

A systematic review of measurements of physical function in critically ill adults

Claire J Tipping, Paul J Young, Lorena Romero, Manoj K Saxena, Joel Dulhunty and Carol L Hodgson

Existing clinical trial data suggest that interventions aimed at encouraging early activity and mobilisation in the intensive care unit may reduce duration of mechanical ventilation and ICU length of stay, while improving physical function in survivors.¹ However, the applicability of these data to the Australian and New Zealand setting is uncertain. A program of research evaluating early activity and mobility in the ICU is therefore underway in Australia and New Zealand, commencing with an observational study of current mobilisation practices in ventilated ICU patients (ClinicalTrials.gov NCT01674608). Our intention is to follow the observational study with a multicentre Phase II trial.

The Australian and New Zealand Intensive Care Society Clinical Trials Group recently published a consensus statement on the use of end points for Phase II trials involving critically ill patients.² This statement highlights the importance of end points that measure limitations in physical function (so-called functional end points) and suggests that such end points could be used in trials investigating mobility interventions in the ICU in particular.

The aim of this systematic review was to identify, describe and evaluate measurements of physical function that have been used to assess early mobilisation in critically ill adults.³ A secondary aim was to evaluate the available evidence for the measurement properties and risk of bias associated with the identified end points when used with ICU patients.³⁻⁵ These data may assist in the design of Phase II trials of early activity and mobility interventions and may also have relevance to evaluating the quality of survival after critical illness.

Methods

This review had two parts: Search Strategy 1 identified studies of ICU rehabilitation or mobilisation that measured physical function; and Search Strategy 2 identified studies that examined the measurement properties and risk of bias associated with the physical function measures in the ICU from Search Strategy 1.

Search Strategy 1

A literature search of Ovid MEDLINE, Embase, CINAHL, Cochrane Library and PEDro (Physiotherapy Evidence Database) was conducted in June 2012 using the search strategy outlined in Table 1. Additional studies were identified through reference and citation tracking, personal communication with a content expert, and by contacting authors of

ABSTRACT

Background: Patients who recover from critical illness may be left with significant limitations to their physical function that can have important consequences for their quality of life. Measures of physical function may be useful end points to consider in studies conducted in critically ill patients and are particularly attractive in studies investigating early mobilisation and rehabilitation.

Objective: To describe measurements of physical function used in studies investigating early mobilisation and rehabilitation in critically ill adults.

Methods: A systematic search of Ovid MEDLINE, Embase, CINAHL, Cochrane Library and PEDro was undertaken to identify studies investigating early mobilisation and rehabilitation in critically ill adults. Two researchers independently extracted data from identified studies that described measurements of physical function and that evaluated the available evidence for the measurement properties and risk of bias associated with the identified end points.

Results: We identified 11 studies of early mobilisation and rehabilitation in critically ill patients, involving 19 distinct measures of physical function. The ability to perform activities such as sitting and standing and the maximum distance ambulated were the most commonly used end points. Only one end point in the included studies, the Functional Status Score for the ICU (FSS-ICU), was designed for use in the ICU setting. Of the end points used, only the Short Form 36 (SF-36), the Medical Research Council (MRC) scale score and handheld dynamometers have proven inter-rater reliability and population validity in the ICU setting.

Conclusion: A wide range of end points have been used to evaluate physical function in critically ill patients. However, further studies are needed to establish the measurement properties of the most commonly used end points in order to recommend their use in clinical trials.

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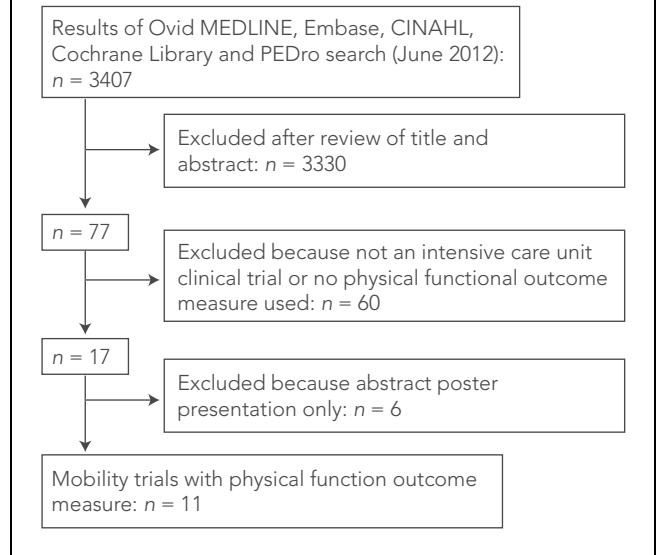
eligible trials. Review papers and meta-analyses were reviewed for publications that may otherwise have been missed. Two independent reviewers extracted data relating to patient and hospital outcomes and assessed the methodological quality of included studies.

