated with trauma patients "out-lying" in three UK hospitals with "positively dangerous" potential implications identified (Lloyd et al 2005). In this survey, only seven (30%) sites had a dedicated trauma physiotherapist, with just five of these reported as senior permanent full-time positions; not surprisingly these tended to be sites with more trauma admissions. In other centres, patients were seen by an array of specialist and rotational physiotherapists with varying levels of experience. It is therefore possible that similar effects may occur for physiotherapy care. Although such research has not been undertaken in a trauma specific context, an association between organisational structure and clinical outcomes has been demonstrated in other patient populations and provides support for specialist health clinicians (Strasser et al 2005). The MTS should consider this in the context of physiotherapy service provision and recognise trauma physiotherapy as a defined speciality. University postgraduate qualifications are emerging in this area for allied health clinicians, which may assist with this process, although further evaluation to optimise service delivery and patient outcomes must also be a priority. Participation in trauma team activities was low, presumably due to few dedicated trauma physiotherapists and varied trauma and physiotherapy

and return to work (Gabbe et al 2008), although its ease of use in the acute hospital and its limitations in the younger trauma patient are unknown.

The case scenarios provided some information around current usual physiotherapy practice with regards to assessments and interventions performed in specific common trauma patient case examples. Despite some consensus around assessment and intervention requirements, variability in practice remained evident. This demonstrates the need for stronger evidence to guide physiotherapy practice for trauma patients, although currently only 26% are involved in any such research. This reflects a need to build capacity in trauma physiotherapy research, the interest for which was found to be high with 87% interested in collaborative work and 91% interested in a trauma network to support allied health clinicians.

Limitations

Due to the variation in physiotherapy service structure to trauma patients across Australia and NZ, it was not always possible to identify one key trauma physiotherapist at each site and the survey may have been completed by more than one physiotherapist working in various areas. As a result, the survey responses may be influenced by the speciality of the

physiotherapist answering the questions. Years of experience or expertise specifically in the area of trauma were also not sought in the questionnaire. As we only accessed the data items from the ATR, these were not available for any of the NZ sites, limiting our analysis of these factors and their relationship to service delivery. Interpretation of the case scenarios may have been influenced by limited details provided, so it may have been difficult for physiotherapists to accurately report their treatment approach without more specific information on assessment findings.

CONCLUSION

This study is the first to provide information around current physiotherapy practice within Australian and NZ MTS. Most MTS do not have an admitting trauma bedcard and do not have a dedicated trauma team coordinating their care beyond the first 24 hours of their admission. Physiotherapy service and structure at the MTS was related to major trauma patient admission numbers, with higher volume sites tending to be more likely to have a dedicated trauma physiotherapist. This factor also impacted on trauma patient access to physiotherapy, with those sites also more likely to have blanket referral for physiotherapy.

The variability documented in this study highlights the need for robust evidence to underpin trauma physiotherapy and service delivery models. Future research should focus on the role of the trauma physiotherapy specialist within a trauma team in an attempt to ensure consistent high quality care, optimal patient outcomes and organisational efficiency.

KEY POINTS

- There is great variation of physiotherapy service delivery, expertise and availability within Australian and NZ adult MTS.
- Sites with higher numbers of major trauma patient admissions are more likely to have a dedicated trauma physiotherapist and a blanket referral system for physiotherapy review.
- Most sites ran a five day/week physiotherapy service for all trauma patients with priority-only cover during the weekends.
- Future research should explore the benefits of specialised trauma physiotherapy roles in optimising patient outcomes.

PERMISSIONS

Ethics approval for this study was obtained from the Alfred Health Human Research Ethics as a low risk project (579/14).

DISCLOSURES

This study was supported in part by an allied health research grant from the Alfred Hospital.

The authors declare no conflicts of interest.

ACKNOWLEDGEMENTS

We thank all the Australian Trauma Quality Improvement

Program Collaborators for the provision of Australian Trauma Registry summary data. Provision of this data in no way constitutes endorsement by the ATR or its collaborators of any conclusion of the authors. We also thank the physiotherapists who participated in completing the surveys.

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APPFNDIX

SURVEY TO PHYSIOTHERAPISTS Trauma Service Model of Care

Q1. What is your trauma service model of care?

- Dedicated Trauma unit for all trauma patients from admission to discharge
- (Trauma bedcard)
- Trauma admission unit where patients are admitted for a designated time period (up to 24 hrs) for assessment and then transferred to subspecialty units
- Trauma admissions immediately triaged to subspecialty units (no dedicated trauma unit or bedcard)
- Other (please state)

Q2. Please select the trauma team activities that the trauma physiotherapist (or any physiotherapist) would usually attend:

- Handover
- Ward Rounds
- Unit meetings
- Unit audits
- X-ray rounds
- Education sessions
- Other (please state)

Trauma Physiotherapy

Q3. Do you have a dedicated trauma physiotherapist/s (who is allocated to the trauma unit or who is the main person to treat trauma patients within your model of care)? Yes or No

Q4. What is the referral process for physiotherapy review of trauma patients?

- Blanket referral (all trauma patients seen by physio)
- · Referral only
- Self-referred
- Other (please state)

Q5. Please state the grade and speciality of the staff who treat the trauma patients and if possible their full time equivalent (FTE) (e.g: 1.0 FTE, grade 2 orthopaedic, 0.2 FTE grade 3 ICU).

Q6. If you have a dedicated trauma physiotherapist, what areas of the acute hospital do they cover?

- ICU
- Ward
- ED
- Other
- N/A

Q7. What is the service provision for the trauma patients?

Monday to Friday

- Business hours only
- Early/Late service
- 24 hour cover
- Saturday and Sunday (dedicated to Trauma unit or trauma patients)
- · Reduced/priority service
- · Business hours only
- Early/Late service
- 24 hour cover
- Other

Q8. Do you use any standardised outcome measures or collect any data on physiotherapy intervention for trauma patients in the acute setting? Yes or No Q9. If yes:

- What data is collected? Open comment box
- At what time points? Open comment box
- Who collects it? Comment box
- Do you routinely use? Yes or No

If yes, please comment

Q10. Do you use any physiotherapy specific trauma clinical guidelines, pathways or competencies for your patients or physiotherapy staff? Yes or No.

If yes, please give details below.

Q11. Do you run education sessions for physiotherapy staff in trauma management? Yes or No.

If yes, please give details below.

Q12. Are your physiotherapy staff involved in any research related to trauma patients (either as a primary investigator or assisting other staff)? Yes or No.

Q13 Patient Scenarios

Patient 1

75 year old female who fell down steps at the shops two days ago.

Injuries sustained:

- C6 fracture managed in a cervical collar for 6 weeks
- Right wrist fracture managed in a plaster of paris (POP) and non-weightbearing (NWB)

Social History (SH): fit, well and independent mobility. Lives alone.

Previous Medical History (PMH)-nil

Her spine has otherwise just been cleared to mobilise.

Would she be seen by physiotherapy:

- Mon-Fri only?
- Weekend?

After reading the patient's medical notes, reviewing imaging and any relevant other information, what would your first physiotherapy review involve? And how long approximately in minutes would each component take? (Multiple options and time taken for each allowed)

Full neurological assessment

- Full musculoskeletal assessment
- Full respiratory assessment
- Exercises
- · Mobilisation including gait aid provision
- Respiratory intervention
- Discharge planning
- · Other- please comment

Patient 2

25 year old male involved in a motor vehicle accident yesterday on a background of alcohol and drug use.

Injuries sustained:

- Perforated right diaphragm requiring a laparotomy and repair
- Fractured right ribs 5-12 with haemopneumothorax managed with an intercostal catheter (ICC)
- Left ankle fracture requiring surgery and an open reduction internal fixation (ORIF), NWB leg for 6 weeks

PMH: Smokes 20 cigarettes/ day and regular recreational drug use.

SH: Usually fully independent and lives at home with his mother.

His pain is well controlled and his respiratory status stable on two litres of oxygen via nasal cannula.

He is now day one post his laparotomy and ankle ORIF. Spine has been cleared.

Would he be seen by physiotherapy:

- Mon-Fri only?
- · Weekend?

After reading the patient's medical notes, reviewing imaging and any relevant other information, what would your first physiotherapy review involve? And how long approximately in minutes would each component take? (Multiple options and time taken for each allowed)

- Full neurological assessment
- · Full musculoskeletal assessment
- Full respiratory assessment
- Exercises
- Mobilisation including gait aid provision
- Respiratory intervention
- Discharge planning
- · Other- please comment

Patient 3

50 year old female after a motorbike accident four days ago.

Injuries sustained:

 Left mid-shaft femur fracture requiring an intramedullary nail four days ago, NWB on leg L3 burst fracture requiring ORIF three days ago, no neurological involvement and no post-op position or mobility restrictions

PMH- nil

SH- lives with supportive husband in a single level house. No steps to access.

So far she has managed just a transfer to sit out of bed with assistance of 2 physiotherapists.

Would she been seen by physiotherapy:

- Mon-Fri only?
- · Weekend?

After reading the patient's medical notes, reviewing imaging and any relevant other information, what would your physiotherapy review involve today (day four post admission)? And how long approximately in minutes would each component take? (Multiple options and time taken for each allowed)

- Full neurological assessment
- Full musculoskeletal assessment
- Full respiratory assessment
- Exercises
- Mobilisation including gait aid provision
- Respiratory intervention
- · Discharge planning
- Other- please comment

Patient 4

80 year old male after a fall at home three days ago onto his coffee table.

Injuries sustained:

- Right pubic rami fracture: conservative management, weightbear as tolerated
- Five right rib fractures (with radiological and clinical flail) and associated haemothorax and ICC

PMH- Atrial fibrillation, osteoporosis, obese

SH- usually lives alone but does require a four wheeled frame to walk outdoors further than 100 metres.

He is currently requiring humidified oxygen (approximate FiO2 of 40%) via a face mask for SpO2 of 93% and has only managed to sit out of bed once using a gutter frame and assistance of two physiotherapists.

He is limited by pain and also has evidence of secretion retention.

Would he been seen by physiotherapy:

- · Mon-Fri only?
- Weekend?

After reading the patient's medical notes, reviewing imaging and any relevant other information, what would your physiotherapy review involve today (day 3 post admission?) And how long approximately in minutes would each component take? (Multiple options and time taken for each allowed)

- Full neurological assessment
- Full musculoskeletal assessment
- Full respiratory assessment
- Exercises
- Mobilisation including gait aid provision
- Respiratory intervention
- Discharge planning
- Other- please comment

Q14. Would you be interested in being part of future collaborative physiotherapy research? Yes or No

Q15. Would you be interested in being part of a trauma network aimed at supporting and sharing knowledge and skills for those working with trauma patients? Yes or No

Q16. Would you like to be acknowledged in any publications or presentations? Yes or No

Thank you for your time completing this survey. Please do not hesitate to contact me if you have any questions regarding this information.

Sara Calthorpe

Senior Trauma

Physiotherapist The

Alfred

Melbourne, Victoria, Australia

Chapter Three: Systematic review

Declaration for thesis Chapter Three, which was published in Trauma in 2020:

Calthorpe S, Kimmel LA, Webb MJ, Gabbe BJ and Holland AE. Measurement of mobility and physical function in hospitalised trauma patients: A systematic review of instruments and their measurement properties. Trauma 2020, Vol. 22(1) pp 7–17. DOI: https://doi.org/10.1177/1460408619879326

The nature and extent of my contribution to the work in Chapter Three was the following:

Nature of contribution	Extent of contribution
Principle author responsible for the concept, design, statistical analysis, manuscript development and writing.	80%

The following co-authors contributed to the work. There are no student coauthors.

Name	Nature of contribution
Lara A Kimmel	Assisted with concept, design, statistical analysis, manuscript development and writing.
Melissa J Webb	Assisted with concept, design, manuscript development and writing.
Belinda J Gabbe	Assisted with concept, design, manuscript development and writing.
Anne E Holland	Assisted with concept, design, statistical analysis, manuscript development and writing.

The undersigned hereby certify that the above declaration correctly reflects the nature and extent of the candidate's and co-authors' contributions to this work.

SCOP droppelled Candidate's Signature: Date: 29/03/2020

Main Supervisor's Signature: Date: 29/03/2020 Measurement of mobility and physical function in hospitalised

trauma patients: a systematic review of instruments and their

measurement properties

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ABSTRACT

Introduction: It is well recognised that organised trauma systems reduce trauma patient mortality. As established systems mature, there is an increasing need to better understand the patient recovery trajectory. Mobility and physical function are key aspects of recovery, but the optimal instruments for measurement in the acute hospital setting remain unclear.

Methods: A systematic review was undertaken to identify and describe mobility and physical function instruments scored by direct patient assessment, in adult trauma patients in an acute hospital setting. Databases were searched with no date restrictions. Instruments that were specific to subgroups or related to individual conditions, diseases or joints, were excluded. The COSMIN checklist was used to assess risk of bias where relevant. Clinimetric properties were reported where possible, including reliability, validity and responsiveness.

Results: 14,114 articles were identified with 37 eligible for final review, including six instruments. None had been specifically designed for use in a heterogeneous range of trauma patients. The Functional Independence Measure (FIM) was most commonly cited (n=10 studies), with evidence of construct validity, responsiveness and minimal floor/ceiling effects (<3%). The Acute Care Index of Function (ACIF, n=1 study) was found to be valid and responsive whilst the modified lowa Level of Assistance (mILOA, n= 2 studies) was reliable and responsive, but ceiling effects ranged from 26% to 37%. Little clinimetric data were available for other measures.

Conclusion: Evidence from a few studies show promise for the use of the FIM, ACIF and mILOA to measure mobility and physical function in trauma patients, however comprehensive clinimetric data are lacking. Future research should test these scores

in specifically designed clinimetric property studies in defined trauma patient populations. This would enable the identification of a gold standard measure for evaluating treatment effectiveness, enabling benchmarking between centres, allow prediction of recovery pathways and optimise trauma patient outcomes.

Keywords: Trauma Patients, Mobility, Physical Function, Wounds and Injuries,
Outcome Assessment, Hospitalisation

INTRODUCTION

It is well recognised that organised trauma systems reduce mortality ^{1, 2}, but disability is prevalent in those who survive traumatic injury, with trauma accounting for approximately 16% of disability worldwide ³. As new trauma systems are developed, and established systems continue to mature, there is an increasing focus on reducing patient morbidity across the recovery trajectory ⁴⁻⁶. To ensure a comprehensive view, this must include early markers of recovery in the acute hospital setting, as well as longer-term outcome assessment. This important information may then be used to evaluate the effectiveness of interventions, provide benchmarking data between services and improve understanding of the factors which affect and predict outcomes.

In mature trauma systems such as North America, Europe, Australia and Canada, specific trauma registries collect information about trauma patient demographics, diagnoses, treatments and clinical outcomes. However, these registries typically focus on the more severely injured patients and process measures (such as hospital length of stay and time to Computerised Tomography scan). A recent literature review found only one out of eighteen established trauma systems worldwide routinely collected any valid morbidity-related outcome data; but not until six months after injury and beyond (Victorian State Trauma Registry, Australia) ⁷.

Extensive literature is available from single centre settings describing morbidity related outcomes following injury. However, these studies often focus on specific joint/body regions or injury-specific instruments for outcome assessment and thus do not capture outcomes across the full range of trauma patients ⁸⁻¹³. Others focus only

on patients admitted to a rehabilitation facility, where some consensus exists that the Functional Independence Measure (FIM) should be collected (Uniform Data System for Medical Rehabilitation, USA and Australasian Rehabilitation Outcomes Centre (ROC) and the UK ROC) ¹⁴⁻¹⁶. There is however no clear consensus on the measures that should be used to document functional recovery in the acute hospital setting.

The aims of this systematic review were to identify instruments used to measure mobility and physical function in trauma patients in the acute hospital setting, describe their characteristics and, where possible, report clinimetric properties in this group (including reliability, validity, responsiveness and interpretability).

METHODS

The protocol was registered on PROSPERO. Databases searched were Medline, Cinahl, Embase, Cochrane and the Physiotherapy Evidence Database (PEDro), with no date restrictions up to the 05/06/2019. Additional instruments were identified through reference and citation tracking. Articles were screened on title and abstract by two independent reviewers. Studies that met the inclusion criteria, or where it was unclear due to minimal required information in the abstract, were reviewed in full text. Any disagreements were discussed and resolved with a third reviewer.

Inclusion criteria:

Articles describing instruments that measured mobility or physical function of adult trauma patients (≥18 years or >80% in this age range) in the acute hospital setting, through direct assessment (rather than patient-reported) were included. Instruments completed using direct assessment were selected because in the acute setting,

traumatic injuries and cognitive issues often limit the ability of patients to self-report. Mobility and physical function were defined as per the World Health Organization classification system (activity limitation and participation domains: mobility and self-care) ¹⁷. Where mixed patient population studies clearly included trauma patients, the authors were contacted if trauma-specific data were not presented.

Exclusion criteria:

Reports were excluded if the identified instrument was condition, disease or joint specific (eg. knee injury, shoulder fracture, Traumatic Brain Injury (TBI) or burns) or if they were not published in English due to lack of resources for translation. Patients following fractured neck of femur often have a different clinical course and are frequently excluded from trauma registries ¹⁸. Therefore, instruments related to measuring physical outcomes in this group were excluded and will be reported separately.

Data extraction and quality assessment:

For all included articles, a standardised form was used to extract relevant data which was then synthesised for each identified instrument including study type, sample size and measurement timepoint/s. Descriptive statistics were reported where available for age, gender and ISS. For studies reporting clinimetric properties, the consensus-based standards for the selection of health measurement instruments (COSMIN) checklist was used to evaluate methodological quality ¹⁹. The COSMIN terminology and definitions of measurement properties were used to standardise reporting into the three key domains of reliability, validity and responsiveness ²⁰. Where clinimetric data were available, we reported any statistical analysis described by the original

author and detailed any further analysis we completed as relevant. Floor and ceiling effects were described where possible by calculating the proportion of patients with the minimum and maximum possible scores for the described instrument, respectively. Floor or ceiling effects were considered to be present if more than 15% achieved the highest or lowest possible score ²¹.

RESULTS

The search identified 14,114 articles from which 69 articles were reviewed in full text and 37 were deemed eligible for final inclusion. The Preferred Reporting Items of Systematic Reviews and Meta-Analyses (PRISMA) checklist and flow diagram were completed (Figure 1).

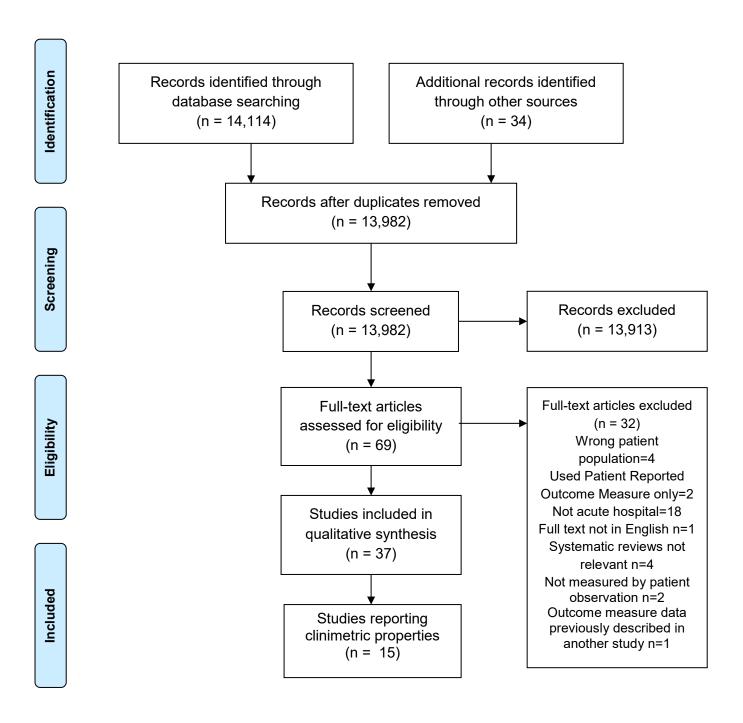


Figure 1: PRISMA chart detailing the study selection process

These articles included six instruments. Three assessed mobility alone; the Modified lowa Level of Assistance Score (mILOA), the Surgical Intensive Care Unit Optimal Mobility Score (SOMS), and the Timed up and Go (TUG) test. Three assessed both mobility and physical function; the Functional Independence Measure (FIM) - including the full original version and four different modified FIM (mFIM) versions, the Acute Care Index of Function (ACIF), and the Chelsea Critical Care Physical Assessment Tool (CPAx). The characteristics, training requirements and scoring system of each instrument are included in supplementary materials (Table S1) as are the relevant COSMIN scoring tables for each study that had included clinimetric properties (Tables S2). Table 1 summarises the COSMIN scores and clinimetric data, where relevant, for each identified outcome measure instrument.

Table 1: COSMIN scores and clinimetric property data (where available) for each identified outcome instrument

OUTCOME	RELIABILITY		VALIDITY		RESPONSIVENESS		INTERPRETABILITY	
MEASURE INSTRUMENT	DATA	COSMIN score	DATA	COSMIN score	DATA	COSMIN score	Floor effects (% of cohort)	Ceiling effects (% of cohort)
Functional Independence Measure (FIM)	NR	NR	Construct: r=NR	Poor	ES: 1.41-1.7	Fair	< 3%	< 3%
mFIMмтоs mFIMv2 mFIMv3 mmFIM	NR NR NR NR	NR NR NR NR	NR Construct: r=NR NR NR	NR NR NR NR	NR NR NR NR	NR NR NR NR	0.6% - 3% NR NR NR NR	15% - 52% NR NR NR
Acute Care Index of Function (ACIF) Modified ACIF	NR NR	NR NR	Construct: r =-0.48 (ACIF and LOS) NR	Fair	ES: 0.68	Poor	NR NR	0.6% NR
Surgical Outcomes Mobility Score (SOMS)	NR	NR	NR	NR	NR	NR	NR	NR
Chelsea Critical Care Physical Assessment Tool (CPAx)	NR	NR	NR	NR	NR	NR	NR	NR
modified Iowa Level Of Assistance Score (mILOA)	Inter-rater reliability: ICC=.975 (95% CI .949948)	Fair	NR	NR	ES: 1.47	Good	1%	26% - 37%
Timed Up and Go Test (TUG)	NR	NR	NR	NR	NR	NR	21%	NR

NR= not reported; ES= effect size, mFIM= modified FIM; mFIMMTOS= mFIM from Major Trauma Outcomes Study; mFIMv2= mFIM version 2; mFIMv3= mFIM version 3; mmFIM= mini-modified FIM version; r= Spearman's correlation coefficient; LOS=length of stay; ICC= intraclass correlation coefficient; CI= Confidence Interval.

Functional Independence Measure (FIM)

We identified 12 articles that used the FIM (Tables S1 and S3). There were seven prospective ²³⁻²⁹ and four retrospective cohort studies ³⁰⁻³³, and one randomised controlled trial (RCT) ³⁴; including a variety of trauma patient cohorts. The sample size with completed FIM scores ranged from 19 ²⁹ to 2327 patients ³¹ and where patient demographics were available, median age ranged from 33-38 years ^{24, 25, 30} or mean age from 41- 51 years ^{32, 33}; percentage males 68-82% ^{24, 25, 30, 32-34} and median ISS 22-36 ^{24, 25, 31}. The FIM was most commonly completed at hospital discharge ^{23-25, 31-34}. Two studies also collected hospital admission scores ^{23, 30}, while several of the studies collected the FIM outside of the hospital setting ^{24, 25, 27, 30, 34}. The FIM was usually completed by the multidisciplinary team involved in patient care ^{23, 24, 30, 31, 33}, but also by a research nurse ²⁶ and a research assistant ³⁴. The only RCT used the FIM as a secondary outcome measure at recruitment, hospital discharge and 3 or 6 month follow-up in a multi-centre trial (four acute hospitals), to investigate the impact of an in-reach rehabilitation team ³⁴.

Clinimetric properties

Reliability: No studies evaluated the reliability of the FIM.

<u>Validity:</u> Two prospective studies reported differences in the FIM according to discharge destination from hospital, a form of construct validity ^{23, 24}. Both scored "poor" for methodological quality (Tables S2: COSMIN table 1). Median discharge FIM scores were significantly higher in both studies for the groups being discharged home (108-124), than those discharged to rehabilitation (52-58) (Figure S1).

Responsiveness: Two studies collected the FIM at admission and discharge ^{23, 30}, while FIM scores were collected at trial recruitment and discharge in the RCT ³⁴. All scored "fair" for methodological quality (Tables S2: COSMIN table 2). The FIM scores improved from hospital admission, and lower scores were observed if the discharge destination was rehabilitation (Figure 2). The effect size (ES) represents the magnitude of the change that is detected by the measure and was calculated from the RCT ³⁵. It was 1.4 in the intervention group and 1.7 in the control group, representing a large effect with either treatment ³⁶.

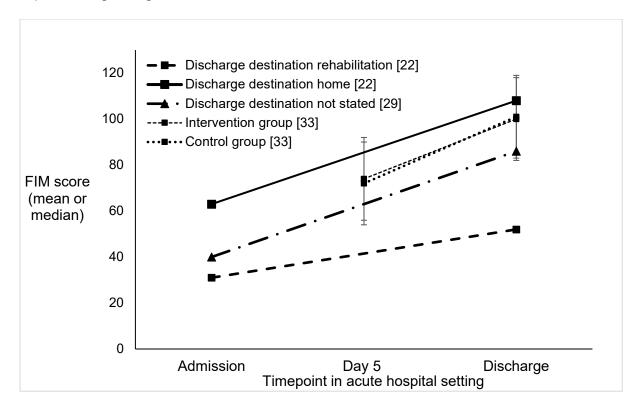


Figure 2: Mean (square) or median (triangle) FIM scores and measures of variability (where available) grouped by discharge destination (responsiveness) ^{23, 30,34}

<u>Interpretability:</u> One study explored the interpretability of the hospital discharge FIM score and its association to more meaningful long-term post injury outcomes in adult trauma survivors with an ISS>15 (n=243) ²⁵. Higher discharge FIM motor scores

(indicating a higher level of motor function at discharge) were associated with an increased likelihood of returning to work or study by six months post injury (Adjusted Odds Ratio (AOR) 1.03, 95% Confidence Interval (CI): 1.01–1.04). The total FIM score was an independent predictor of functional outcome at six months. For every point increase in the discharge FIM score (ie. better function), the odds of experiencing a poor outcome (Glasgow Outcome Score <5) at six months postinjury, decreased by 3% (AOR 0.97; 95% CI: 0.96–0.99).

<u>Floor and Ceiling Effects:</u> Only one study provided data at hospital discharge with no evidence of FIM floor or ceiling effects (<3% of the cohort for both) ²⁶.

Modified Functional Independence Measure (mFIM)

The mFIM is an adapted version of the FIM (Table S1) and 13 articles used four different versions of the mFIM (Table S4). The most common version was developed from the Major Trauma Outcomes Study (mFIMMTOS) and was based on unpublished data ³⁷. There were four retrospective ³⁷⁻⁴⁰ and four prospective studies ^{25, 26, 41, 42} using this version, involving various trauma patient cohorts. The sample size ranged from 44 ⁴² to 269,614 ³⁹. Where patient demographics were available, median age ranged from 31-40 years ^{25, 41, 42} or the mean age ranged from 39-44 years ^{39, 40}; percentage male 63-82% ^{25, 39-42} and median ISS 24-28 ^{25, 39, 42}. The mFIMMTOS was most commonly completed at discharge ^{25, 26, 37-42} by a FIM trained nurse, trauma registry data collector and/or physiotherapist ^{26, 42}. One study using the mFIMMTOS at discharge in a TBI cohort described and interpreted its scoring system in reverse ⁴³.

Version two of the mFIM (mFIMv2) was used in one retrospective study involving elderly (≥65 years) trauma admissions (n=30,786) ⁴⁴ and one prospective study

involving adult trauma admissions with non-fatal TBI (n=1866) ⁴⁵. Total cohort demographics were not reported for either study and the mFIMv2 was only collected at discharge. Only one study described how it was completed (patient observation) and by whom (nursing staff or trauma registry coordinator) ⁴⁵.

Version three of the mFIM (mFIMv3) was used in one prospective observational study investigating the effect of obesity on functional recovery after trauma (n=235) ⁴⁶. Total cohort demographics were not reported and the mFIMv3 was completed at admission, discharge and six months post discharge. Details outlining completion procedures were not described.

Finally, the fourth version was the further abbreviated mini-mFIM (mmFIM) ⁴⁷. It was used as a secondary outcome measure for a RCT investigating early mobilisation in an ICU setting, which included a cohort of trauma patients (52/200) but specific demographic data were not reported. It was completed at ICU discharge, by trained blinded assessors.

Clinimetric properties

Reliability: No studies evaluated the reliability of any versions of the mFIM.

<u>Validity:</u> One study investigated known groups validity, a form of construct validity for the mFIMv2 exploring the relationship between acute discharge scores and age, also stratifying for ISS (n=43,297) ⁴⁴. The study scored "poor" for methodological quality (Tables S2: COSMIN table 3) but the mFIMv2 discharge scores did demonstrate less independence in patients who were older (≥80 years) and more severely injured (ISS >20), providing some evidence of construct validity (Figure S2).

Responsiveness: One study reported mFIMv3 and one study mmFIM scores at two different timepoints ^{46, 47}, but trauma specific data was only available for the mFIMv3 ⁴⁶. This study scored "good" for methodological quality (Tables S2: COSMIN table 4). The mFIMv3 (score range 18-72; 5 domains) was completed at admission and discharge (n=235), with scores grouped by obesity status (nonobese, overweight, obese and morbidly obese). They found a significant difference between groups for mFIMv3 scores at discharge (p=0.027) (Figure S3).

<u>Interpretability</u>: No studies discussed the interpretability of any versions of mFIM or mentioned the MCID.

Floor and Ceiling Effects: Six studies provided data on floor and ceiling effects at hospital discharge for the mFIMMTOS total score ^{26, 38-40} and/or individual component scores ^{25, 38, 39, 41, 42}. Data on ceiling effects for component scores in one study were excluded from analysis due to their reverse interpretation of the scoring ⁴³. The mFIMMTOS total score exhibited a ceiling effect at hospital discharge in three out of the four studies, occurring in 37% to 52% of patients. No floor effects were observed. Further analysis of relevant individual mFIMMTOS domain scores (locomotion and feeding) revealed ceiling effects in 22-84% of patients, that were greatest for feeding (46-84%). Floor effects were present in two of the three studies for locomotion (21% and 36%), but not feeding (consistently <11% (Table S6)

Acute Care Index of Function (ACIF)

We identified four articles that had used the ACIF for our cohort and setting (Tables S1 and S5). There were two retrospective ^{48, 49} and two prospective cohort studies ^{50, 51}. Only one study included only trauma patients (n=526) with a mean age of 54

years (SD 24), an ISS 16.5 (SD 10.6) and hospital length of stay (LOS) of 8.9 days (SD 9.5) ⁴⁸. The ACIF was completed at various timepoints including initial contact, weekly during admission and at discharge from the ICU and/ or hospital. The ACIF was always completed by a physiotherapist/s through direct assessment. One of the original authors modified the ACIF and used it in a retrospective study of orthopaedic patients ⁵². The patient sample included a trauma patient cohort (n=115 /173) but trauma specific data were not available.

Clinimetric properties

<u>Reliability:</u> The inter-rater reliability of the ACIF was assessed in two studies but trauma specific data were not available ^{50, 51}.

Validity: Four studies investigated the validity of the ACIF but trauma specific data was only available for one ⁴⁸⁻⁵¹. This study investigated known groups validity of the ACIF in relation to ISS, age, discharge destination from hospital and LOS ⁴⁸. It scored "fair" for methodological quality (Tables S2: COSMIN table 5). Those with an ISS>15 had significantly lower initial ACIF scores (SD) (mean 38.3 (28.8) vs 56 (30.2), p<0.001) and ACIF scores remained lower at discharge (62.2 (29.9) vs 74.7 (27.1), p<0.001) (Figure 3). Discharge ACIF scores were significantly lower as age increased (≤40 years 80.1(26.8) vs 41-65 years 68.3 (29.5) vs >65 years 57.6 (26.9)). The ACIF discharge scores were significantly lower for those being discharged to a care facility compared with those going home with services (Figure S4). There was a fair association between LOS and ACIF scores at discharge (Spearman's correlation coefficient= -0.48; p=0.0001).

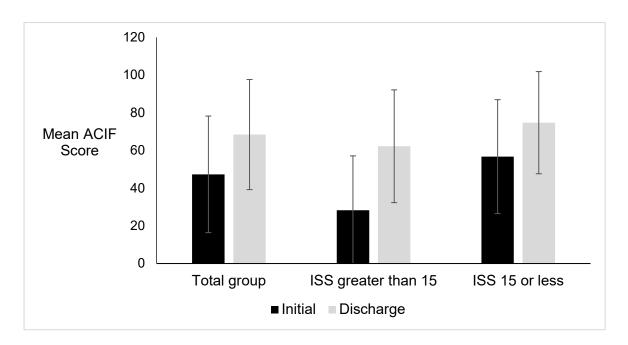


Figure 3: Mean (SD) ACIF scores at initial physiotherapy review and discharge (construct validity) 48

<u>Responsiveness:</u> Two studies collected the ACIF and one the modified version at more than one timepoint, but only one reported trauma specific data ^{48, 50, 52}. It scored "poor" for methodological (Tables S2: COSMIN table 6) ⁴⁸. The mean ACIF score on initial physiotherapy review was 47.3 (SD 30.9) and at physiotherapy discharge was 68.4 (SD 29.2) (Figure 3). The ES ³⁵ was calculated as 0.68, representing a moderate effect ³⁶.

Interpretability: No studies investigated the interpretability of the ACIF.

<u>Floor and Ceiling Effects</u>: No studies investigated the floor and ceiling effects of the ACIF.

Surgical Intensive Care Unit Optimal Mobility Score (SOMS)

The SOMS was the most common outcome measure used with trauma patients in an ICU setting (Table S1). We identified five articles that had used the SOMS in trauma patients; one RCT ⁴⁷ and four prospective observational studies ⁵³⁻⁵⁶. The trauma patients were a subgroup comprising between 6-26% (or n=4 to 52) of the surgical ICU cohorts which were the main focus of all the studies. The most common timepoint for completion of the SOMS was day one of ICU admission with the assessment carried out by physiotherapists and/ or nurses. No trauma specific data were available and no clinimetric properties explored.

Chelsea Critical Care Physical Assessment Tool (CPAx)

The CPAx was developed in 2010 as a bedside scoring system to grade physical morbidity in an ICU population (Table S1) ⁵⁷. We identified two studies that used the CPAx in ICU which included trauma patients (n=5/33 and n=10/499) ^{57, 58}. The CPAx was completed by physiotherapists and assessed at ICU admission, discharge and three times per week during ICU stay. No trauma specific data were available and no clinimetric properties explored.

Modified Iowa Level of Assistance Score (mILOA)

The mILOA (Table S1), was adapted from the original ILOA ⁵⁹ for use in patients following fractured neck of femur ⁶⁰. We identified one RCT that used the mILOA as the primary outcome measure to investigate whether an intensive physiotherapy program improved mobility for trauma patients ⁶¹ and one prospective cohort study investigating mILOA measurement properties ⁶². In the RCT, demographic data was

presented for the control and experimental groups separately (mean age 24-28 years, ISS 13-14 and 62% males) ⁶¹. The mILOA was completed at day three and five of enrolment, or the day of discharge if that timepoint was sooner. In the other study, demographic data varied across each sub-study with mean age from 60-61 years (SD 20-12); 43-57% males and median LOS 7-11 days ⁶². The timepoint for completion of the mILOA was not defined for the reliability study (n=30) but was during first and last physiotherapy review for the validity (n=14), responsiveness and interpretability study components (n=52). In both studies the mILOA was completed by physiotherapist/s through direct patient assessment.

Clinimetric properties

Reliability: The inter-rater reliability of the mILOA scored by two physiotherapists was investigated in 30 trauma patients who were deemed functionally stable ⁶². This paper scored "fair" for methodological quality (Tables S2: COSMIN table 7). The mean difference in mILOA score between the two raters was 1.43 points and the intraclass correlation coefficient (ICC) was 0.975 (95% CI 0.949 to 0.948), revealing excellent inter-rater reliability ⁶³. The standard error of the measurement (SEM) ⁶⁴ was 2.17 (95% CI 1.7-2.9).

<u>Validity:</u> The construct validity of the mILOA was assessed using known groups validity, but only 14/80 participants were trauma patients so the findings were not reported due to the low numbers ⁶².

<u>Responsiveness:</u> The responsiveness of the mILOA was calculated between scores at first and last physiotherapy review (n=52) ⁶². This study scored "good" for methodological quality (Tables S2: COSMIN table 8). The mean mILOA score on

admission was 23.8 (SD 8.5) and on discharge was 11.3 (SD 11.6). The ES 35 was 1.47 representing a very large effect, indicating the mILOA was responsive to change over the course of the admission 36 . The mILOA was used as the primary outcome measure in the RCT which scored "fair" for methodological quality (Tables S2: COSMIN table 8) 61 . The mILOA score was significantly better in the intervention than control group at \leq day three (median 7 points vs 10 points; p=0.02) and day four/five (median 7.5 points vs 16 points; p = 0.04), indicating it was responsive to early changes in mobility and physical function.

Interpretability: Using additional data supplied by the authors and methods consistent with the original study, we calculated that the standard error of the measurement (SEM) was 1.35 points, indicating that changes greater than 2.7 points (2 x SEM) in either direction are likely to be beyond the bounds of measurement error on 96% of occasions ⁶². The minimal detectable change at the 95% CI (MDC₉₅) was 3.74 points, indicating that 95% of participants who were truly stable would have a difference in mILOA scores of less than 4 points between testing occasions ⁶⁵.

Floor and Ceiling Effects: No floor effects were observed in either study, however ceiling effects were present in both ranging from 10-37% $^{61, 62}$. In the RCT, scores indicating complete independence in all mILOA tasks at ≤ day three of enrolment were found in14 patients (14/87 or 16%), all measured at hospital discharge 61 . In day four or five scores, nine patients (9/46 or 10%) scored the maximum mILOA score. Similarly in the other study, ceiling effects were seen in nineteen patients (19/52 or 37%) 62 .

Timed up and Go (TUG) test

The TUG test was originally designed to assess mobility, balance, walking ability, and fall risk in older adults (Table S1) ⁶⁶. We found one study that used the TUG test as a secondary outcome measure in a RCT, which reported 36/171 (21%) of trauma patients were unable to complete it at discharge (floor effect), but no further data were available ³⁴.

DISCUSSION

This review identified 37 articles that had utilised six instruments to measure mobility and physical function in trauma patients in the acute hospital setting through direct patient assessment. None of these instruments had been specifically designed for use in this cohort or setting. The most extensively tested measures were the mILOA, FIM and ACIF. There were no clinimetric data available for the SOMS, CPAx or mmFIM, and only minimal for the TUG, mFIMMTOS, mFIMv2 and mFIMv3.

Of the 15 articles that mentioned or investigated any clinimetric properties, most scored only "poor" to "fair" for their methodological quality, as the studies were usually not designed for this purpose (Table 1) ¹⁹. This needs to be considered when interpreting their findings. From this review, it is clear no one instrument has been investigated robustly enough to be defined as the gold standard, but the mILOA, FIM and ACIF show promise and all measure domains of relevance to trauma patients.

These three measures have different strengths and weaknesses which might also influence their use in the clinical setting. For example, the FIM involves a licensing cost and has a formalised training process for clinicians whereas use of the mILOA

and ACIF do not require either. As the FIM includes items not specifically related to mobility and physical function (such as cognition), it takes longer to complete compared with the more specific mILOA. The FIM is however routinely collected on patients requiring rehabilitation facility care, so it does appeal when considering handover and assessment across the two settings. All these factors must be considered when assessing the feasibility for use of any of the measures. In order to build on all the information this review provides, we recommend further testing of the mILOA, FIM and ACIF in specifically designed clinimetric property studies.

Identifying a gold standard instrument for measuring mobility and physical function in the acute setting is imperative to comprehensively describe the outcomes of care provided to trauma patients during this important phase of their recovery. It would enable assessment of change during hospital admission, facilitate testing of new interventions, assist with predicting discharge destination and enable benchmarking across centres. This would also help demonstrate the efficacy of various treatments, guide resource allocation and ultimately ensure optimal patient outcomes.