Table 1. Search Strategy 1

No. Searches

1	exp *Critical Illness/ or exp *Critical Care/ or exp *Intensive Care Units/ or exp *Intensive Care/ or exp *Respiration, Artificial/ or exp *Ventilators, Mechanical/ or exp *respiratory distress syndrome, adult/ or exp *respiratory insufficiency/
2	exp *physical endurance/ or exp *physical exertion/ or exp *physical fitness/ or exp *physical medicine/ or exp *physical therapy department, hospital/ or exp *physical therapy modalities/ or exp *"physical therapy (specialty)"/ or exp *exercise/ or exp *exercise movement techniques/ or exp *exercise therapy/ or exp *exercise tolerance/ or exp *Movement/ or exp *Motion/ or exp *"Recovery of Function"/ or exp *Rehabilitation/ or exp *"Range of Motion, Articular"/ or exp *muscle strength/ or rh.fs. or exp *Occupational Therapy Department, Hospital/ or exp *Occupational Therapy/
3	1 and 2
4	((movement* or ambulat* or rehab* or mobili* or physical* or activity or exercis* or physiotherap* or motion* or locomotion* or function* or animation* or endurance or exertion* or walk* or occupational*) adj5 (critical care or critically ill or critical illness or intensive care or ICU*)).ti,ab.
5	((movement* or ambulat* or rehab* or mobili* or physical* or activity or exercis* or physiotherap* or motion* or locomotion* or function* or animation* or endurance or exertion* or walk* or occupational*) adj5 ((mechanical* adj2 ventilat*) or (mechanical* adj2 respirat*) or respiratory failure or (artificial* adj2 respirat*) or (artificial* adj2 ventilat*))).ti,ab.
6	((immobili* or bedrest or bed-rest or atroph* or wasting or weakness or disabilit* or muscle* or muscular or neuromuscular or polyneuropath* or neuropath*) adj5 (critical care or critically ill or critical illness or intensive care or ICU*)).ti,ab.
7	((immobili* or bedrest or bed-rest or atroph* or wasting or weakness or disabilit* or muscle* or muscular or neuromuscular or polyneuropath* or neuropath*) adj5 ((mechanical* adj2 ventilat*) or (mechanical* adj2 respirat*) or respiratory failure or (artificial* adj2 respirat*) or (artificial* adj2 ventilat*))).ti,ab.
8	3 or 4 or 5 or 6 or 7
9	limit 8 to (English language and yr="2000-Current")
10	limit 9 to ("all infant (birth to 23 months)" or "all child (0 to 18 years)")
11	9 not 10
12	11 not (baby or babies or neonat* or infan* or child* or adolesc* or pediatr* or paediatr*).mp.
13	(animals not (animals and humans)).sh.
14	12 not 13

Figure 1. Flow diagram of Search Strategy 1



Inclusion criteria

Eligible studies were prospective randomised controlled trials (RCTs) or prospective controlled clinical trials that: investigated mobilisation or activity-related rehabilitation in the ICU setting; reported a measurement of physical function in the ICU, such as mobility, activity, changing of body position, strength, balance, or quality of life with functional status;⁶ and were published in the past 10 years.

Exclusion criteria

Studies were excluded if they were conducted in a paediatric population (age < 16 years), long-term weaning units (or intermediate ICUs requiring long-term ventilation) or a post-ICU rehabilitation setting, or if the article was not published in English. Studies of musculoskeletal interventions other than early mobilisation or functional rehabilitation (eg, electrical stimulation or inspiratory muscle training) and those that did not include at least one measure of physical function were excluded.