Strengths and Limitations of the included studies

There were several limitations of the included studies. Inconsistencies were found between the identified instruments with regards to structure and scoring (eg. four different versions of the mFIM) and the timepoint at which the instrument was completed, making comparisons difficult. The studies often included either mixed patient groups or narrowly defined groups, limiting the applicability of the information to a broad trauma patient population. Very few of the studies had been designed specifically to investigate clinimetric properties, further highlighting the lack of robust

testing for many of the instruments. There is a clear need to further investigate and test identified instruments that show most promise, to improve this body of literature.

Strengths and Limitations of the review process

The strengths of this review include a prior registration of the protocol, a comprehensive search strategy and thorough review process, including two reviewers for study identification and data extraction. It provides a comprehensive summary and evaluation of the current mobility and physical function instruments used in trauma patients in an acute hospital setting. Limitations include that only published articles in English were reviewed so it is possible that measures developed in other languages were not included. Patient reported outcome measures were also excluded as trauma patients ability to self-report in the acute setting is often limited due to injuries, pain, medications or cognitive issues, so limiting their applicability. Many studies used mixed patient populations and we were unable to obtain data for the trauma subgroup, which limited the data that could be included. Finally, only instruments completed whilst the patient was in an acute hospital setting were included, which may have limited available clinimetric data. However, this was consistent with the aim of the review, which was to ensure that the instrument was relevant and could be completed in the acute hospital setting.

CONCLUSION

No single outcome measure met all recommended criteria for measurement of physical function of trauma patients in the acute setting. The mILOA, FIM and ACIF may be useful, but extensive gaps exist with regard to specific clinimetric property information. Further work must be done to identify the gold standard measure in this

patient group, allowing a greater understanding and standardisation of outcome reporting across trauma services throughout the world.

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Figure Captions

Figure 1: PRISMA flow diagram

Figure 2: FIM responsiveness graph: mean (square) or median (triangle) FIM scores and measures of variability (where available) grouped by discharge destination

Figure 3: Mean (SD) ACIF scores at initial physiotherapy review and discharge

Table Caption

Table 1: COSMIN scores and clinimetric property data (where available) for each identified outcome instrument

Table S1: Table of identified outcome measure instrument characteristics, training requirements and scoring systems

Outcome measure	What it measures/ License or training?	Number of items to score	Domains	Scoring	Min-max score
Full Functional Independence Measure FIM	Functional assessment measure to assess	18 activities of daily living items across 6 domains	Self-care (eating, grooming, bathing, dressing upper body, dressing lower body, toileting)	Rates patient's level of disability: 1: total dependence)	Full FIM= 18-126
	patient ability to perform certain tasks Requires a license	Motor FIM score=13 items across 4 domains	Sphincter control (bladder management, bowel management) Transfers (bed to chair, toilet transfer, shower transfer)	2: maximal assistance3: moderate assistance4: minimal assistance	Motor FIM= 13-91
	and training	Cognitive FIM score=5 items	Locomotion (walking or wheelchair, stairs)	5: supervision6: modified independence	Cognitive FIM=
		across 2 domains	Communication (comprehension, expression) Social cognition (social interaction, problem solving, memory)	7: complete independence	5-35
Modified FIM score (FIMMTOS)	As FIM No mention of license and training	3 activities of daily living across 3 domains	Self-care (eating) Locomotion (walking or wheelchair) Communication (expression)	Rates patient's level of disability 1: total dependence 2: modified dependence 3: independent with assistive device 4: complete independence	3-12
Modified FIM score (mFIMv2)	As FIM No mention of license and training	5 activities of daily living items across 5 domains	Self-care (eating) Transfers (bed to chair) Locomotion (walking or wheelchair) Communication (expression) Social cognition (social interaction)	Rates patient's level of disability 1: total dependence 2: modified dependence 3: independent with assistive device 4: complete independence Does give more detailed descriptors for each item assessment	5-20

Modified FIM score (mFIMv3)	As FIM No mention of license and training	18 activities of daily living items across 6 domains	Self-care (eating, grooming, bathing, dressing upper body, dressing lower body, toileting) Sphincter control (bladder management, bowel management) Transfers (bed to chair, toilet transfer, shower transfer) Locomotion (walking or wheelchair, stairs) Communication (comprehension, expression) Social cognition (social interaction, problem solving, memory	Rates patient's level of disability 1: total dependence 2: dependent on human assistance for supervision and minimal or moderate assistance 3: dependent on nonhuman devices 4: complete independence	18-72
Mini modified FIM score (mmFIM)	As FIM Report this version adapted from the modified FIM score No mention of license and training	2 items across 2 domains	Transfers (bed to chair) Locomotion (walking)	Rate's patient's level of disability 1:near complete dependence 2:not described 3: not described 4: complete independence	2-8
Acute Care Index of Function (ACIF)	Functional status including basic mental functions and mobility activities Freely available in Australia and no specific training required	20 items across 4 sub-sets	Mental Health Status (Verbal commands, commands, learning, safety awareness) Bed Mobility (roll supine to right, roll supine to left, supine to sit, sit to supine) Transfers (wheelchair to mat, mat to wheelchair, sit to stand, sitting balance, standing balance) Mobility (gait with device, gait without device, ascend stairs, descend stairs, propel wheelchair, set-up wheelchair)	Mental Health Status: Yes (indicating a present behaviour) / No (indicating an absent behaviour) answers for For other items scoring is either: Unable-patient cannot physically assist to perform the activity (=0) Dependent-patient assists to perform activity but requires physical or verbal assistance to complete the activity (=4-21) Independent-patient performs the activity	1-100

				meeting all stated criteria without verbal or physical assistance (=10-30)	
"Modified" ACIF (mACIF)	Since population they were investigating didn't use wheelchairs or climb stairs (not required to access their homes), 4 mobility items were removed	16 items across 3 sub-sets Removed ascend stairs, descend stairs, propel wheelchair, set-up wheelchair)	Mental Health Status (Verbal commands, commands, learning, safety awareness) Bed Mobility (roll supine to right, roll supine to left, supine to sit, sit to supine) Transfers/Mobility (wheelchair to mat, mat to wheelchair, sit to stand, sitting balance, standing balance, gait with device)	As ACIF above	1-100
Surgical Intensive Care Unit Optimal Mobility Score (SOMS)	Consists of a simple numeric scale that describes mobilisation capacity of patients	One item	Optimal level of activity for patient	0: no mobilisation 1: passive range of motion exercises in bed (upper limb and lower limb PROM) 2: able to sit >45 degrees or in a chair (transferring to a chair via mechanical lift and/or sitting on the side of the bed. Indicated if patients followed 1 step commands and performed volitional movements) 3: able to stand with or without assistance (standing from a chair or the side of the bed) 4: able to ambulate	0-4
Chelsea Critical Care Physical Assessment Tool (CPAx)	The level of physical morbidity	10 aspects of physicality	-Respiratory function -Cough -Moving within the bed (eg. rolling) -Supine to sitting on the edge of the bed -Dynamic sitting -Standing balance -Sit to stand	Each item is scored from level 0 (complete dependence) -level 5 (complete independence) Clear descriptions of each level, relating specifically to each aspect	0-50

			-Stepping -Grip strength		
Modified Iowa Level of Assistance Score (mILOA)	The level of assistance required to complete four mobility tasks, walking distance in meters and assistive device used for all tasks	5 mobility items	- Supine to sitting on the edge of the bed - Sitting on the edge of the bed to standing - Walking - Negotiation of 1 step	Each mobility item graded according to level of assistance required: 0: independent 1: standby supervision 2: minimal assistance 3: moderate assistance 4:maximal assistance 5: failed 6: not tested	0-36
			Walking distance	0: >40 metres 1: 26- 40 metres 2: 10- 25 metres 3: 5- 9 metres 4: 3-4 metres 5: 2 metres 6: <2 metres	-
			Assistive device use	0: no assistive device 1: one stick or crutch 2: two sticks 3: two elbow crutches 4: two crutches 5: frame standard or rollator 6: gutter or platform frame	_
Timed Up and Go test (TUG)	To determine fall risk and measure the progress of balance through time taken for sit to stand,	2 mobility items	Sit to stand Mobility 3 metres out and back again to chair	Time taken (in seconds) to complete task Assistive device used (none, cane, walker, other)	High falls risk (>13.5 secs) Low falls risk (<13.5 secs)

-Transferring bed to chair

	wa	alking	6 metr	es								
	and	d star	ıd to si	t								

Tables S2: COSMIN scoring tables for each relevant study

Tables S2: COSMIN Table 1

Box E: Structural Validity (Construct Validity)- COSMIN assessment for the FIM articles

	Emhoff et al, 1991[22]	Hetherington et al, 1995 [23]
Does the scale consist of effect indicators, i.e. is it based on a reflective model?	No	No
Design requirements 2. Was the percentage of missing items given?	Percentage of missing items NOT described= good	Percentage of missing items described=excellent
Was there a description of how missing items were handled?	Not clear how missing items handled= fair	Not clear how missing items handled= fair
4. Was the sample size included in the analysis adequate?	n=109 Adequate sample size (≥100 per analysis)= excellent	n=66 Sample size <100=good
5. Were there any important flaws in the design or methods of the study?	Other minor methodological flaws in the design or execution of the study= fair	Other minor methodological flaws in the design or execution of the study= fair
Statistical Methods 6. No other important methodological flaws in the design or execution of the study	No exploratory or confirmatory factor analysis performed= poor	No exploratory or confirmatory factor analysis performed= poor
6. for IRT: Were IRT tests for determining the (uni-) dimensionality of the items performed?	IRT test for determining (uni)dimensionality NOT performed= poor	IRT test for determining (uni)dimensionality NOT performed= poor
Methodological quality score:	POOR	POOR

Box I: Responsiveness- COSMIN assessment for the FIM articles

	Emhoff et al, 1991[22]	Akmal et al, 2003 [29]	Wu et al, 2017 [33]
Design requirements 1. Was the percentage of missing items given?	Percentage of missing items NOT described= good	No missing items to describe N/A	Percentage of missing items described= excellent
2. Was there a description of how missing items were handled?	Not clear how missing items handled= fair	No missing items to describe N/A	Not described but it can be deduced how missing items were handled= good
3. Was the sample size included in the analysis adequate?	n=109 Adequate sample size (≥100 per analysis)= excellent	n=175 Adequate sample size (≥100 per analysis)= excellent	n=220 Adequate sample size (≥100 per analysis)= excellent
4. Was a longitudinal design with at least two measurement used?	Longitudinal design used= excellent	Longitudinal design used= excellent	Longitudinal design used= excellent
5. Was the time interval stated?	Time interval adequately described= excellent	Time interval adequately described= excellent	Time interval adequately described= excellent
6. If anything occurred in the interim period (e.g. intervention, other relevant events), was it adequately described?	Assumable what occurred during the interim period= good	Anything that occurred during the interim period (e.g. treatment) adequately described= excellent	Assumable what occurred during the interim period= good
7. Was a proportion of the patients changed (i.e. improvement or deterioration)?	Part of the patients were changed (evidence provided)= excellent	Part of the patients were changed (evidence provided)= excellent	Part of the patients were changed (evidence provided)= excellent
Design requirements for hypotheses testing For constructs for which a gold standard was not available: 8. Were hypotheses about changes in scores formulated a priori (i.e. before data collection)?	Hypotheses vague or not formulated but possible to deduce what was expected= fair	Hypotheses vague or not formulated but possible to deduce what was expected= fair	Hypotheses vague or not formulated but possible to deduce what was expected= fair
9. Was the expected direction of correlations or mean differences of the change scores of HR-PRO instruments included in these hypotheses?	Expected direction of the correlations or differences NOT stated= good	Expected direction of the correlations or differences NOT stated= good	Expected direction of the correlations or differences NOT stated= good
10. Were the expected absolute or relative magnitude of correlations or mean differences of the change scores of HR-PRO instruments included in these hypotheses?	Expected magnitude of the correlations or differences NOT stated= good	Expected magnitude of the correlations or differences NOT stated= good	Expected magnitude of the correlations or differences NOT stated= good

<u>Tables S2: COSMIN Table 3</u> <u>Box E: Structural Validity (Construct Validity)- COSMIN assessment for version 2 of mFIM</u>

	Grossman et al, 2003 [43]
Does the scale consist of effect indicators, i.e. is it based on a reflective model?	No
Design requirements	
Was the percentage of missing	Percentage of missing items NOT
items given?	described= fair
3. Was there a description of how	Not clear how missing items were
missing items were handled?	handled= poor
4. Was the sample size included in	n= 30,786
the analysis adequate?	Adequate sample size (≥100 per
	analysis)= excellent
5. Were there any important flaws	Other minor methodological flaws in
in the design or methods of the	the design or execution of the
study?	study= poor
Statistical Methods	No exploratory or confirmatory
6. No other important	factor analysis performed= poor
methodological flaws in the design	
or execution of the study	
6. for IRT: Were IRT tests for	IRT test for determining
determining the (uni-)	(uni)dimensionality NOT
dimensionality of the items	performed= poor
performed?	
IRT	
Methodological quality score:	POOR

Box I: Responsiveness - COSMIN assessment for the mFIM

BOX 1. INCOPORTATIONS - CO	Dhungal et al. 2015 [45]
	Dhungel et al, 2015 [45]
Design requirements 1. Was the percentage of missing items given?	Percentage of missing items described= excellent
2. Was there a description of how missing items were handled?	Described how missing items were handled= excellent
3. Was the sample size included in the analysis adequate?	n=235 Adequate sample size (≥100 per analysis)= excellent
4. Was a longitudinal design with at least two measurement used?	Longitudinal design used= excellent
5. Was the time interval stated?	Time interval adequately described= excellent
6. If anything occurred in the interim period (e.g. intervention, other relevant events), was it adequately described?	Anything that occurred during the interim period (e.g. treatment) adequately described= excellent
7. Was a proportion of the patients changed (i.e. improvement or deterioration)?	Part of the patients were changed (evidence provided)= excellent
Design requirements for hypotheses testing For constructs for which a gold standard was not available: 8. Were hypotheses about changes in scores formulated a priori (i.e. before data collection)?	Hypotheses formulated a priori= excellent
9. Was the expected direction of correlations or mean differences of the change scores of HR-PRO instruments included in these hypotheses?	Expected direction of the correlations or differences stated= excellent
10. Were the expected absolute or relative magnitude of correlations or mean differences of the change scores of HR-PRO instruments included in these hypotheses?	Expected magnitude of the correlations or differences NOT stated= good
11. Was an adequate description provided of the comparator instrument(s)?	No comparator instrument used N/A
12. Were the measurement properties of the comparator instrument(s) adequately described?	No comparator instrument used N/A
13. Were there any important flaws in the design or methods of the study?	No other important methodological flaws in the design or execution of the study= excellent
Statistical methods 14. Were design and statistical methods adequate for the hypotheses to be tested?	Statistical methods applied appropriate= excellent
Methodological quality score:	GOOD

Box E: Structural Validity (Construct Validity)- COSMIN assessment for the ACIF

	Parker et al, 2013 [47]
Does the scale consist of effect indicators, i.e. is it based on a reflective model?	No
Design requirements 2. Was the percentage of missing items given?	Percentage of missing items NOT described= good
3. Was there a description of how missing items were handled?	Not clear how missing items handled= fair
4. Was the sample size included in the analysis adequate?	n=109 Adequate sample size (≥100 per analysis)= excellent
5. Were there any important flaws in the design or methods of the study?	Other minor methodological flaws in the design or execution of the study= fair
Statistical Methods 6. No other important methodological flaws in the design or execution of the study	Exploratory or confirmatory factor analysis performed and type of factor analysis appropriate in view of existing information= excellent
6. for IRT: Were IRT tests for determining the (uni-) dimensionality of the items performed?	Not applicable
Methodological quality score:	FAIR

Box I: Responsiveness- COSMIN assessment for the ACIF

BOX 1. 1(csporisiveness- CO)	Parker et al, 2013 [47]
D	Parker et al, 2013 [47]
Design requirements 1. Was the percentage of missing items given?	Percentage of missing items described= excellent
Was there a description of how missing items were handled?	Described how missing items were handled= excellent
3. Was the sample size included in the analysis adequate?	n=526 Adequate sample size (≥100 per analysis)= excellent
4. Was a longitudinal design with at least two measurement used?	Longitudinal design used= excellent
5. Was the time interval stated?	Time interval adequately described= excellent
6. If anything occurred in the interim period (e.g. intervention, other relevant events), was it adequately described?	Anything that occurred during the interim period (e.g. treatment) adequately described= excellent
7. Was a proportion of the patients changed (i.e. improvement or deterioration)?	Part of the patients were changed (evidence provided)= excellent
Design requirements for hypotheses testing For constructs for which a gold standard was not available: 8. Were hypotheses about changes in scores formulated a priori (i.e. before data collection)?	Unclear what was expected=poor
9. Was the expected direction of correlations or mean differences of the change scores of HR-PRO instruments included in these hypotheses?	Expected direction of the correlations or differences NOT stated= good
10. Were the expected absolute or relative magnitude of correlations or mean differences of the change scores of HR-PRO instruments included in these hypotheses?	Expected magnitude of the correlations or differences NOT stated= good
11. Was an adequate description provided of the comparator instrument(s)?	No comparator instrument used N/A
12. Were the measurement properties of the comparator instrument(s) adequately described?	No comparator instrument used N/A
13. Were there any important flaws in the design or methods of the study?	No other important methodological flaws in the design or execution of the study= excellent
Statistical methods 14. Were design and statistical methods adequate for the hypotheses to be tested?	Statistical methods applied appropriate= excellent
Methodological quality score:	POOR

Box B: Reliability: relative measures (including test-retest reliability, inter-rater reliability) and intra-rater reliability)- COSMIN assessment for the mILOA

	Kimmel et al, 2016 [61]
Design requirements 1. Was the percentage of missing items given?	N/A
Was there a description of how missing items were handled?	N/A
3. Was the sample size included in the analysis adequate?	n= 30 Moderate sample size (30-49)= fair
Were at least two measurements available?	Longitudinal design used= excellent
5. Were the administrations independent?	Independent measurements= excellent
6. Was the time interval stated?	Time interval adequately described= excellent
7. Were patients stable in the interim period on the construct to be measured?	Assumable that patients were stable= good
8. Was the time interval appropriate?	Time interval appropriate= excellent
9. Were the test conditions similar for both measurements? e.g. type of administration, environment, instructions	Unclear if test conditions were similar= fair
10. Were there any important flaws in the design or methods of the study?	No other important methodological flaws in the design or execution of the study= excellent
Statistical methods 11. for continuous scores: Was an intraclass correlation coefficient (ICC) calculated?	ICC calculated and model or formula of the ICC is described= excellent
Methodological quality score:	FAIR

Box I: Responsiveness- COSMIN assessment for the mILOA

	Calthorpe et al, 2014 [60	Kimmel et al, 2016 [61]
Dosian roquiromento	Cantilotpe et al, 2014 [00	Tallinio of al, 2010 [01]
Design requirements	Doroontogo of missing items	Doroontage of missing items
Was the percentage of missing items given?	Percentage of missing items described= excellent	Percentage of missing items described= excellent
2. Was there a description of how	Described how missing items were	Described how missing items
missing items were handled?	handled= excellent	were handled= excellent
3. Was the sample size included in	n=90	n=52
the analysis adequate?	Good sample size (50-99)= good	Good sample size (50-99)= good
4. Was a longitudinal design with	Longitudinal design used=	Longitudinal design used=
at least two measurement used?	excellent	excellent
5. Was the time interval stated?	Time interval adequately described= excellent	Time interval adequately described= excellent
6. If anything occurred in the	Anything that occurred during the	Assumable what occurred
interim period (e.g. intervention,	interim period (e.g. treatment)	during the interim period= good
other relevant events), was it	adequately described= excellent	
adequately described?		
7. Was a proportion of the patients	Part of the patients were changed	NO evidence provided, but
changed (i.e. improvement or	(evidence provided)= excellent	assumable that part of the patients
deterioration)?		were changed= good
Design requirements for hypotheses testing For constructs for which a gold		
standard was not available:		
8. Were hypotheses about	Hypotheses vague or not	Hypotheses formulated a priori=
changes in scores formulated a	formulated but possible to deduce	excellent
priori (i.e. before data collection)?	what was expected=fair	OXOGIIOTIL
First (131 2 2 2 2 2 2 2 2 2 2 2 2 2 2 2 2 2 2		
9. Was the expected direction of	Expected direction of the	Expected direction of the
correlations or mean differences of	correlations or differences stated=	correlations or differences stated=
the change scores of HR-PRO	excellent	excellent
instruments included in these		
hypotheses?		
10. Were the expected absolute or	Expected magnitude of the	Expected magnitude of the
relative magnitude of correlations	correlations or differences stated=	correlations or differences NOT
or mean differences of the change scores of HR-PRO instruments	excellent	stated= good
included in these hypotheses?		
11. Was an adequate description	No comparator instrument used	No comparator instrument used
provided of the comparator	N/A	N/A
instrument(s)?		
12. Were the measurement	No comparator instrument used	No comparator instrument used
properties of the comparator	N/A	N/A
instrument(s) adequately		
described?		
13. Were there any important	No other important methodological	No other important methodological
flaws in the design or methods of	flaws in the design or execution of	flaws in the design or execution of
the study?	the study= excellent	the study= excellent
Statistical methods		
14. Were design and statistical	Statistical methods applied	Statistical methods applied
methods adequate for the	appropriate= excellent	appropriate= excellent
hypotheses to be tested?		
Methodological quality	FAIR	GOOD
score:		

<u>Table S3- Table of Functional Independence Measure (FIM) data</u>

Author Year of publication Country	Study design Any intervention under investigation? Total sample	Trauma population (+/- ISS) Age mean (SD) or median (IQR)	Timepoint of FIM How assessed? By whom? FIM	Full FIM data reported	Full FIM scores (n) Mean (SD) or median (IQR)	Full FIM scores (n) Mean (SD) or median (IQR)	Full FIM scores (n) Mean (SD) or median (IQR)	Full FIM scores (n) Mean (SD) or median (IQR)	Full FIM scores (n) Mean (SD) or median (IQR)
	size (n)	Gender male (%)	completed (n)	ed (n)	Admission scores	Discharge scores	3 months postinjury	6 months postinjury	12 months postinjury
Emhoff et al 1991 [22] (USA)	Prospective cohort study Usual trauma care n=109	Hospitalised adult trauma patient survivors identified on admission as requiring trauma Multi-disciplinary Team (MDT) input (surgeon, Physiotherapy, Occupational Therapy, Speech Pathology, Social Work) Age and gender not reported	FIM acute hospital admission and discharge (D/C) Direct patient observation by MDT n=109 Individual scores for each of the 18 categories of FIM only available for n=84	Mean admission and D/C scores and average difference between admit and D/C scores grouped for D/C destination FIM scores equated to % of normal function Rates of change in FIM units/day (change of one in any area)	Home (n=42): mean 63 (no SD reported) 50% normal function Rehab (n=67): mean 31 (no SD reported) 25% normal function	Home (n=42): median 108 (IQR: 105-111) 83-88% normal function Difference between average admission & D/C scores: FIM total:50 Self care: 18 Sphincter control: 7 Mobility: 10 Locomotion: 6 Communication/ social: 9 1.9 units/day change (mean, SD 1.4) Rehab (n=67): median 52 (IQR: 48-60) 38-48% normal function Difference between admission & D/C scores: FIM total: 21 Self care: 8 Sphincter control: 3	Not applicable to study	Not applicable to study	Not applicable to study

						Mobility: 3 Locomotion: 2 Communication/ social: 5 0.85 units/day change (mean, SD 1.05)			
Hetherington et al, 1995 [23] (UK)	Prospective cohort study Usual trauma care n=93	Trauma survivors >16 years old admitted via Helicopter Emergency Medical Services Median ISS 36 (21-75) 37.5 years (1- 92) 65 male (70%)	FIM each week of acute hospital stay, within 48 hours prior to discharge (direct observation), 3 and 6 months post injury (phone interview or direct observation) OT +/- other MDT members n=66 (27 deaths)	Median scores at discharge, 3 and 6 months post injury grouped by discharge destination	Not applicable	D/C home (n=48): median 124 (IQR 85- 126) D/C Acute (n=11): median 63 (IQR 22-126) D/C Rehab (n=7): median 58 (IQR 48-122)	Home (n=53): median 126 (IQR 102- 126) Acute (n=6): median 94 (IQR 27-120) Rehab (n=7): median 115 (IQR 48-125)	Home (n=59): median 126 (IQR 114-126) Acute (n=2): 22 and 71 Rehab (n=5): median 77 (IQR 48-120)	Not applicable to study
Akmal et al, 2003 [29] (UK)	Retrospective review Usual trauma care n=175	Survivors admitted via Helicopter Emergency Medical Services with a spinal injury (Abbreviated Injury Severity AIS score 1-5 for spine) Includes proportion with SCI (33% abnormal neurology with Frankel score A- C initially) ISS <16: n=78 (45%)	FIM acute hospital admission, discharge (direct observation), 3, 6 and 12 months post injury (75% direct observation, 25% telephone interview) Physician and MDT including OT, social worker (SW), physiotherapis t (PT) and	Median FIM scores at all timepoints with Tukey's box plot of 25th to 75th percentile, correlation between FIM scores at set timepoints. 12 month FIM scores relating to gender, age, ISS and AIS spine	Median 40 (Tukey box plot guesstimate scores IQR 18-60) 49% of patients had low admission FIM scores of 18-35 n= 175	Median 86 (IQR 58-110) n= 175	Median 113 (IQR 88-122) n= 175	Median 119 (IQR 102-124) n=175	Median124 (IQR 116- 124) n=175 14% of patients had residual disability at 12 months (FIM <108)

		ISS 16-30: n=73 (42%) ISS >30: n=23 (13%) 36 years (range 17-84) 134 male (77%)	nurses in hospital Physician or OT post D/C n=175						
LeBlanc et al, 2006 [30] (Canada)	Retrospective review of data from the Trauma Registry and Traumatic Brain Injury (TBI) programme databank Usual trauma care n=2327	All patients admitted with a diagnosis of TBI ISS 21.91 (10.92) Mild TBI (GCS 13-15): n=1479 Mod TBI (GCS 9-12): n=273 Severe TBI (GCS 3-8): n=484 Total n=2236 Age 18-39 (young): n=971 Age 40-59 (middle): n=672 Age 60-99 (elderly): n=684 Total n=2327 Gender not reported	FIM acute hospital discharge Direct observation TBI MDT members n=2327	Total FIM score, physical and cognitive scores at discharge according to age groups and TBI severity	Not applicable to study	Total FIM, physical and cognitive scores at discharge presented graphically by TBI severity (assume mean scores but not reported and no SD)	Not applicable to study	Not applicable to study	Not applicable to study

Gabbe et al, 2008 [24] (Australia)	Prospective cohort study Usual trauma care n=243	Survivors admitted to two adult major trauma centres aged 15-80 years, blunt mechanism and estimated ISS >15 Actual median ISS 25 (IQR 18- 34) 33 years (21-47) 199 male (81.8%)	FIM (and mFIM) acute hospital discharge Direct observation n=243 6 month post injury Telephone interview n=236 Not clearly stated who completed the FIM	Total FIM, physical and cognitive scores at acoute D/C and 6 months (total mFIM, mFIM individual scores with % of total cohort scoring each disability level (95% CI) at acute D/C and 6 months)	Not applicable to study	n=243 FIM motor score: median 61 (IQR 44-79) FIM cognitive score: median 35 (IQR 33-35) Total FIM score: median 95 (IQR 76-112)	Not applicable to study	n=236 FIM motor score: median 91 (IQR 89- 91) FIM cognitive score: median 35 (IQR 33- 35) Total FIM score: median 125 (IQR 122- 126)	Not applicable to study
Dagher et al, 2010 [31] (Canada)	Retrospective cohort study Usual trauma care n=415	Hospitalised moderate and severe traumatic brain injury admitted due to motor vehicle collision (MVC) or assault 41 years (SD 19) 302 male (73%)	FIM acute hospital discharge Direct observation Interdisciplinar y team members n=415	Mean, SD and SEM total FIM, physical and cognitive scores grouped by MVC or assault	Not applicable to study	MVC FIM physical (n=324): mean 36 (SD 30) SEM:1.7 FIM cognitive (n=324): mean 14 (SD 11) SEM: 0.6 FIM total (n=318): 51 (40) SEM: 2.3	Not applicable to study	Not applicable to study	Not applicable to study
						Assault FIM physical (n=91): mean 38 (SD 37) SEM: 4 FIM cognitive (n=91): mean 12 (SD 12) SEM: 1.3 FIM total (n=85):mean 54 (SD 28) SEM: 5.3			

Williamson et al, 2011 [25] (Australia)	Prospective cohort study Usual trauma care n=243 Reliability study of telephone versus direct observation of FIM at 6 months n=55	Survivors admitted to two adult major trauma centres aged 15-80 years, blunt mechanism and estimated ISS >15 Actual ISS 28 (19-34) 33 years (21-46) 199 male (82%)	FIM and mFIM at acute hospital discharge Direct observation n=243 6 month post injury Telephone interview n=236 Telephone PLUS direct observation n=55 Experienced research nurse trained in the FIM	Median and IQR of FIM, FIM motor, FIM cognitive and mFIM scores at D/C and 6 months Floor and ceiling effects of all scores calculated at D/C and 6 months by proportion of patients with minimum and maximum scores Reliability of FIM telephone versus direct observation at 6 months Bootstrapped responsivenes s for each index (effect size, standardised response mean, Guyatt Responsivene ss Index and Area Under Reciever Operating Curve) and mFIM, FIM motor, FIM cognitive and total FIM	Not applicable to study	Same as Gabbe paper as above: n=243 FIM motor score: median 61 (IQR 44-79) FIM cognitive score: median 35 (IQR 33-35) Total FIM score: median 95 (IQR 76-112) Floor effect n (%) FIM motor score: 6 (2.6%) FIM cognitive score: 7 (3%) Total FIM score: 4 (1.7%) Ceiling effect n (%) FIM motor score: 5 (2.1%) FIM score: 119 (50.9%) Total FIM score: 119 (50.9%) Total FIM score: 3 (1.3%)	Not applicable to study	Same as Gabbe paper above: n=236 FIM motor score: median 91 (IQR 89- 91) FIM cognitive score: median 35 (IQR 33- 35) Total FIM score: median 125 (IQR 122- 126) Floor effect n (%) FIM motor score: 3 (1.3%) FIM cognitive score: 0 (0%) Total FIM score: 3 (1.3%) Ceiling effect n (%) FIM motor score: 3 (1.3%) Ceiling effect n (%) FIM cognitive score: 133 (56.8%) FIM cognitive score: 134 (57.3%) Total FIM score: 3 (1.3%)	Not applicable to study
Dagher et al, 2013 [32] (Canada)	Retrospective cohort study Usual trauma care n=2127	Hospitalised mild traumatic brain injury 51.2 years (21.8)	FIM acute hospital discharge	Mean and SD for total FIM, FIM physical and FIM cognitive	Not applicable to study	n=1526 Total FIM score: mean 101 (SD 27)	Not applicable to study	Not applicable to study	Not applicable to study

 1476 male	Not reported	scores at	FIM physical
(69%)	how or who	acute hospital	score: mean 73
	completed FIM	discharge	(SD 22)
	n=1526		FIM cognitive
			score: mean 28
			(SD 7)
			Mean Total FIM
			score:
			Positive CT
			scan group: 99
			compared with
			negative CT
			scan group: 106
			(p=0.01) n=1499
			Mean FIM
			physical score:
			Positive CT
			scan group: 73
			compared with
			negative CT
			scan group: 74
			(p=0.2)
			n=1526
			Mean FIM
			cognitive score:
			Positive CT
			scan group: 27
			compared with
			negative CT
			scan group: 33
			(p<0.001)
			n=1499 ´

Herridge et al, 2016 [26] (Canada)	Multi-centre prospective cohort study Usual ICU (including trauma) care n=463 Trauma cohort n=44 (trauma and trauma surgery ICU admit diagnosis code)	Patients admitted to ICU and requiring mechanical ventilation for >7 days, ≥16 years and no current neurologic injury (cohort of trauma patients) 58 years (47-67) for total group 233 male (58%) for total group Trauma specific numbers not reported	FIM day 7 (D7) post ICU D/C or acute hospital D/C if left prior, 3, 6 and 12 months post ICU D/C Direct observation Not reported who completed FIM n=343 Trauma specific FIM numbers not reported	Median D7 FIM Disability risk groups generated by recursive partitioning model and based on total FIM at D7 post ICU D/C and 4 groups identified characterised by increasing disability. % completely independent for each FIM item, FIM motor and FIM cognitive subscale score in each disability group at D7, 3, 6 and 12 months depicted in a line graph D7 FIM as a risk factor for mortality (hazard ratio, 95% CI and p value)	FIM D7 post ICU D/C Total group n=343: median 54 (IQR 36-84) Young short LOS (<42 yrs <2 wks ICU): (n=20) median 107 (IQR 94- 115) Mixed age variable LOS (≥42 yrs <2 weeks in ICU and <45 yrs ≥2 wks ICU): (n=117) median 69 (IQR 43-93) Older long LOS (45-66 yrs ≥2 wks in ICU): (n=127) median 51 (IQR 35-77) Oldest long LOS (≥66 yrs ≥2 wks in ICU): (n=79) median 44 (IQR 31-56)	Not applicable to study	3 month scores post ICU D/C timepoint: values in a line graph only and not trauma specific data	6 month scores post ICU D/C timepoint: values in a line graph only and not trauma specific data	12 month scores post ICU D/C timepoint: values in a line graph only and not trauma specific data
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Wu et al, 2017 [33] Australia	Multi-centre randomised controlled trial (secondary outcome measure) Investigating the effect of an in-reach rehabilitation team n=214	Admitted to a trauma service with injuries related to road trauma, ≥18years and with an expected LOS >5 days ISS intervention group median 12 (IQR 8-21) and control group median 11 (IQR 8-17) Age intervention group mean 49 years (SD 19) and control group mean 46 years (SD 18) 145 male (68%)	FIM pre-injury score at recruitment, acute hospital discharge, rehabilitation discharge (if applicable) and 3 month (mild/moderate injuries) or 6 months (serious/sever e injuries) Pre-injury score: patient reported Acute and/or rehabilitation hospital discharge: direct assessment 3 or 6 months: phone interview Research assistant n=164	Reported as mean FIM pre-injury at recruitment (table 1 in article), however score values reflect this score as actually being at recruitment and post-injury (table 4 in article). Mean full FIM at acute hospital discharge and follow-up for intervention and control groups Sub-group scores for those who went to rehabilitation with FIM data (n=65/81)	At recruitment median of day 5 LOS (IQR intervention group 4-8, control 3-7): n=164 Intervention-mean 74 (SD 18) Control- mean 72 (SD 17) Rehabilitation group at recruitment: n=65/81 Intervention-mean 65 (SD 15) Control- mean 64 (SD 14)	Acute Hospital discharge: Intervention- mean 99.9 (SD 18.1) Control- mean 101 (SD 19) n=164 Rehabilitation group at acute hospital discharge: Intervention- mean 88 (SD 16) Control- mean 83 (SD 16) Rehabilitation group at rehabilitation group at rehabilitation hospital discharge: Intervention- mean 114 (SD 11) Control- mean 111 (SD 11) n=65	Follow-up (3 or 6 month post injury data combined): Interventionmean 120.2 (SD 11.7) Controlmean 122.2 (SD 6.7) n=164 Rehabilitation group follow-up (3 or 6 month post injury data combined): Interventionmean 122 (SD 5) Controlmean 120 (SD 20) n=65	Reported combined with 3 month post injury scores in that section	Not applicable to study
Bartolo et al, 2016 [28] (Italy)	Multi-centre prospective observational study Usual ICU care (included trauma cohort) n=102 Trauma cohort n=19	Admitted to ICU with severe TBI that produced a state of coma for lasting at least 24 hours (acute traumatic or not traumatic) Trauma specific numbers not reported	ICU discharge How and by whom assessed not reported n=87 survivors to ICU discharge But trauma specific data not available	Median FIM total score, FIM motor and FIM cognitive scores and IQR	Not applicable to study	At ICU D/C scores Total group: Median FIM 20 (IQR 18-26) FIM motor 13 (IQR 13-15) FIM cognitive 7 (IQR 5-12)	Not applicable to study	Not applicable to study	Not applicable to study

Bartolo et al,	Multi-centre	Admitted to ICU	ICU discharge	FIM full, motor	Not applicable to	At ICU D/C	Not	Not applicable	Not
2017 [27]	prospective observational	with severe TBI that produced a	How and by whom	and cognitive scores	study	scores Total FIM score	applicable to study	to study	applicable to study
taly)	study	state of coma for	assessed not	compared		mobility group			10 010.00
	Usual ICU (including	lasting at least 24 hours (acute	reported n=103	between a group that		21 (95% CI 18; 27) versus non			
	trauma) care	traumatic or not	Trauma	were mobilised		mobility group			
	n=103 [′]	traumatic)	specific data	and a group		18 (95% CI 18;			
	Trauma cohort	Trauma specific	not available	that were not		21)			
	n=21 (severe TBI due to	numbers not reported		mobilised (95% CI)		Motor FIM score mobility group			
	trauma)			(001001)		13 (95% CI 13;			
						15) versus non			
						mobility group 13 (95% CI 13;			
						13)			
						Cognitive FIM			
						score mobility group 7 (95% CI			
						5; 14) versus			
						non mobility			
						group 5 (95% CI 5; 9)			

Table S4- Table of all modified Functional Independence Measure (mFIM) versions data

Author Year of publication Country	Study design Any intervention under investigation? Total sample	Trauma population (+/- ISS) Age mean (SD) or median (IQR)	mFIM version and scoring system	mFIM data reported Timepoint of mFIM How assessed?	mFIM data reported	mFIM scores (n) Mean (SD) or median (IQR) Admission	Full FIM scores (n) Mean (SD) or median (IQR)
	size (n)	Gender male (%)		By whom? mFIM completed (n)			Discharge
Gennarelli et al, 1994 [36] (USA)	Retrospective review of data from the Major Trauma Outcome Study (MTOS) involving 65- 165 hospitals by the end (1982-1989) Usual trauma care n=174,160	All trauma patients admitted to hospital or ICU (including deaths) Age and gender not reported	mFIMMTOS Self-care (eating): 1-4 Locomotion (walking or wheelchair): 1-4 Communication (expression):1-4 Total score interpretation: 3= total dependence 12=complete independence	Unclear timepoint- assume acute hospital discharge Direct observation Not clearly stated who completed the mFIM n=174,160	Mean total mFIMMTOS and individual component scores (expression, feeding and locomotion) grouped by whether patient had head injury (HI) or not (NHI) and by AIS code 1- 6 ECI= extracranial injury	Not applicable to study	Presented in a line graph by AIS and HI or not
Glance et al, 2004 [39] (USA)	Retrospective cohort study from the National Trauma Data Bank (NTDB) (includes 67 hospitals in 29 states, all levels of trauma centre designations) Usual trauma	Patients admitted to hospital during 1999, aged ≥ 18 years who sustained blunt trauma without associated TBI /head or spinal cord injury Mean ISS 9.7 (SE 0.1) Also only included	mFIMMTOS Total score interpretation in this study: Good functional outcome= total mFIM 12	Acute hospital discharge Not reported how assessed or by whom n=14,980	Numbers and % of total cohort scoring each individual mFIM score from 3-12 at acute hospital discharge	Not applicable to study	mFIM total score (n=14,980): n (%) 3: 91 (0.61) 4: 40 (0.27) 5: 56 (0.37) 6: 153 (1.02) 7: 158 (1.05) 8: 274 (1.83) 9: 561 (3.74) 10: 1390 (9.28) 11: 4140 (27.64) 12: 8117 (54.19)

	care n=15,712	hospitals that recorded functional					
		outcomes on >90% of survivors and with at least 100 patients meeting inclusion criteria Mean age 44.4 years (SE 0.16) 9898 male (63%)					
Demetriades et al, 2005 [37] (USA)	Retrospective cohort study from the NTDB to investigate the effect of trauma centre designation and volume on outcome in patients with specific severe injuries Usual trauma care n=12,254	Major trauma patients >14 years with ISS >15 who were alive on admission to hospital and had a least one of the following severe injuries: aortic, vena cave, iliac vessles, cardiac, garde IV/V liver injuries, quadraplegia or complex pelvic fractures Age and gender not reported Mortality rate 27.3% (n=3345)	mFIMMTOS Total score interpretation in this study: Severe functional disability= total mFIM <9	Acute hospital discharge Not reported how assessed or by whom n=8909	Number of patients (%) who were fully dependent (mFIM score=1) for expression, feeding and locomotion Those with any deficit (total mFIM score <12) Incidence of severe disability (total mFIM <9) by injury type and trauma centre designation	Not applicable to study	Number of patients (%) Discharged to rehabilitation 1933 (22%) Discharged to skilled nursing facility 508 (6%) Feeding: fully dependent (mFIM=1) 891 (10%) Locomotion: fully dependent (mFIM=1) 1871 (21%) Expression: fully dependent (mFIM=1) 445 (5%) Any deficit (total mFIM=<12) 5345 (60%)