Data extraction

For all studies meeting the inclusion criteria and none of the exclusion criteria, the type of study, sample size, median (or mean) patient age, measure of physical function, timing of measurement, and effect size were extracted independently by two of us (C T, C H). Measures of physical function were classified into domains based on the World Health Organization classification.⁶

Quality assessment of studies

For RCTs meeting the inclusion criteria, the quality criteria were extracted.³ For the primary outcome

REVIEW

Table 2. Summary of studies reporting an outcome measure of physical function from early mobilisation and rehabilitation studies in the intensive care unit

Study	Study type	n	Patient age*	Physical function outcome measure	Primary outcome	Timing of assessment
Titsworth 2012 ⁸	Prospective cohort study	166	59 (mean)	I-MOVE	Yes	Hourly
Winkelman 2012 ⁹	Prospective study	75	66.6 (mean)	Katz ADL scale MRC scale (muscle strength)	No No	ICU DC ICU DC
Nordon-Craft 2011 ¹⁰	Case series	19	48	FIM scale (three items)	ns	Baseline and hospital DC
				Timed up-and-go	ns	Baseline and hospital DC
				Five-times sit-to-stand test	ns	Baseline and hospital DC
				2-minute walk test	ns	Baseline and hospital DC
				MRC scale (muscle strength)	ns	Baseline and hospital DC
Needham 2010 ¹¹	Prospective before–after quality improvement project	57	52	Functional mobility during PT/OT session	No	Daily
Zanni 2010 ¹²	Prospective observational cohort study	32	49	FSS-ICU	No	ICU and hospital DC [†]
				Duration of unsupported sitting on edge of bed	No	ICU and hospital DC
				Ambulation (max distance)	No	ICU and hospital DC [†]
				MRC scale (muscle strength)	No	ICU initial assessment and ICU and hospital DC
Burtin 2009 ¹³	Randomised controlled trial	90	57 (mean)	6-minute walk test	Yes	Hospital DC [†]
				SF-36	No	Hospital DC [†]
				Berg Balance Scale	No	ICU and hospital DC
				FAC	No	ICU and hospital DC
				Handheld dynamometer (quadriceps force)	No	ICU and hospital DC [†]
Schweickert 2009 ¹	Randomised controlled trial	104	57.7	Return to functional independence (six activities from Katz ADL scale, and mobility using FIM scale)	Yes	Every 48 hours ICU and hospital discharge [†]
				Barthel Index	No	Hospital DC [†]
				Ambulation (max distance)	No	Hospital DC [†]
				Handheld dynamometer (hand grip strength)	No	ICU and hospital DC
				MRC scale (manual muscle testing)	No	Hospital DC
Morris 2008 ¹⁴	Prospective cohort study	330	54.7	Days until first out of bed	No	Daily
Thomsen 2008 ¹⁵	Pre–post cohort study	104	57.9 (mean)	Functional mobility during PT/OT session	No	Daily
				Ambulation (yes/no, distance)	Yes	Daily
van der Schaaf 2008 ¹⁶	Prospective observational cohort study	109	60	Barthel Index	Yes	3–7 days after ICU DC
				Handheld dynamometer (hand grip strength)	No	3–7 days after ICU DC
				FAC	No	3–7 days after ICU DC
				MRC scale (muscle strength)	No	ICU DC
Bailey 2007 ¹⁷	Feasibility study	103	63	Functional mobility during PT/OT session	No	Daily

ADL = activities of daily living. DC = discharge. FAC = Functional Ambulation Classification. FIM = Functional Independence Measure. FSS-ICU = Functional Status Score for the ICU. I-MOVE = Independent Mobility Validation Examination. max = maximum. MRC = Medical Research Council. ns = not specified. OT = occupational therapy. PT = physiotherapy. SF-36 = Short Form 36. * Median age, unless otherwise specified. † Statistical significance ($P < 0.05$).

reported in each RCT, methodological quality was assessed using the COSMIN (Consensus-based standards for the selection of health status measurement instruments) guidelines.³⁻⁵

Search Strategy 2

A further literature search of Ovid MEDLINE was conducted using the terms “critical illness”, “critical care”, intensive care unit”, “intensive care”, “mechanical ventilation”,

Table 3. Quality assessment of the included randomised controlled trials

Study	Burtin 2009 ¹³	Schweickert 2009 ¹
Primary outcome	6-minute walk test	Return to functional independence
Random allocation	Yes	Yes
Concealed allocation	Yes	Yes
Similarity at baseline	No	Yes
Intention-to-treat analysis	No	Yes
Subject blinding	No	No
Therapist blinding	No	No
Assessor blinding	No	Yes
> 85% follow-up	No	Yes
Between-group difference reported	Yes	Yes
Point estimate and variability reported	Yes	Yes

Table 4. Evaluated measurement properties of the primary outcome reported in the included randomised controlled trials