Gabbe et al, 2006 [40] (Australia)	Prospective cohort study Usual trauma care n=1102 total group n=739 reported with discharge and 6 month mFIM	Major trauma patients (ISS>15) who survived to acute hospital discharge ISS 22 (range 1-66) Median age 40 (range 15-94 years) 529 male (72%)	mFIMмтоs	Acute hospital discharge and 6 months post injury Not reported how or by whom discharge score assessed but 6 months via phone interview n=739	mFIM individual scores with n (%) of total cohort scoring each disability level at discharge and 6 months 6 months scores grouped and reported into those with and those without head injury (AIS severity >2)-not reported	Not applicable to study	mFIM at D/C: n (%) Locomotion (n=658) Independent: 321 (49%) Indep with device: 76 (12%) Dependent-partial help: 167 (25%) Dependent- total help: 94 (14%) Feeding (n=662) Independent: 537 (81%) Indep with device: 9 (1%) Dependent-partial help: 74 (11%) Dependent- total help: 42 (6%) Expression (n=658) Independent: 576 (88%) Indep with device: 28 (4%) Dependent-partial help: 29 (4%) Dependent- total help: 25 (4%)
Gabbe et al, 2007 [41] (Australia)	Prospective cohort study Usual trauma care n=50 for reliability study of medical record acquired FIM versus direct observation	Survivors admitted to two adult major trauma centres aged 15-80 years, blunt mechanism and estimated ISS >15 Actual median ISS 24 (IQR 16- 59) Median age 31 years (IQR 15- 78) 43 male (86%)	mFIMMTOS	Acute hospital discharge by direct patient observation by a FIM trained nurse Retrospectively from the medical records by 1 FIM trained nurse, 1 nurse, 1 Physiotherapist and 1 trauma registry data collector n=44 who had medical records available	Frequencies of 4 retrospective rater scores & 1 direct observation scores with n (%) for each item of the mFIM from medical record	Not applicable to study	Direct observation mFIM at D/C scores: n (%) Locomotion (n=44) Independent: 12 (27%) Indep with device: 4 (9%) Dependent-partial help: 12 (27%) Dependent- total help: 16 (36%) Feeding (n=44) Independent: 37 (84%) Indep with device: 1 (2%) Dependent-partial help: 4 (9%) Dependent- total help: 2 (5%) Expression (n=44) Independent: 21 (5%) Indep with device: 4 (9 %) Dependent-partial help: 16 (36%) Dependent- total help: 3 (7%)

Gabbe et al, 2008 [24] (Australia)	Prospective cohort study (described as vaildation study of outcome measures) Usual trauma care n=243	Survivors admitted to two adult major trauma centres aged 15-80 years, blunt mechanism and estimated ISS >15 Actual median ISS 25 (IQR 18- 34) Median 33 years (IQR 21-47) 199 male (81.8%)	mFIMмтоs	mFIM acute hospital discharge Direct observation Not clearly stated who completed the FIM n=243 6 month post injury Telephone interview n=236	Total mFIM, mFIM individual scores with % of total cohort scoring each disability level (95% CI) at acute D/C and 6 months	Not applicable to study	n=243 mFIM total score: median 9 (IQR 7-11) mFIM at D/C: % (95% CI) Locomotion Independent: 22% (95% CI:16-27) Indep with device: 9% (6-13) Dependent-partial help: 33% (27-39) Dependent- total help: 36% (30-42) Feeding Independent: 46% (95% CI: 39-52) Indep with device: 13% (9-17) Dependent-partial help: 31% (25-36) Dependent- total help: 11% (7-15) Expression Independent: 81% (95% CI: 76-86) Indep with device: 5% (2-8) Dependent-partial help: 11% (7-15)
Haider et al, 2009 [38] (USA)	Retrospective cohort study from the National Trauma Data Bank Usual trauma care n=515,464 n=269,614 with mFIM data	Patients >14 years admitted with moderate to severe blunt trauma with an ISS ≥9 Mean ISS 16.9 (SD 6.25) Mean age 39 years 355,670 male (69%)	mFIMMTOS Score interpretation in this study: Cateogorised in each domain (not total score) as: No deficit mFIM=4 Presence of deficit mFIM<4	Acute hospital discharge Not reported how or by whom assessed n=269,614	% of patients with any deficit in each domain as a whole group and also categorised into mechanism of injury (motor vehicle collision (MVC), pedestrian struck by motor vehicle (MV), motorcycle crash,	Not applicable to study	Dependent- total help: 3% (1-6) % with presence of any deficit (mFIM <4) at D/C: All patients n=269,614: Any impairment: 63% Locomotion: 52% Feeding: 16% Expression: 10% MVC n=126,629: Any impairment: 56% Locomotion: 53% Feeding: 14% Expression: 9% Pedestrian struck by MV n=15,948: Any impairment: 70% Locomotion: 68% Feeding: 16% Expression: 11% Motorcycle Crash n=19,184: Any impairment: 61% Locomotion: 56% Feeding: 15%

					bicycle crash, falls at same level and falls from any height)		Expression: 8% Bicycle crash n=7096: Any impairment: 42% Locomotion: 38% Feeding: 10% Expression: 7% Falls at same level n=68,878: Any impairment: 74% Locomotion: 70% Feeding: 17% Expression: 11% Falls from any height n=31879 Any impairment: 60% Locomotion: 56% Feeding: 15% Expression: 9%
Williamson et al, 2011 [25] (Australia)	Prospective cohort study to complare the responsiveness of outcome measures Usual trauma care n=243	Survivors admitted to two adult major trauma centres aged 15-80 years, blunt mechanism and estimated ISS >15 Actual ISS 28 (19-34) 33 years (21-46) 199 male (82%)	mFIMмтоs	mFIM at acute hospital discharge Direct observation n=243 6 month post injury Telephone interview n=236 Telephone PLUS direct observation n=55 Experienced research nurse trained in the FIM	Median and IQR of mFIM scores at D/C and 6 months Floor and ceiling effects calculated at D/C and 6 months by proportion of patients with minimum and maximum scores	Not applicable to study	Same as Gabbe paper as above: n=243 mFIM total score: median 9 (IQR 7-11) Floor effect n (%) mFIM total score =3: 8 (3.4%) Ceiling effect n (%) mFIM total score= 12: 34 (14.5%)
Susman et al, 2002 [42] (USA)	Retropective review of data from the New York State Trauma Registry Usual trauma	All head-injured patients (classified by ICD9 diagnosis code) with age ≥15 years Mean ISS 17.52 (SD 10.5)	mFIMMTOS Self-care (eating): 1-4 Locomotion (walking or wheelchair): 1-4 Communication (expression):1-4	Acute hospital discharge Not reported how or by whom assessed n=11,772 (means all	Report % of patients with abnormal FIM (score of>1) in each domain (expression, feeding and	Not applicable to study	n=11,772 mFIM at D/C (% abnormal score of >1): Elderly n=3,203 Nonelderly n=8,569 mFIM Expression: Elderly 16.9% Nonelderly 8% p<0.01

	care n=11,772	Mean age 46.6 years (SD 23) 8289 male (70.4%)	Total score interpretation in this study: *NB: reverse of all other studies using FIMMTOS 3= normal function 12=poorest function	patients survived despite mortality)	locomotion) grouped by whether elderly (≥65 years) or nonelderly (<65 years)		Nonelderly 17	tion: Elderly 35.8%
Grossman et al, 2003 [43] (USA)	Retrospective analysis of the Pennsylvania Trauma Sytems Foundation State Registry Usual trauma care n=43,297	All elderly (≥65 years) admissions with a trauma diagnosis code of external casue of injury, hospital LOS ≥72 hours or admission directly to ICU or operating room. Those with GCS=3 who were intubated at the time of admission were excluded (isolated hip fractures also not included in their registry) Total group ISS, age and gender not reported Patient's divided into 2 cohorts on the basis of age: Geriatric trauma patients (GTPs)= 65-79 years Octogenarian trauma patients	mFIM (version 2) Self-care (eating): 1-4 Transfers (bed to chair): 1-4 Locomotion (walking or wheelchair): 1-4 Communication (expression): 1-4 Social cognition (social interaction): 1-4 Total score interpretation: 5= total dependence 20= complete independence	Acute hospital discharge Not reported how or by whom assessed n=30,786	Mean (SD) mFIM score in each domain at discharge in GTPs versus OTPs overall and stratified by ISS (ISS<10, 10≤ISS≤20, ISS >20)	Not applicable to study	Mean (SD) mFIID/C:	M in each domain at GTPs $(n=12,207)$ 3.5 ± 0.8 3.7 ± 0.7 3.5 ± 0.9 3.0 ± 1.2 2.9 ± 1.0 3.1 ± 0.9 2.9 ± 1.1 2.4 ± 1.1 3.7 ± 0.7 3.9 ± 0.5 3.7 ± 0.7 3.4 ± 1.0 3.0 ± 1.0 3.1 ± 0.9

		(OTPs)= ≥80 years GTPs mean ISS 12 (SD 9) OTPs mean ISS 11 (SD 8)					ISS<10 3.6 ± 0.8 $10 \le ISS \le 20$ 3.4 ± 1.0 ISS > 20 3.0 ± 1.2	3.9 ± 0.5 3.7 ± 0.7 3.4 ± 1.0
Wagner et al, 2003 [44] (USA)	Prospective cohort study to determine the association of reciept and timing of physical medicine and rehabilitation (PM&R) consult on functional outcome at acute hospital discharge, discharge planning and acute LOS for people hospitalised with TBI n=1866	All adults >17 years admitted with nonfatal TBI Total group ISS and age not reported 1278 male (68.5%)	mFIM (version 2) as above	Acute hospital discharge Direct patient observation Nursing staff or trauma registry coordinator n=1866	Univariate relationship of reciept and timing of PM&R consult (≥48hr versus <48hr) to acute outcome using univariate analysis mFIM outcomes are cateogorised as low (1-3) vs high (4) with low=risk cateogory	Not applicable to study	PM ≥48h v<48hr n=1799 95% CI FIM locomotion 2-9* FIM transfer 1-6* FIM expression 1-3 FIM feeding 0.7-2 FIM social 0.9-3	17 13-22* 3
Dhungel et al, 2015 [45] (USA)	Prospective observational study to investigate the effect of obesity on functional recovery after trauma Usual trauma care n=235	Adult trauma patients (>18 years) admitted for >24 hours and able to consent themselves Total group ISS, age and gender not reported	mFIM (version 3) Self-care (eating, grooming, bathing, dressing upper body, dressing lower body, toileting): 1-4 Sphincter control (bladder management, bowel management): 1-4	Acute hospital admission, discharge and 6 months post discharge Not reported how or by whom assessed for admission and discharge scores n=235 6 month post	Mean total mFIM scores (SD) and n (%) independent (total mFIM=72) at each timepoint grouped by obesity status	Mean total mFIM (SD) Nonobese n=61: 38.2 (13.9) Overweight n=95: 40 (11.1) Obese n=42: 38.3 (15.1) Morbidly obese n=37: 41.6 (13.9) Independent (total mFIM=72) n (%): Nonobese: 2 (3%) Overweight: 2 (2%) Obese: 0 (0%) Morbidly obese: 1 (3%)	(%): Nonobese: 15 (Overweight: 15 Obese: 3 (8%) Morbidly obese	1: 62 (8) 95: 60 (8) 7 (13) n=37: 59 (9) otal mFIM=72) n (25%) (16%) : 6 (17%) total mFIM gain

			Transfers (bed to chair, toilet transfer, shower transfer): 1-4 Locomotion (walking or wheelchair, stairs): 1-4 Communication (comprehension, expression): 1-4 Social cognition (social interaction, problem solving, memory): 1-4 Total score interpretation: 18= total dependence 72=complete independence	discharge scores via survey n=186			Nonobese: Overweight 3.3/day (3) Obese: 19 (Morbidly ob 1.7/day (1)	: 20.0 (11.5) (13) and 3/da	and `´and `´
Schaller et al, 2016 [46] (Austria, Germany and USA)	Multicentre international parallel-group RCT to investigate early mobilisation in ICU (secondary outcome measure) Usual care versus early, goal directed mobilisation n=200 total cohort n=52 trauma cohort	Patients admitted to surgical ICU aged ≥18 years, mechanically ventilated for <48 hours and expected to require it for at least a further 24 hours, previously functionally independent based on proxy completion of a measure. Excluded if motor component of GCS <5, raised ICP, disorder with 6 month	Mini-modified FIM score (mmFIM) Transfers (bed to chair): 1-4 Locomotion: 1-4 Total score interpretation: 2=total dependence 8=complete independence	ICU discharge and acute hospital discharge Direct patient observation and chart review as appropriate by trained blinded assessors n=200	Median total mmFIM score and individual domain scores (IQR) at ICU discharge and acute hospital discharge in the usual care and control group with between group difference, for odds ratio (95% CI) and p value	Not applicable to study	3 (1-4) 1 (0 Locomotion: 0 (0-1) Transfers: 0 (0-1) Acute hosp	2 (1-3) 2 (1-3) Dital D/C: tervention group (n=104) 1: 8 (4-8)	Control group (n=96) 4 (2-5) 2 (0-2) 2 (1-2) Control group (n=96) 5 (2-8) 2 (1-4) 3 (2-4)

unstable	
fractures with	Online supplement has domain
probable	individual scores n (%) scoring 0-4
immobility,	in both domains
cardiopulmonary	
arrest, acute MI,	
pregnant or had	
ruptured	
aneurysm	
Median age 65	
years (46-74)	
126 male (63%)	
No trauma	
group specific	
numbers	
reported	

Table S5- Table of Acute Care Index of Function (ACIF) data

Author Year of publication Country	Study design Any intervention under investigation?	Trauma population (+/- ISS) Age mean (SD) or median (IQR)	Timepoint of ACIF assessment Total sample size (n)	ACIF data reported	ACIF scores (n) Mean (SD) or median (IQR)	ACIF scores (n) Mean (SD) or median (IQR)
		Gender male (%)	(-)		Initial physiotherapy review	Discharge scores
Roach et al, 1988 [48] (USA)	Designed ACIF, neurological disorders in an acute care setting with then a retrospective review of data collected Literature review, method for index development, description of ACIF, scoring system development and feasibility, precision tested in specific post CVA cohort only	Head and SCI included in mixed cohort of patients treated by physical therapists admitted to a neuromedicine - neurosurgery service at a major University medical centre No trauma specific group demographics	Initial contact and at weekly intervals/ discharge from acute care n=75	Only reported on n=28 cohort of CVA patients only grouped by discharge destination (NH or Rehab) at initial and discharge	Graph of mean scores by D/C destination group: D/C to nursing home: 18 D/C to rehabilitation: 32	Graph of mean scores by D/C destination group: D/C to nursing home: 22 D/C to rehabilitation: 55
Van Dillen et al, 1988 [50] (USA)	Prospective cohort study (5 week period ?1986), acute neurologic ward Test the interrater reliability and concurrent validity of the ACIF in the acute neurological setting	Acute neurology setting including neurosurgery and requiring physiotherapy input	Each patient rated weekly by a pair of physical therapists Total group=91 Trauma cohort: head injury=7, SCI=12 (?also some craniotomy trauma related n=11)	No ACIF scores reported, only agreement between raters for each item of the ACIF	Data not reported	Not relevant to this study
Parker et al, 2013 [47] (USA)	Retrospective analysis (January 2008-December 2009), acute trauma ward To describe the functional status of patients in the acute phase after trauma	Trauma patients admitted to the Brigham and women's hospital trauma service who received physiotherapy during their admission 54 years (SD 24)	Initial physiotherapy evaluation and at discharge from physiotherapy services n=526	ACIF scores for whole group at initial review and discharge as well as grouped by ISS >15 or ≤15 Discharge mean ACIF scores by age groups ≤40 years; 41-65 years and median change in ACIF	Whole group: Mean ACIF score: 47.3 (SD 30.9) Median ACIF score: 42.5 Whole group by ISS: ISS ≤15 (n=257): mean 56.7 (SD 30.2) ISS >15 (n=267): mean 38.3 (SD 28.8)	Whole group: Mean ACIF score: 68 (SD 29) Median ACIF score: 71 By ISS: ISS ≤15 (n=257): mean 74 (SD 27) ISS >15 (n=267): mean 62 (SD 30)

		ISS 16.5 (SD 10.6) (median 16 IQR 9- 22) Acute LOS 8.9 days (SD 9.5) median 5 IQR 3-11) Gender not reported		scores (from initial to discharge) Mean values of D/C ACIF scores for 6 groups by D/C destination		By Age: ≤40 years: mean 80 (SD 27) But report Median change: 21 (0-43) 41-65 years: mean 68 (SD 30) Median change: 25 (8-40) >65 years: mean 58 (SD 27) Median change: 8 (0- 21) D/C destination n (%) and mean ACIF (SD) Rehabilitation: 226 (44%): 45 (20) Home:
						161 (31%: 94 (15) Home+help: 93 (18%): 86 (16) Nursing home: 27 (3%): 46 (22) Other: 14 (3): 66 (30) Expired: 4 (0.8%): N/A Psychiatric: 3 (0.6%): 100 (0)
Bissett et al, 2016 [49] Australia	Prospective observational study, ICU setting (September to December 2014) To establish interrater reliability of the ACIF in ICU patients and determine whether scores have predictive value beyond ICU	ICU at a MTS	Weekly after D3 of ICU stay and at ICU discharge n=100 Trauma specific group n=42	ACIF score of 2 assessors presented in graph only top compare the 2 ACIF and IMS scores in a graph to look at correlation	No trauma specific data reported	No trauma specific data reported
Roach et al, 1998 [51] USA	Retrospective cohort study, acute trauma/orthopaedic	Patients with orthopaedic problems seen by	First PT review then every 3 days and	Mean ACIF score (SD) on initial PT review and D/C	No trauma specific data reported	No trauma specific data reported

ward (August- December 1993) Examine the relationship between minutes of physical therapy (PT) provided to patients with lower extremity orthopaedic problems and their functional status at	physical therapists during acute care hospitalisation, including fracture of pelvis, femur and tibia as trauma cohort, >18yo No trauma group specific demographics	within 48 hours of discharge n=173 Trauma specific group n=23	Mean subset scores (SD) for mental status, bed mobility and transfer/mobilty on initial PT review and D/C	
functional status at acute hospital discharge	demographics			

Table S6- Table of floor and ceiling effects for individual component scores of the mFIMMTOS

			S total score 12)	mFIMMTOS domain score (1-4)			
		•	,	Locor	motion	Fee	eding
Study (n)	Trauma patient cohort	Floor effect n (%)	Ceiling effect n (%)	Floor effect n (%)	Ceiling effect n (%)	Floor effect n (%)	Ceiling effect n (%)
Glance 2004 n=14,980 USA	Blunt trauma without associated head or spinal cord injury, >18 years Mortality 5%, mean age 44.4 years, 63% male, mean ISS 7	91 (0.6)	8117 (52)	Not reported	Not reported	Not reported	Not reported
Demetriades 2005 n=8909 USA	Major trauma patients >14 years, ISS >15 alive on admission and at least one of defined severe injuries Age, gender and ISS not reported, mortality 27%, 22% to IPR at discharge	Not reported	3564 (40)	1871 (21)	Not reported	891 (10)	Not reported
Williamson 2011 n=243 Australia	Blunt trauma and ISS >15, 15-80 years Median age 33 years (21-46) 82% male, median ISS 28 (19-34), 60.9% to IPR at discharge	8 (3)	34 (15)	Not reported	Not reported	Not reported	Not reported
Haider 2009 n=269,614 USA	Patients >14 years, moderate to severe blunt trauma with an ISS ≥9, mean age 39 years, 69% male, mean ISS 16.9 (SD 6.25)	Not reported	99,757 (37)	Not reported	129,415 (48)	Not reported	226,476 (84)
Gabbe 2006 n=658 Australia	Major trauma patients (ISS>15) who survived to acute hospital discharge ISS 22 (range 1-66), median age 40 (range 15-94 years), 529 male (71.6%)	Not reported	Not reported	94 (14)	321 (49)	42 (6)	237 (81)

Gabbe 2008 n=243 Australia Australia Survivors admitted to two major trauma centres age 80 years, blunt mechanism and estimated ISS >15 Actual median ISS 25 (IQI 18-34), median 33 years (21-47), 199 male (81.8%)	d 15- ⁿ Not reported R IQR	Not reported	87 (36)	53 (22)	28 (11)	111 (46)
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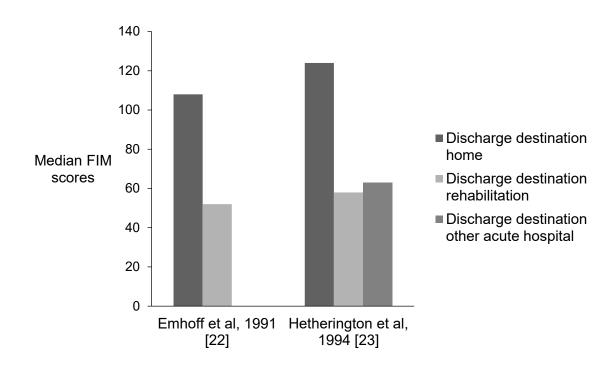


Figure S1- Median discharge FIM scores by discharge destination (construct validity) [22], [23]

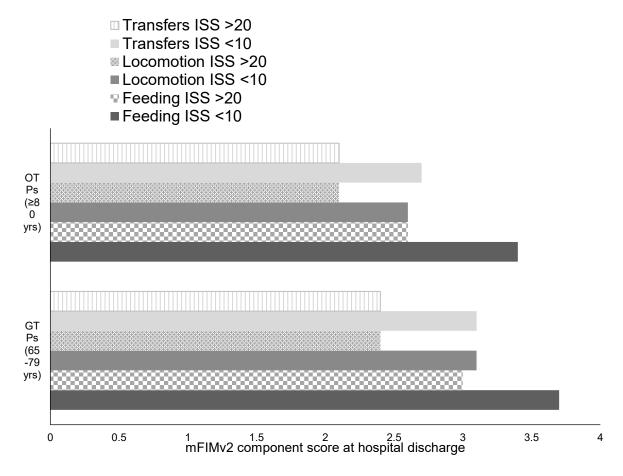


Figure S2: Mean mFIMv2 component scores at discharge for transfers, locomotion and feeding, stratified by ISS and grouped into Octogenarian Trauma Patients (OTPs) and Geriatric Trauma Patients (GTPs) [43]

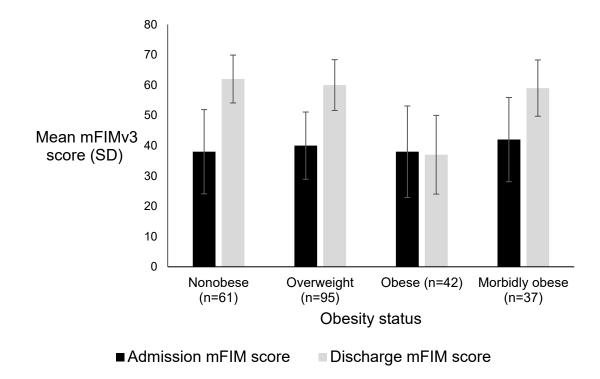


Figure S3- Mean mFIMv3 scores (SD) at admission and discharge grouped by obesity status (responsiveness) [45]. Significant difference between groups for FIM at discharge (p=0.027)

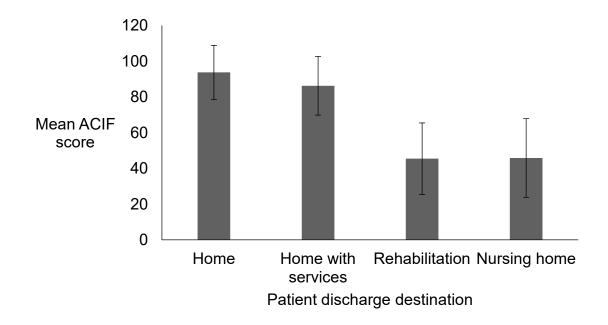


Figure S4- Mean discharge ACIF scores (SD) by discharge destination (construct validity) [46]

Chapter Four: Outcome measures study

Declaration for thesis Chapter Four, which was submitted to Physical Therapy Journal on the 29/03/2020:

Calthorpe S, Kimmel LA, Fitzgerald M, Webb MJ and Holland AE. The Reliability, Validity, Feasibility and Responsiveness of Measures for Assessing Mobility and Physical Function in Patients following Traumatic Injury in the Acute Hospital Setting: A Prospective Study.

The nature and extent of my contribution to the work in Chapter Four was the following:

Nature of contribution	Extent of
	contribution
Principle author responsible for the concept, design,	
study management, statistical analysis, manuscript	80%
development and writing.	

The following co-authors contributed to the work. There are no student coauthors.

Name	Nature of contribution
Lara A Kimmel	Assisted with concept, design, statistical analysis, manuscript development and writing.
Melissa J Webb	Assisted with concept, design, manuscript development and writing.
Mark Fitzgerald	Assisted with manuscript development and writing.
Anne E Holland	Assisted with concept, design, statistical analysis, manuscript development and writing.

The undersigned hereby certify that the above declaration correctly reflects the nature and extent of the candidate's and co-authors' contributions to this work.

Candidate's Signature: SCAP Date: 29/03/2020

Main Supervisor's Signature: Date: 29/03/2020

The Reliability, Validity, Feasibility and Responsiveness of Measures for

Assessing Mobility and Physical Function in Patients following Traumatic Injury in
the Acute Hospital Setting: A Prospective Study.

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ABSTRACT

<u>Background</u>: The longer-term impact of injury is increasingly recognised, but the early phases of recovery are less well understood. The best tools to measure early recovery of mobility and physical function following traumatic injury are unclear.

Objective: To assess the feasibility, validity, reliability and responsiveness of four mobility and physical function measures in patients following traumatic injury.

Methods: A cohort, measurement-focussed study (n=100). The modified lowa Level of Assistance Score, Acute Care Index of Function, "6 Clicks" Short Forms and Functional Independence Measure were completed during first and last review physiotherapy review. Feasibility was collected and floor and ceiling effects were documented. Known-groups validity (early vs late in admission); predictive validity (using 6-month post injury outcomes data) and responsiveness were assessed. Inter-rater reliability was assessed in 30 patients with stable mobility and function.

Results: Participants had median age 52 years (IQR 33-68 years) and 68% were male. The modified Iowa Level of Assistance Score, Acute Care Index of Function and "6 Clicks" Short Forms were quick to administer (1 minute to 90 seconds), but the Functional Independence Measure took much longer (>7 minutes). Ceiling effects were present for all measures except the Functional Independence Measure (in 18-33% of the group). All had strong known groups validity (early versus late in admission p<0.01) and there was some evidence of predictive validity for all measures (weak to moderate correlations with 6-month outcomes). All were responsive (effect sizes >1.0) and had excellent inter-rater reliability (Intra-class correlation coefficients 0.79-0.94).

Conclusion: All four measures were reliable, valid and responsive but their

feasibility varied. This study is a critical building block towards evidence-based

measurement in acute trauma physiotherapy care.

Impact Statement

Early recovery of mobility and physical function in the acute hospital setting after

traumatic injury is poorly understood and inconsistently measured by

physiotherapists.

This study documented robust clinimetric properties of four instruments to

measure mobility and physical function following traumatic injury, however

feasibility varied and ceiling effects were common.

This study provides critical information to guide assessment of mobility and

physical function in acute trauma physiotherapy, which may facilitate

benchmarking across physiotherapy services and development of more effective

physiotherapy interventions.

Word Count Manuscript: 3881

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INTRODUCTION

Traumatic injury is a significant global public health problem, responsible for 9% of the world's total deaths each year and accounting for 6% of all years lived with temporary or permanent disability ¹. The longer-term impact of injury on health and quality of life is increasingly recognised ²⁻⁵, but the impact of early recovery during the acute hospital setting is less well understood. Improvements in mobility and physical function are key aspects of early recovery. Documenting early recovery would allow the relationship between early function and longer-term outcomes to be explored, identify patients who may benefit from additional interventions, and enable benchmarking across different hospitals.

We recently completed a systematic review of instruments used to assess mobility and physical function of trauma patients through direct observation in an acute hospital setting ⁶. For an instrument to be suitable for use in patients following traumatic injury it must be feasible to use in the acute setting, be reliable, have construct and predictive validity, be sensitive to change with intervention and display minimal floor and ceiling effects. Three measures identified in the systematic review (the modified lowa Level of Assistance Score-mILOA ⁷; Functional Independence Measure- FIM ⁸; and the Acute Care Index of Function- ACIF ⁹) showed some promise, but most data came from studies that did not document clinimetric properties. One additional measure of interest is the Activity Measure for Post-Acute Care (AM-PAC) "6 Clicks" Short Forms ¹⁰, which has been used extensively in acute hospital settings ^{11, 12}. As none of these instruments had sufficient clinimetric data to support routine use, we designed a study to further investigate and explore their use in this cohort and setting.

METHODS

Aims

The aims of this study were to assess the feasibility of four mobility and physical function measures and analyse their validity, reliability and responsiveness to change over the course of the admission in patients following traumatic injury in the acute hospital setting.

Design

This was a single centre, prospective study conducted at the Alfred Hospital, a level 1 trauma centre in Melbourne, Australia. Ethics approval was obtained from the Alfred Hospital Human Research Ethics Committee. All participants were recruited during their inpatient hospital stay and provided written informed consent.

Role of the Funding Source

This study was supported by an Alfred Hospital Research Trust Small Projects
Grant (awarded September 2018). The funders played no role in the study
design, data collection, data analysis or reporting of this study.

Participants and Setting

Between January and June 2019, consecutive adult patients (aged 18 years or older) admitted to the trauma ward under the care of the trauma service were screened for inclusion, with a total of 100 participants included. Patients were excluded if they had no injuries expected to affect their usual level of mobility and function; required physical assistance to mobilise prior to their admission or were

nursing home residents; had complete spinal cord injuries or were unable to consent themselves due to neurological or cognitive impairment (pre-existing or as a result of their injuries such as traumatic brain injury). Written informed consent was obtained by the principal investigator or research assistant, prior to the first physiotherapy review for mobilisation.

Outcome Measures

The description of the four outcome measures used can be found in the supplementary data section (Supplementary Table 1). For the AMPAC "6 Clicks" Short Forms ¹⁰, only the Basic Mobility and Daily Activity forms were relevant for use in this study.

<u>Assessors</u>

The outcome measures were completed by the treating physiotherapists (n=18) as part of usual physiotherapy care. The physiotherapists had varying levels of experience in the acute hospital trauma ward setting, from several months (grade 1 classification) to many years (grade 2 and grade 3 classifications), which reflected the existing physiotherapy team caring for these patients. All the assessors attended an information session about the study and the outcome measures, with the opportunity to ask any questions. All were credentialed in the use of the FIM.

Testing Procedure

Demographic data were collected including patient characteristics, injury mechanism, injury type, discharge destination from the acute hospital (home or ongoing inpatient care), weightbearing status and injury severity score (ISS).

Testing was completed during first and last physiotherapy review, when patients were asked to complete the mobility or functional items included within each outcome measure to the best of their ability. Physiotherapists used their clinical judgement to assess if it was appropriate to try a specific task (eg. transfer to sit out of bed, going up and down a step or stairs). Each measure was then scored by the physiotherapist on the paper data collection forms. The measures were completed in random order, predefined for each participant by the order of forms in each assessment pack, to avoid any order effects. Extra reference information was available where required to assist with scoring (eg. the FIM booklet).

Clinimetric Properties

Feasibility

In a random sample of 30 participants, the physiotherapists were asked to record the time each measure took them to complete (additional to their usual physiotherapy review), and any issues or comments they had with regards to completing the measures. Floor and/or ceiling effects were calculated from first and last physiotherapy review scores in the entire sample (n=100) by calculating the proportion of patients with the minimum and maximum possible scores for each outcome measure.

<u>Validity</u>

Known groups validity was assessed by comparing scores on each measure in groups known to be different with regards to their physical function and mobility: i) Early in admission versus ready for discharge: The scores taken at the first physiotherapy mobility review (usually within 48 hours of hospital admission) in one group of patients (n=50) were compared with scores taken during last

physiotherapy review (just prior to hospital discharge) in a different group of patients (n=50). These groups were randomly selected from the total cohort (n=100) through a random number generator in excel, with first scores taken from the first 50 patients and last scores from the remaining 50 patients.

ii) Discharge destination: Last physiotherapy review scores for the whole cohort (n=100) were compared between those who were discharged home and those who were discharged to ongoing inpatient care.

Predictive validity was assessed by examining the relationship between discharge scores and routinely collected outcomes at six-months following injury from either the Victorian Orthopaedic Trauma Outcomes Registry or Victorian State Trauma Registry. Outcomes of interest were: return to work in those who were working prior to injury (yes/no); the Glasgow Outcomes Score Extended (GOSE) ¹³, the World Health Organization Disability Assessment Schedule (WHODAS- 12 parts version) ¹⁴ and the Euro Quality of Life-5 Dimensions-5 Levels (EQ-5D-5L) ^{15, 16}. Details of these patient reported outcome measures are provided in the supplementary data section (Supplementary Table 2)

Interrater Reliability

Reliability was assessed by comparing scores from two assessors for each measure. Once the patient was at a "stable" level of mobility and deemed unlikely to change within a 24-hour timeframe, the patient was reviewed and all scores were calculated by an additional physiotherapist (n=30). The second physiotherapist was given all the information required to safely review the patient, but was blinded to any previous treatment or assessment scores.

Responsiveness

Responsiveness was assessed for each instrument by comparing scores at first physiotherapy review (n=100) with those at last physiotherapy review (n=100).

Sample Size

Sample size estimates were based on detecting responsiveness to change over time, using data from a study using the mILOA ¹⁷. This study was used as there were sufficient data available to determine sample size in a cohort of acute hospital patients. A total of 90 participants was required to detect a 6-point improvement in mILOA between admission and discharge with 80% power and a two-sided 0.05 significance level, assuming a standard deviation of 10 points. Assuming 10% missing values at discharge, a total of 100 participants were recruited to ensure sufficient power for all analyses.

Sample size estimates for the inter-rater reliability were based on the methods of Walter ¹⁸, with 2 observations per participant, assuming an expected ICC of .6, a null ICC of .2, a type I error of .05, and a type II error of .2. To allow for potential non-completion, we included 30 participants in the reliability study. These participants were also included in the validity and responsiveness study.

Data Analysis

Analysis was performed using SPSS version 25.0 ¹⁹. Data are presented as means and standard deviations (SD) or medians and inter-quartile range for data not normally distributed.

Feasibility

Floor or ceiling effects were considered present if more than 15% achieved the highest or lowest possible score ²⁰.

Known Groups Validity

Since data were not normally distributed, Mann Whitney U tests were performed to compare scores between first (early in admission) and last (just prior to discharge) physiotherapy review, and to compare groups defined by discharge destination (home or ongoing inpatient care).

Predictive Validity

Mann Whitney U tests were performed to compare scores at last physiotherapy review between those who did or did not return to work; those with unfavourable vs favourable outcome (GOSE score dichotomised as unfavourable 1-4 and favourable 5-8) and those with problems vs no problems on the EQ5D total and domain scores. The relationship between last physiotherapy review scores and all 6 month outcome measures final scores were investigated using scatterplots and Spearman's Rank Order Correlation coefficient (rho=r), with the strength of the relationship between the two variables interpreted as small for r=0.1-0.29; medium for r= 0.3-0.49 and large for r=0.5-1.0 ²¹.

Interrater Reliability

The interclass correlation coefficient (ICC) with 95% confidence intervals (CI) was calculated to assess reliability of each measure in patients defined as stable.

Type ICC (1,1) was chosen because each patient was assessed by a different pairing of physiotherapists, and the calculation was from a single measurement

 22 . An ICC is considered poor if <0.4; fair if 0.4-0.59; good if 0.6-0.74 and excellent if 0.75-1.0 23 .

Responsiveness

An effect size was calculated for each measure to quantify the improvement over admission using the formula:

Effect size = $(\mu 1 - \mu 2)/\sigma 1$, where $\mu 1$ = mean score at baseline (first physiotherapy review), $\mu 2$ = mean at follow-up (last physiotherapy review) and $\sigma 1$ = baseline SD (first physiotherapy review), with all scores expressed as positive numbers to allow comparison across the four measures. The ES was interpreted using guidelines from Cohen 24 .

The Standard Error of Measurement (SEM) was also calculated as a further test of reliability using the formula:

SEM = $\sigma 1 \times \sqrt{1}$ -r (where r is the test-retest reliability of the measure or the Intraclass Correlation Coefficients (ICC), calculated for each measure in the interrater reliability part of the study described above).

Finally, the Minimal Detectable Change at the 95% confidence interval (MDC95) was calculated. The MDC95, which represents a change in score that is not related to measurement error with 95% confidence, was calculated using the formula:

MDC95= 1.96 x SEM x $\sqrt{2}$

RESULTS:

One hundred patients participated in the study, completing first and last physiotherapy reviews. Demographics are shown in Table 1. The group had a median age of 52 years (IQR 33-68 years), were predominantly male (68%) and

most commonly injured in a motorcycle (25%) or motor vehicle crash (20%). The median ISS was 14 (n=93; IQR 9-19), with the most frequently injured regions of the body being the spine (48%), upper limb (46%) and lower limb (44%), in isolation or combination with other regions. More than 50% (n=56) were required to non-weightbear (NWB) one of their lower limbs, with 43% NWB on one of their upper limbs. Only 13% were bilaterally NWB on both lower limbs, with 5% NWB on both upper limbs.

Feasibility

The average extra time taken to score each measure was <1 minute for the mILOA and < 90 seconds for both "6 Clicks" Short Forms and ACIF, with only the FIM taking considerably longer at 7 minutes and 30 seconds (n=30). Most physiotherapists did not identify any issues with the use of the mILOA, "6 Clicks" Short Forms and ACIF, but several commented that the FIM had large number of items to score and that extensive liaison was required with other team members caring for the patient (nursing staff and occupational therapy), particularly for items not considered within usual physiotherapy review. The feasibility of the FIM was affected by the time point of measurement; at first physiotherapy review many patients had not opened their bowels and often had no clothes available to get dressed. Table 2 shows the number of patients who scored the lowest or highest scores on each measure at first and last physiotherapy review. No measures had a floor or ceiling effect at first review. At last review, a ceiling effect was seen with the mILOA (21%), ACIF (18%), "6 Clicks" basic mobility (33%) and "6 Clicks" daily activity (22%). There was no ceiling effect for the FIM.

Known Groups Validity

All measures demonstrated statistically significant differences between patients early versus late in admission (all p<0.0005, Table 3). All measures also demonstrated significantly better scores in those being discharged home compared to those discharged to other inpatient care (Table 3).

Predictive Validity

Final six-month outcomes data were available for 82% of the cohort (n=82), although not all of the measures were available in all participants. For RTW (n=82), 53 participants (65%) were working or studying prior to their injury and 32 participants (60%) had RTW by 6 months. There was no statistically significant difference between final physiotherapy review scores in those who had RTW at 6 months and those who had not RTW, although there was a trend towards total FIM scores being higher in those who had returned to work (p=0.089) (Supplementary Table 3).

The GOSE was available for 54% of the cohort. The median GOSE score at six months was 6 (upper moderate disability, IQR 5-7) with correlation coefficients from 0.16 to 0.24, indicating a weak relationship between all final physiotherapy review scores and the GOSE at 6 months, however this did not reach statistical significance (Table 4, p=0.08 to 0.24). There was no statistically significant difference between final physiotherapy review scores and dichotomised GOSE (favourable versus unfavourable outcome) (Supplementary Table 4).

The WHODAS scores were available for 70% of the cohort (n=70). The median WHODAS total simple score at 6 months was 9.5 (IQR 2-20) with correlation

coefficients from 0.26 to 0.34, indicating a weak to moderate relationship between all final physiotherapy review scores and the WHODAS at 6 months (Table 4). All were statistically significant (p=0.004 to 0.03).

Finally, the EQ-5D-5L scores were available for 81% of the cohort (n=81). The median EQ-5D-5L total simple score at 6 months was 10 (IQR 7-14) with correlation coefficients from 0.19 to 0.27, indicating a weak relationship between all final physiotherapy review scores and EQ-5D-5L at six months (Table 4), with mILOA (p=0.03), ACIF (p=0.02), "6 Clicks" basic mobility (p=0.02) and "6 Clicks" daily activity (p=0.04) all statistically significant. For dichotomised data, there was no statistically significant difference between final physiotherapy review scores and EQ-5D-5L total simple score (no problems versus problems), however some differences were apparent in the domain scores, primarily related to mobility and usual activities (Supplementary Table 5).

Interrater Reliability

The demographics and characteristics of the 30 patients included in the reliability study are shown in Table 1. Sixteen physiotherapists completed the measures with the median time between the two scores 3 hours and 25 minutes (IQR 1 hour 20 minutes to 21 hours). All measures showed excellent reliability (ICC>0.75) (Table 5).

Responsiveness

The responsiveness of each measure was calculated using all 100 scores from first and last physiotherapy reviews. Very large ES were seen for all measures (all >1.00), with the SEM and MDC95 of each shown in Table 6. The average

change in all measures from admission to discharge was greater than the MDC95 (Table 6).

DISCUSSION:

This study has documented the clinimetric properties of four different mobility and physical function outcome measures in a cohort of trauma patients in an acute hospital ward setting. The mILOA, "6 Clicks" Short Forms and ACIF were all quick to administer (from 1 minute to 90 seconds each) making them feasible in the acute setting. None of the measures had any floor effects, but ceiling effects were present for all measures except the FIM (in 18-33% of the group). All the measures had excellent inter-rater reliability (ICC 0.79-0.94) and strong known groups validity. They were all responsive to change in mobility and physical function during the acute hospital admission (all ES >1.0). The mean changes in scores were all greater than the calculated MDC95 value, suggesting a true change in the mobility and physical function of the patients could be detected (Table 6).

Feasibility for use in the acute setting was demonstrated for the "6 Clicks" Short Forms, mILOA and ACIF which were all quick to administer. None of these measures require formal training, but a licence is required for use of the "6 Clicks" Short Forms (AU\$265/ 12 months). The FIM took much longer to complete (average of 7 minutes and 30 seconds) and required greater consultation with other healthcare professionals. The FIM is also a licensed product and requires a formal day training course (AU\$278.30) then an on-line refresher course every 2 years to maintain competency (\$82.50). However, it must be recognised that the FIM assesses a larger number of domains than the other measures, so the goal of measurement may affect the choice of instrument.

When considering which to use for clinical practise or research, both the feasibility and ceiling effects must be explored in more detail. Firstly, the feasibility of each measure with regards to both the time taken for completion (over 7 minutes for the FIM); time required for training (1 full day, plus an exam every 2 years for the FIM) and any costs involved for training or licensing (FIM costs AU\$278 plus biannual refresher AU\$83 and "6 Clicks" Short Forms costs AU\$265/ 12 months). If minimal time and no funding is available, the ACIF and mILOA may be more suitable. Secondly, the more detailed specifics of the content of each measure should be considered in relation to the planned clinical use. Trauma patients often require gait aids in order to mobilise with their injuries, particularly if they are required to non-weightbear a leg (such as use of a gutter frame, pick-up frame or crutches). The "6 Clicks" Short Forms, FIM and ACIF do not allow consideration of the type of gait aid required and therefore may lack sensitivity in capturing patient mobility and physical function in relation to gait aid use. If patients require a wheelchair for their "mobility" due to non-weightbearing requirements (of an arm and leg or both legs), only the ACIF and FIM account for this in their scoring, so a limit may be reached quickly in these patients if using the mILOA and "6 Clicks" Short Forms. The mILOA and ACIF also do not include any activities of daily living tasks, so if these are important as part of broader physical function, the FIM or "6 Clicks" Short Forms may be more suitable. If the measures are for use in younger trauma patient cohorts, greater mobility distances and higher-level activity components may be preferable. As the "6 Clicks" Short Forms only requires distances of around 3 metres and the mILOA only 1 step, FIM which requires a full flight of stairs and distances of >45m and the ACIF which assesses >15m and five steps, may be more appropriate.

When considering the ceiling effects (present for all measures except the FIM at last physiotherapy review in 18-33% of cases), the planned timepoint/s of the assessment would be very important. For research purposes, use of any measure with an in-hospital ceiling effect may not be appropriate as an outcome measure, as it may not be responsive to an effective intervention. For routine clinical use in the acute setting, this may not be the decisive factor. Ceiling effects were only present in those patients deemed physically safe for discharge home again at last physiotherapy review, indicating a level of mobility and physical function that no longer requires ongoing acute inpatient care and support from physiotherapists.

The strengths of this research are the rigorous assessment of a range of important clinimetric properties and inclusion of a wide range of physiotherapists to complete the measures, across various levels of skills and expertise in working with trauma patients. This enables a broader applicability of the findings, particularly with regards to inter-rater reliability scores which were performed by two different physiotherapists on separate occasions. Measures were also completed in random orders, to prevent any learning effects and minimise bias.

Limitations

The limitations of our study include the exclusion of those patients unable to consent themselves and those with spinal cord injury, so omitting important groups of patients who often require physiotherapy resources and intervention in this setting. Since patients were recruited within our level 1 trauma service, results may not be applicable to other services which may have less severely injured patients, although the injury severity score of our cohort includes many with less severe injuries. Two of the measures also included items not considered

as mobility and physical function tasks: the FIM cognitive items and ACIF mental status items. However, as they did not form the bulk of either measure and since we also excluded patients with any new or old cognitive issues who could not consent, all participants scored well on these items at all time points, so they had little influence on the scores and their analysis.

CONCLUSION:

This study investigated and documented the clinimetric properties of four outcome measure instruments of mobility and physical function for use in acute hospitalised patients after traumatic injury. Several factors require consideration for routine use both clinically and for research purposes, including the domains represented by each measure, its feasibility for use in the required setting, as well as the planned timepoint/s for assessment after injury. The study is a critical building block towards evidence-based practice in acute trauma physiotherapy, both locally and in acute trauma services across the world. Next steps must include the use of such measures to benchmark outcomes across different hospitals and trauma centres, to further progress the knowledge base and understanding of what impacts on trauma patient outcomes, both in the acute hospital setting and beyond.

Table 1: Patient Demographics

Patient characteristics	Whole	Inter-rater	Known groups	validity	
	group		subgroups		
	n=100	n=30	Early first	Last	
			physiotherapy	physiotherapy	
			score	score	
			n=50	n=50	
Age (years), mean (SD)	52 (33-	54 (20)	44 (30-65)	62 (36-70	
or median (IQR)	68)				
Sex (male), n (%)	68 (68)	21 (70)	38 (76)	30 (60)	
Mechanism of Injury, n					
(%)	20 (20)	7 (23)	7 (14)	13 (26)	
Motor vehicle	25 (25)	7 (23)	16 (32)	9 (18)	
Motorcycle	13 (13)	3 (10)	6 (12)	7 (14)	
Pedal cyclist	5 (5)	1 (3)	3 (6)	2 (4)	
Pedestrian	14 (14)	3 (10)	7 (14)	7 (14)	
Low fall	15 (15)	4 (13)	5 (10)	10 (20)	
High fall (>1m)	3 (3)	2 (7)	3 (6)	0 (0)	
Struck by/collision					
with object/person	5 (5)	3 (10)	3 (6)	2 (4)	
Other					
Body region of injury, n					
(%)	10 (10)	3 (10)	6 (12)	4 (8)	
Head	39 (39)	11 (36)	19 (38)	20 (40)	
Chest	46 (46)	13 (43)	23 (46)	23 (46)	
Upper Limb	34 (34)	10 (33)	17 (34)	17 (34)	
Pelvis	44 (44)	14 (47)	22 (44)	22 (44)	
Lower Limb	12 (12)	4 (13)	7 (14)	5 (10)	
Abdomen	48 (48)	14 (47)	25 (50)	23 (46)	
Spinal		,	, ,	,	
Injury Severity Score,	n=93	n=29	n=46	n=47	
median (IQR)	14 (9-	14 (9-22)	17 (13-24)	13 (9-17)	
, ,	19)	, ,			
Non-weightbearing					
management for injury, n					
(%)	21 (21)	8 (27)	10 (20)	11 (22)	
Left Upper Limb	22 (22)	6 (20)	13 (26)	9 (18)	
Right Upper Limb	28 (28)		16 (32)	12 (24)	
Left Lower Limb	28 (28)		15 (30)	13 (26)	
Right Lower Limb	5 (5)	1 (3)	3 (6)	2 (4)	
Bilateral Upper	13 (13)	4 (13)	7 (14)	6 (12)	
Limbs	(- /	, ,	, ,		
Bilateral Lower					
Limbs					
Patient identified as					
physically independent, n					
(%)	4 (4)	18 (60)	1 (2)	Not	
At physiotherapy review/				applicable	
reliability score 1 review	64 (64)	18 (60)		' '	

At last physiotherapy review/ reliability score 2 review			Not applicable	33 (66)
Acute Hospital Length of Stay in days, median (IQR)	7 (5- 10)	9 (6-14)	first 7 (5-14)	7 (5-10)
Discharge destination Home Ongoing inpatient care	63 (63) 37 (37)	18 (60) 12 (40)	29 (58) 21 (42)	34 (68) 16 (32)

SD- Standard deviation; IQR- Interquartile range

<u>Table 2- Floor and ceiling effects at first and last physiotherapy review for each measure</u>

Outcome Measure	First physioth score	First physiotherapy review score		Last physiotherapy review score	
	Lowest score, n (%)	Highest score, n (%)	Lowest score, n (%)	Highest score, n (%)	
mILOA (0-36)	2 (2)	0 (0)	*21 (21)	1 (1)	
FIM motor (13-91)	4 (4)	0 (0)	1 (1)	2 (2)	
FIM total (18-126)	0 (0)	0 (0)	0 (0)	2 (2)	
ACIF (0-1)	0 (0)	1 (1)	0 (0)	*18 (18)	
6 Clicks Mobility (16.59- 57.68)	6 (6)	3 (3)	0 (0)	*33 (33)	
6 Clicks Daily Activity (17.07- 57.54)	2 (2)	4 (4)	1 (1)	*22 (22)	

mILOA- modified Iowa Level of Assistance Score; FIM- Functional Independence Measure; ACIF- Acute Care Index of Function.

^{*}Floor or ceiling effects considered present (>15% of the cohort)

Table 3- Known-groups validity: outcome measure scores in early versus late in admission and by discharge destination

	Early versus late in admission scores (median, IQR)			Last PT review s dest (medi		
Outcome Measure	Early in admission score (n=50)	Late in admission score (n=50)	p value	Discharge destination: Home (n=63)	Discharge destination: Inpatient Care (n=37)	p value
mILOA	28 (22-34)	8.5 (3-17)	<0.001	3 (0-6.5)	24 (13-30)	<0.0005
FIM motor	26 (19-34)	71.5 (53-80)	<0.001	77 (71-83)	40 (32-59)	<0.0005
FIM total	61 (54-69)	106.5 (87-115)	<0.001	112 (106-117.5)	75 (67-94)	<0.0005
ACIF	0.38 (0.26-0.48)	0.76 (0.53-0.95)	<0.001	0.86 (0.76-1.00)	0.47 (0.38-0.59)	<0.0005
6 Clicks Mobility	29.19 (22.61- 36.97)	45.55 (36.97-57.68)	<0.001	57.68 (45.55- 57.68)	35.55 (30.25-39.67)	<0.0005
6 Clicks Daily Activity	35.96 (29.04- 38.66)	44.27 (37.26-51.12)	<0.001	47.10 (42.03- 57.54)	37.26 (33.39-42.03)	<0.0005

IQR- Interquartile range; mILOA- modified Iowa Level of Assistance Score; FIM- Functional Independence Measure; ACIF-Acute Care Index of Function

Table 4: Spearman rho test for correlations between discharge scores and 6-month GOSE, WHODAS and EQ5D5L scores

	GOSE	WHODAS	EQ-5D-5L
Outcome	Correlation	Correlation	Correlation
Measure	Coefficient	Coefficient	Coefficient
mILOA	-0.16	0.27*	0.24*
FIM motor	0.18	-0.26*	-0.19
FIM total	0.18	-0.26*	-0.2
ACIF	0.17	-0.34*	-0.26*
6 Clicks Mobility	0.24*	-0.33*	-0.27*
6 Clicks Daily Activity	0.19	-0.3*	-0.23*

mILOA- modified Iowa Level of Assistance Score; FIM- Functional Independence Measure; ACIF- Acute Care Index of Function; GOSE- Glasgow Outcomes Score Extended; WHODAS- World Health Organization Disability Assessment Schedule- 12 parts version; EQ-5D-5L- Euro Quality of Life-5 Dimensions-5 Levels

^{*} Statistically significant (p= < 0.05)

Table 5- Interrater reliability data for all outcome measures

Outcome Measure	Mean reliability score 1 (SD)	Mean reliability score 2 (SD)	Mean difference between scores 1 and 2 (+ or -)	ICC (1,1)	95% CI of the ICC
mILOA	13.00 (11.91)	13.90 (12.22)	+0.9	0.940	0.81-0.95
FIM motor	62.03 (21.14)	63.30 (21.25)	+1.27	0.904	0.81-0.95
FIM total	97.00 (21.16)	98.27 (21.26)	+1.27	0.903	0.81-0.95
ACIF	0.70 (0.25)	0.73 (0.24)	+0.03	0.794	0.61-0.90
6 Clicks Mobility	43.81 (11.36)	43.44 (12.19)	-0.37	0.867	0.74-0.93
6 Clicks Daily Activity	42.95 (10.31)	44.93 (10.39)	+1.98	0.909	0.82-0.96

mILOA- modified Iowa Level of Assistance Score; FIM- Functional Independence Measure; ACIF- Acute Care Index of Function; SD- Standard deviation; ICC-Interclass correlation coefficient; 95% CI- 95% Confidence intervals,

Table 6- Responsiveness

Outcome Measure	First physiotherapy review, mean (SD)	Last physiotherapy review, mean (SD)	Mean difference between scores (SD of difference)	Effect Size	Standard Error of Measurement	Minimal Detectable Change
mILOA	24.66 (9.30)	11.82 (11.63)	-12.84	1.38	2.28	6.32
FIM motor	31.03 (16.82)	64.19 (19.68)	+33.16	1.97	5.21	14.44
FIM total	65.15 (17.56)	98.73 (20.08)	+33.58	1.90	5.47	15.16
ACIF	0.41 (0.18)	0.71 (0.24)	+0.30	1.67	0.08	0.22
6 Clicks Mobility	30.90 (9.17)	45.02 (10.98)	+14.13	1.54	3.34	9.26
6 Clicks Daily Activity	35.70 (8.12)	44.42 (9.31)	+8.72	1.07	2.45	6.79

mILOA- modified Iowa Level of Assistance Score; FIM- Functional Independence Measure; ACIF- Acute Care Index of Function; SD- Standard deviation

Author Contributions and Acknowledgements

All authors provided concept/ idea/ research design, writing, data analysis and consultation (including review of manuscript before submission).

S. Calthorpe managed the data collection and project management.

The authors thank Sarah McCormack, Patricia Loh, Asher Kirk, Nikki Littlewood and Amy Catlin for their assistance with his project. We also gratefully acknowledge all the members of the physiotherapy team who were involved in the data collection, as well as the study participants.

Ethics Approval

Ethics approval was obtained from the Alfred Hospital Human Research Ethics

Committee. All participants were recruited during their inpatient hospital stay and provided written informed consent.

Role of the Funding Source

This study was supported by an Alfred Hospital Research Trust Small Projects
Grant (awarded September 2018). The funders played no role in the study
design, data collection, data analysis or reporting of this study.

Conflict of Interest Statement

The authors completed the ICMJE Form for Disclosure of Potential Conflicts of Interest and reported no conflicts of interest.

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Supplementary Table 1: Outcome measurement instrument characteristics, training requirements and scoring systems

Outcome measure	What does it	Number of	Domains	Scoring	Min-max score
License or training	measure?	items to			
requirements?		score			
Full Functional	Functional	18 activities	Self-care (eating,	Rates patient's level	Full FIM=
Independence Measure	assessment	of daily living	grooming, bathing,	of disability:	18-126
FIM	measure to	items across	dressing upper body,	1: total dependence)	
Requires a license	assess patient	6 domains	dressing lower body,	2: maximal	Motor FIM=
Paid formal training (1	ability to perform	Motor FIM	toileting)	assistance	13-91
day course (\$278.30)	certain tasks	score=13	Sphincter control	3: moderate	
plus two yearly		items across	(bladder	assistance	Cognitive FIM=
credentialing and exam		4 domains	management, bowel	4: minimal	5-35
\$82.50)		Cognitive	management)	assistance	
Training open to nurses,		FIM score=5	Transfers (bed to	5: supervision	
allied health and doctors		items across	chair, toilet transfer,	6: modified	
with tertiary		2 domains	shower transfer)	independence	
qualifications			Locomotion (walking	7: complete	
			or wheelchair, stairs)	independence	
			Communication		
			(comprehension,		
			expression)		
			Social cognition		
			(social interaction,		
			problem solving,		
			memory)		
Acute Care Index of	Functional	20 items	Mental Health Status	Mental Health	0.00-1.00
Function (ACIF)	status including	across 4 sub-	(Verbal commands,	Status:	
	basic mental	sets, with			

Freely available and no specific training required	functions and mobility activities	score divided by the maximum total in each sub-set	commands, learning, safety awareness) Bed Mobility (roll supine to right, roll supine to left, supine to sit, sit to supine) Transfers (wheelchair to mat, mat to wheelchair, sit to stand, sitting balance, standing balance) Mobility (gait with device, gait without device, ascend stairs, descend stairs, propel wheelchair, set-up wheelchair)	Yes (indicating a present behaviour) / No (indicating an absent behaviour) For other items scoring is either: Unable-patient cannot physically assist to perform the activity (=0) Dependent-patient assists to perform activity but requires physical or verbal assistance to complete the activity (=4-21) Independent-patient performs the activity meeting all stated criteria without verbal or physical assistance (=10-30)	
Modified Iowa Level of Assistance Score (mILOA) Freely available and no specific training required	The level of assistance required to complete four mobility tasks, walking distance	6 mobility items	Supine to sitting on the edge of the bed Sitting on the edge of the bed to standing Walking Negotiation of 1 step	Each mobility item graded according to level of assistance required: 0: independent	0-36

	:		\\\ - \dagger_1 \dagger_2 \dagger_1 \dagger_2 \dagger_1 \dagger_2 \dagger_1 \dagger_2 \dagge	4. standler	
	in meters and		Walking distance	1: standby	
	assistive device		Assistive device used	supervision	
	used for all tasks			2: minimal	
				assistance	
				3: moderate	
				assistance	
				4: maximal	
				assistance	
				5: failed	
				6: not tested	
Activity Measure for	Activity limitation	12 items (6	Basic Mobility form	"Raw" sum score	Raw scores: 6-
Post-Acute Care (AM-	across acute to	on each	(rolling in bed without	from 6 items rated	24
PAC) "6-Clicks" Short	post-acute care	form)	bedrails, moving from	by "how much help	
Forms: Basic Mobility	settings		lying to sitting from a	from another person	Basic Mobility
form and Daily Activity			flat bed, moving	do you currently	"t-scale" score:
form			to/from a bed to a	need?"	16.59- 57.68
Requires a license (\$265			chair, standing up	1: total	
for 12 months) with			from a chair using	2: a lot	Daily Activity
training manual included			arms, walking and	3: a little	"t-score":
			climbing 3-5 steps	4: none	17.07- 57.54
			using a handrail)	Standardised "t-	
			Daily Activity form	scale" score using	
			(putting on and taking	specific conversion	
			off regular lower body	tables	
			clothing, bathing,		
			toileting, grooming		
			and eating meals)		
			and dating media)		

Supplementary Table 2: Patient reported outcome measures collected at 6 months

Outcome measure	What does it measure?	Number of items to score	Domains	Scoring	Min-max for basic sum score
Global Outcomes Assessment (GOA)	Patient reported level of disability	1 question	None specified	1 No disability 2 Mild disability 3 Mod disability 4 Marked disability 5 Severe disability	1-5
Glasgow Outcomes Score Extended (GOS-E)	Global scale for functional outcomes	19 questions	Consciousness Independence at home Independence outside home Work Social and leisure activities Family and friendships Return to normal life	1 Dead 2 Vegetative state 3 Lower severe disability 4 Upper severe disability 5 Lower moderate disability 6 Upper moderate disability 7 Lower good recovery 8 Upper good recovery	1-8 Can be dichotomised: Favourable outcome (scores 5-8) Unfavourable outcome (scores 1-4)

World Health Organization Disability Assessment Schedule (WHODAS)	A generic assessment instrument for health and disability	12 questions	Cognition: understanding & communicating Mobility: moving & getting around Self-care: hygiene, dressing, eating & staying alone Getting along: interacting with other people Life activities: domestic responsibilities, leisure, work & school Participation: joining in community activities	Patient reported level of difficulty/problem: 0= None 1= Mild 2= Moderate 3= Severe 4= Extreme or cannot do	0- 48
Euro Quality of Life-5 Dimensions- 5 Levels (EQ-5D-5L)	Standardised measure of generic health status	5 questions	Mobility: walking about Self-care: washing and dressing Usual activities: eg. Work, study, housework, family or leisure Pain/discomfort Anxiety/ depression	Patient reported level level of problem/ presence of symptom: 1= No problem/ none 2= Slight problem/ slight presence 3= Moderate problem/ moderate presence 4= Severe problem/ severe presence 5= Extreme problem/ extreme presence	5- 25 Can be dichotomised for component and total scores: No problems (scores 1 or 5) Problems (scores 2-5 or 10-25)

Supplementary Table 3- Predictive validity: discharge scores of return to work versus not returned to work at 6 months after injury

Last PT review scores (median, IQR)			
Outcome Measure	Returned to work at 6 months (n=32)	Not returned to work at 6 months (n=21)	p value
mILOA	4 (0.5-29)	13 (4-28)	0.2
FIM motor	73.5 (62.5-79.5)	69 (49-73)	0.113
FIM total	108.5 (97.5-114.5)	104 (84-108)	0.089
ACIF	0.84 (0.52-0.97)	0.65 (0.5-0.83)	0.4
6 Clicks Mobility	47.4 (36.26-57.68)	43.99 (36.97-50.88)	0.284
6 Clicks Daily Activity	47.1 (41.13-57.54)	44.27 (40.22-47.1)	0.246

mILOA- modified Iowa Level of Assistance Score; FIM- Functional Independence Measure; ACIF- Acute Care Index of Function.

Supplementary Table 4- Predictive validity: discharge scores of dichotomised GOSE (favourable versus unfavourable) outcome at 6 months after injury

	Last PT review scores (median, IQR)		
Outcome Measure	6 month dichotomised GOSE Favourable (Scores 5-8) n= 47	6 month dichotomised GOSE Unfavourable (Scores 1-4) n=8	p value
mILOA	6 (1-29)	3.5 (1.5-29.5)	0.89
FIM motor	70 (51-78)	72 (35-83)	0.94
FIM total	105 (85.5-113)	107 (69.5-118)	0.95
ACIF	0.76 (0.5-1)	0.83 (0.43-0.96)	0.93
6 Clicks Mobility	45.55 (36.97-57.68)	44.77 (32.9-54.3)	0.62
6 Clicks Daily Activity	44.27(38.66-54.33)	39.44 (34.65-49.11)	0.3

mILOA- modified Iowa Level of Assistance Score; FIM- Functional Independence Measure; ACIF- Acute Care Index of Function;

GOSE- Glasgow Outcomes Score Extended

Supplementary Table 5- Predictive validity: Discharge scores with no problems versus any problems on dichotomised EQ-5D-5L at 6 months after injury

		Last PT review sco	Last PT review scores (median, IQR)		
EQ-5D Domain	Outcome Measure	6 month EQ5D: No problems (Score=1)	6 month EQ5D: Any problems (Scores=2-5)	p value	
EQ-5D Total Score		n=11	n=70		
	mILOA	3 (0-11.5)	6 (3-28)	0.16	
	FIM motor	73 (57-82.5)	70 (46-78)	0.28	
	FIM total	108 (91.5-117.5)	104.5 (81-113)	0.26	
	ACIF	0.96 (0.6-1.00)	0.76 (0.5-0.95)	0.11	
	6 Clicks Mobility	47.4 (41.05-57.68)	45.55 (35.55-57.68)	0.19	
	6 Clicks Daily Activity	44.27(40.34-57.54)	44.27 (37.26-47.1)	0.33	
Mobility		n=35	n=46		
	mILOA	3 (0-15.5)	7.5 (4-29)	*0.02	
	FIM motor	71 (58.5-78)	69 (40-79)	0.31	
	FIM total	106 (93.5-113)	104 (74-114)	0.32	
	ACIF	0.86 (0.53-1)	0.68 (0.46-0.83)	*0.03	
	6 Clicks Mobility	47.4 (39-57.68)	44 (34-50.88)	*0.02	
	6 Clicks Daily Activity	44.27(37.96-57.54)	44.27 (37.26-47.1)	0.33	

Self-care		n=35	n=46	
	mILOA	6 (1.5-13.5)	16.5 (0-30)	0.09
	FIM motor	71 (58-79)	61.5 (36-77)	0.07
	FIM total	106 (93-114)	96.5 (67-112)	0.07
	ACIF	0.76 (0.58-0.97)	0.55 (0.34-0.93)	*0.01
	6 Clicks Mobility	45.55 (39-57.68)	39.67 (28-57.68)	*0.03
	6 Clicks Daily Activity	47.1(40.22-54.33)	40.22 (35.96-47.1)	0.05
Usual Activities		n=20	n=61	
	mILOA	3.5 (0-11.5)	8 (3-29)	0.08
	FIM motor	71.5 (59.5-79.5)	70 (40-78)	0.22
	FIM total	106.5 (94.5-114.5)	104 (74-113)	0.194
	ACIF	0.90 (0.6-1)	0.69 (0.46-0.93)	*0.02
	6 Clicks Mobility	49.14 (40.36-57.68)	43.99 (35.55-57.68)	0.05
	6 Clicks Daily Activity	45.69(41.13-57.54)	44.27 (37.26-47.1)	0.11
Pain		n=20	n=61	
	mILOA	3 (0-14.5)	6 (3-29)	0.08
	FIM motor	71.5 (57-82.5)	70 (40-77)	0.19
	FIM total	106.5 (92-117.5)	105 (75-112)	0.18
	ACIF	0.91 (0.53-1)	0.74 (0.47-0.93)	*0.04
	6 Clicks Mobility	52.24 (39.67-57.68)	45.55 (35.55-57.68)	0.08

	6 Clicks Daily Activity	45.69 (37.97-57.54)	44.27 (37.26-47.1)	0.19
Anxiety/ Depression		n=40	n=41	
	mILOA	5 (0-14.5)	13 (3-29)	0.10
	FIM motor	72 (57-79)	67 (40-75)	0.11
	FIM total	107 (92-114)	101 (74-110)	0.09
	ACIF	0.76 (0.53-0.97)	0.76 (0.46-0.93)	0.24
	6 Clicks Mobility	47.4 (38.32-57.68)	43.99 (35.55-50.88)	0.09
	6 Clicks Daily Activity	47.1 (38.66-57.54)	42.03 (35.96-47.1)	*0.03

mILOA- modified Iowa Level of Assistance Score; FIM- Functional Independence Measure; ACIF- Acute Care Index of Function; EQ-5D-5L- Euro Quality of Life-5 Dimensions-5 Level *Statistically significant (p= < 0.05)

Chapter Five: Conclusion

Overview of main findings

The overarching aim of this thesis was to optimise physiotherapy assessment of trauma patients in the acute hospital setting.

Chapter One highlighted the burden of traumatic injury due to mortality, but also beyond that for those who survive. Although the development of trauma systems of care has reduced mortality, gaps exist with regards to further understanding patient recovery in the early phases within the acute hospital setting. Any interventions provided in this setting may have the ability to improve or indeed worsen patient outcomes, but little is known about the composition of the allied health team who provide this care. Physiotherapists are key members of this team in mature trauma systems (such as in Australia) and more information regarding their roles and responsibilities was sought.

The first study in Chapter Two described physiotherapy service structure and practice in adult major trauma services across Australia and New Zealand, through a benchmarking survey [92]. The response rate was high (92% or 23/25 sites), with results demonstrating great variability in service delivery, expertise and access for trauma patients. Just 30% of major trauma services had a dedicated trauma physiotherapist, which was more common in centres with greater numbers of major trauma admissions (p=0.07). Only 35% had a blanket or automatic referral for physiotherapy (ensuring early physiotherapy review) and most ran a five day/ week service with priority only cover over the weekends (78%). Both these factors may affect consistency of physiotherapy access for trauma patients. Although only 26% of physiotherapists were currently involved in

any research activities, interest in building this capacity was found to be high, with 87% open to collaborative work. Physiotherapists reported use of outcome measures at only three sites (13%). Further investigation is required to understand the optimal outcome measure instruments physiotherapists should be using in the acute care of trauma patients.

The systematic review in Chapter Three described the available literature relating to mobility and physical function outcome measures previously used in trauma patients in the acute hospital setting [93]. Six measures were identified, but none had been specifically designed for use in trauma patients. Evidence for use with regards to important clinimetric properties (such as reliability validity, responsiveness and feasibility), was lacking and no measure could be identified as the "gold standard". Guided by these results, a prospective study was undertaken to further investigate the clinimetric properties of four mobility and physical function outcome measure instruments in trauma patients admitted to an Australian level 1 major trauma service. This study assessed the feasibility, validity, reliability and responsiveness of the modified lowa Level of Assistance Score (mILOA) [94]; the Functional Independence Measure (FIM) [95]; the Acute Care Index of Function (ACIF) [85] and the Activity Measure for Post-Acute Care (AM-PAC) "6 Clicks" Short Forms [96], and is described in Chapter Four. All were found to be valid, reliable and responsive to patient change in mobility and physical function during the acute hospital. Recommendations for use of outcome measures in research or clinical practice therefore requires further consideration of feasibility in this setting (eg. funding, licencing and time to administer), as well as the documented ceiling effects which may affect its ability to measure patient outcomes over the longer-term following discharge.

Strengths and limitations of the research undertaken for this thesis

The strengths of the research presented in this thesis include the variety of methods used including a benchmarking survey, a systematic review and prospective clinical study, which all provided valuable and diverse information.

These findings have direct clinical relevance to physiotherapists and other allied health, medical and nursing working in trauma patient care. Access to information regarding how physiotherapy services are structured within Australia and New Zealand is now available in order for hospital clinical staff and administrators to benchmark their own service provision.

The outcome measures study reported in Chapter Four is the first to provide specific information about some clinimetric properties of at least three of the measures in trauma patients in the acute hospital setting (the Functional Independence Measure (FIM) [95]; the Acute Care Index of Function (ACIF) [85] and the Activity Measure for Post-Acute Care (AM-PAC) "6 Clicks" Short Forms [96]). The use of registry data from the Victorian State Trauma Registry and Victorian Orthopaedic Trauma Registry further strengthened our work as we could consider the longer-term implications and progress of the patients at six months after injury, allowing us to explore predictive validity of the outcome measure instruments.

Limitations of the work presented in this thesis relate to the systematic review, as despite our rigorous methods, limited data were available for the identified outcome measure instruments, with most from lower quality studies. As a result, definitive conclusions were difficult to draw. This was however a necessary step towards acknowledging and documenting the gaps in knowledge, to guide further

work. The outcome measures study was also only completed in a single major trauma centre, so may limit its applicability to other settings. This study only considered administration of outcome measures by physiotherapists, and thus the clinimetric properties of these measures when administered by other disciplines involved in trauma care was not documented. Other more specific strengths and limitations are described in each paper.

Key findings and recommendations for clinical practice

The thesis has documented the role and responsibilities of physiotherapists in major trauma services in Australia and New Zealand. It highlighted the varied service delivery, with lack of outcome measure instrument use to monitor patient recovery. The results of the systematic review went some way to explaining why this is so, as no gold standard outcome measure instrument could be identified based on its clinimetric properties. Finally, the outcome measures study in Chapter Four provided this information for the most commonly identified and utilised instruments.

Based on these findings, a number of recommendations for clinical practice can be made:

i. Routine collection of outcome measure instruments by physiotherapists working with trauma patients. This would enable objective markers of mobility and physical function to be tracked and monitored during the acute hospital admission, allowing discussion around this aspect of patient recovery with other care providers, as well as patients and their families. This would also allow benchmarking across other services, and further

- exploration of how specific interventions and models of service delivery may affect this outcome.
- ii. Consideration for the inclusion of a mobility and physical function outcome measures score in the acute setting and longer-term by trauma registries worldwide. This would increase understanding of this aspect of recovery, allowing it to be tracked over time, as well as exploration of different models of service delivery that may impact outcomes.
- iii. The development of a special interest group for physiotherapists caring for trauma patients, with specific aims around building capacity, expertise and networks with interested clinicians in other hospitals. The high response rate from the benchmarking survey and enthusiasm for this idea indicates keen interest from physiotherapists in Australia and New Zealand. This may provide a platform for consistent implementation of outcome measures and interventions across settings, allowing greater standardisation of physiotherapy care following trauma. It may also provide a platform for future collaborative research.

Recommendations for research

Further research is needed to continue to advance the literature in this area. The recommendations for future research include:

- i. Conduct a multi-centre randomised controlled trial to explore the impact of intervention targeting mobility and physical function in trauma patients in the acute hospital setting. This thesis highlighted some of the evidence for early and more intensive physiotherapy, however its impact on important outcomes (eg physical function, length of stay and costs) was not convincingly demonstrated by existing trials, which are generally small and conducted at single centres. Such a trial would provide more robust data across multiple sites. The outcome measurement information provided in this thesis would also allow the trial to be more accurately powered for physical function outcomes.
- ii. Explore mobility and physical function outcomes in relation to physiotherapy service provision across different major trauma services through an observational study. Such a study could examine the relationship between delivery of specialist physiotherapy services and important patient outcomes, and inform physiotherapy models of care for acute trauma patients.
- iii. Documentation of the clinimetric properties of outcome measure instruments of mobility and physical function in important trauma populations that were not included in the current research, particularly traumatic brain injury and fractured neck of femur. These patient groups are frequently seen by physiotherapists in the acute trauma setting, but may have unique needs and recovery trajectories. Measuring and

- understanding physical outcomes in these groups is critical to advancing physiotherapy care.
- iv. Application of the research methods used in this thesis to explore other aspects of patient recovery relevant to the wider allied health team involved in trauma patient care. This thesis focused solely on the domain of mobility and physical function. Other domains highly relevant to trauma recovery include mental health, level of consciousness, memory, community access, return to work and social participation [97]. These domains are frequently addressed by other members of the trauma team, including occupational therapists, psychologists, social workers and speech pathologists. Given the well-recognised broad impact of traumatic injury highlighted in this thesis, this would enable a more comprehensive overview and understanding of the impact of different allied health team members.

Concluding observations

The work presented in this thesis highlights the variation of physiotherapy service delivery in Australia and New Zealand major trauma services, with systematic measurement of physical outcomes rarely undertaken. Existing measures of mobility and physical function show strong clinimetric properties in the acute trauma setting but differ in feasibility and utility for longitudinal measurement. These measures are suitable for routine use by physiotherapists in acute trauma settings. Implementation of routine measurement of mobility and physical function by physiotherapists would allow more comprehensive and collaborative benchmarking to be completed. These robust measurement tools could also be

used to assess outcomes in multi-centre randomised controlled trials to definitively explore early physiotherapy intervention.

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Appendices



ETHICS COMMITTEE CERTIFICATE OF APPROVAL

This is to certify that

Project No: 579/14

Project Title: Benchmarking of Physiotherapy Services at Australian Adult Major Trauma Services

Principal Researcher: Ms Sara Calthorpe

was considered for Low Risk Review and APPROVED on 4/2/2015

It is the Principal Researcher's responsibility to ensure that all researchers associated with this project are aware of the conditions of approval and which documents have been approved.

The Principal Researcher is required to notify the Secretary of the Ethics Committee, via amendment or report, of

- Any significant change to the project and the reason for that change, including an indication of ethical implications (if any);
- Serious adverse effects on participants and the action taken to address those effects;
- Any other unforeseen events or unexpected developments that merit notification;
- The inability of the Principal Researcher to continue in that role, or any other change in research personnel involved in the project;
- A delay of more than 12 months in the commencement of the project; and,
- Termination or closure of the project.

Additionally, the Principal Researcher is required to submit

A Final Report on completion of the project.

Approval covers the project as described in the application (including any modifications made prior to approval). Low Risk projects are subject to audit and ethical approval may be withdrawn if the project deviates from that proposed and approved.

SPECIAL CONDITIONS:

- Provide evidence of permission to access ATR data once received from each site.
- Comply with any research governance/ethics requirements for each site as advised

SIGNED:

Professor John J. McNeil Chair, Ethics Committee

Please quote project number and title in all correspondence



COLLEGE OF SCIENCE, HEALTH & ENGINEERING

MEMORANDUM

To: Anne Holland

Student: Sara Calthorpe

From: Secretariat, SHE College Human Ethics Sub-Committee (SHE CHESC)

Reference: SHE CHESC acceptance of The Alfred HREC approved project – 597/15.

Title: Benchmarking of Physiotherapy Services at Australian Adult Major Trauma Services

Date: 1 March, 2016

Thank you for submitting the above protocol to the SHE College Human Ethics Sub-Committee (SHE CHESC). Your material was forwarded to the SHE CHESC Chair for consideration. Following evidence of a full review and subsequent final approval by the **The Alfred HREC**, the SHE CHESC Chair agrees that the protocol complies with the National Health and Medical Research Council's National Statement on Ethical Conduct in Human Research and is in accordance with La Trobe University's Human Research Ethics Guidelines.

Endorsement is given for you to take part in this study in line with the conditions of final approval outlined by The Alfred HREC.

Limit of Approval. La Trobe SHE CHESC endorsement is limited strictly to the research protocol as approved by The Alfred HREC.

Variation to Project. As a consequence of the previous condition, any subsequent modifications approved by The Alfred HREC for the project should be notified formally to the SHE CHESC

Annual Progress Reports. Copies of all progress reports submitted to The Alfred HREC are to be forwarded to the SHE CHESC. Failure to submit a progress report will mean that endorsement for your involvement in this project will be rescinded. An audit related of your involvement in the study may be conducted by the SHE CHESC at any time.

Final Report. A copy of the final report is to be forwarded to the CHESC within one month of it being submitted by The Alfred HREC.

If you have any queries related to the information above or require further clarifications, please contact chesc.she@latrobe.edu.au. Please quote reference number **597/15** – **Holland/Calthorpe**.

On behalf of the College Human Ethics Sub-Committee, best wishes with your research!

Ms Kate Ferris
Human Ethics Officer
Secretariat – SHE College Human Ethics Sub-Committee
Ethics and Integrity / Research Office
La Trobe University Bundoora, Victoria 3086

E: chesc.she@latrobe.edu.au

P: (03) 9479 - 3370

http://www.latrobe.edu.au/researchers/ethics/human-ethics



ETHICS COMMITTEE CERTIFICATE OF APPROVAL

This is to certify that

Project No: 571/18

Project Title: To assess the reliability, validity and responsiveness of four outcome measures for assessing mobility and physical function in hospitalised trauma patients.

Principal Researcher: Ms Sara Calthorpe

was considered for Low Risk Review and APPROVED on 19/11/2018

It is the Principal Researcher's responsibility to ensure that all researchers associated with this project are aware of the conditions of approval and which documents have been approved.

The Principal Researcher is required to notify the Secretary of the Ethics Committee, via amendment or report, of

- Any significant change to the project and the reason for that change, including an indication of ethical implications (if any);
- Serious adverse effects on participants and the action taken to address those effects;
- Any other unforeseen events or unexpected developments that merit notification;
- The inability of the Principal Researcher to continue in that role, or any other change in research personnel involved in the project;
- A delay of more than 12 months in the commencement of the project; and,
- Termination or closure of the project.

Additionally, the Principal Researcher is required to submit

A Final Report on completion of the project.

Approval covers the project as described in the application (including any modifications made prior to approval). Low Risk projects are subject to audit and ethical approval may be withdrawn if the project deviates from that proposed and approved.

SPECIAL CONDITIONS

None

SIGNED:

Professor John J. McNeil Chair, Ethics Committee

Please quote project number and title in all correspondence



6 December 2018

Research Office

То	Anne Holland
From	University Human Ethics Committee
Reference Number	AlfredHealth571/1
Project title	To assess the reliability, validity and responsiveness of four outcome measures for assessing mobility and physical function in patients following traumatic injury
Subject	Externally Approved Project
Date	6 December 2018

The externally approved project submitted above was reviewed and **noted** by the University Human Ethics Committee Chair.

Please note that all requirements and conditions of the original ethical approval for this project still apply.

Should you require any further information, please contact the Human Research Ethics Team on: T: +61 3 9479 1443 | E: humanethics@latrobe.edu.au.

Warm regards,

David Finlay Chair, University Human Ethics Committee