Study	Burtin 2009 ¹³	Schweickert 2009 ¹
Primary outcome	6-minute walk test	Return to functional independence
Internal consistency	No	Yes
Reliability	Yes	Yes
Measurement error	Yes	Yes
Content validity	Yes	Yes
Structural validity	Yes	Yes
Hypothesis testing	Yes	Yes
Cross-cultural validity	No	No
Criterion validity	Yes	No
Responsiveness	Yes	Yes
Interpretability	Yes	Yes
Generalisability	Yes	Yes

“artificial respiration” and the measures of physical function identified by Search Strategy 1, with a search filter reported previously for finding measurement properties of measurement instruments with a sensitivity of 93.1% and precision of 9.4%.⁷ Each title and abstract was examined for relevance by two of us (CT, CH), and the full text was reviewed if the inclusion criteria were met. Reference lists of sourced articles were manually reviewed to identify additional relevant articles. Authors were contacted directly if it was unclear whether outcome measures had been assessed for reliability and validity in the ICU.

Inclusion criteria

Articles were included if they: described a measure of physical function reported in Search Strategy 1; were conducted in an ICU population; and reported inter-rater and intra-rater reliability, face validity, structural validity, content validity, criterion validity and cross-cultural validity.^{4,5}

Results

Measures of physical function identified

Search Strategy 1 identified 3407 articles, of which 77 were reviewed in full. No further articles were identified on review of the reference lists in sourced articles (Figure 1). Eleven studies of ICU rehabilitation met the inclusion criteria and were included in this review (Table 2).^{1,8-17} Most were observational cohort studies assessing the feasibility of early mobility strategies in the critical care setting. There were two RCTs that assessed the effect of early mobilisation on recovery after critical illness.^{1,13} Quality assessment of the

RCTs is presented in Table 3. Measurement properties of the primary outcome variable in each RCT are shown in Table 4.

Overall, 19 measures of physical function were identified in the 11 included studies (Table 5). In accordance with the WHO classification system,⁶ they were classified into domains that evaluate (i) mobility: including balance, lying, sitting, standing, shifting the body’s centre of gravity; (ii) muscle function: strength; (iii) walking and moving: including walking independently, walking with assistance, walking short and long distances; (iv) self-care: activities of daily living (ADL) such as washing, dressing, toileting, grooming and eating; and one additional area that the WHO describes as future work, which includes self-reported quality of life (QOL).

The most commonly used measurements of physical function were part of the WHO classification of mobility⁶ — that is, the assessment of highest functional mobility in the ICU, measured either at each therapy session or daily,^{11,15,17} and the maximum distance ambulated, measured at ICU and/or hospital discharge.^{1,12} Measures of self-care using the Barthel Index were included in two of the 11 studies.^{1,16} The two RCTs used different measures of function as the primary outcome: Burtin and colleagues used the 6-minute walk test (6MWT) at hospital discharge,¹³ whereas Schweickert and colleagues used a composite measure of functional independence (using the Katz ADL scale, Functional Independence Measure [FIM] scale, and independent walking) at hospital discharge.¹

Table 2 outlines the time points at which physical function was measured and the statistical significance of the findings. The majority of outcomes were measured at hospital discharge.

Table 5. Summary of measures of physical function in the included studies

Outcome measure	WHO domain ⁶	No. of studies	Original population	Description	Key reference
Barthel Index	Self-care	2	Neuromuscular and musculoskeletal disorders	10 items rated on 2-, 3- or 4-point scale Total score ranges from 0 (dependent) to 100 (independent) Performance can be based on observation or interview	Mahoney 1965 ¹⁸
Return to functional independence	Self-care	1	ICU	Developed for use in an ICU mobility trial Defined by ability to independently perform six Katz ADL scale items (bathing, dressing, eating, grooming, transferring from bed to chair, and using the toilet) and walking independently Uses FIM 1–6 rating scale Patients with ADL score \geq 5 deemed as being independent	Schweickert 2009 ¹
Katz ADL scale	Self-care	1	Older adults in aged care facilities	Six-item measure assessing ADL (bathing, dressing, eating, toileting, transferring, and remaining continent) Each item is marked either 0 (total dependence) or 1 (total independence), with a total score ranging from 0 to 6	Wallace 2008 ¹⁹
FIM scale	Self-care	1	Rehabilitation	18 items rated on a scale of 1–7 Total score ranges from 7 (total dependence) to 126 (total independence) Mixture of motor, ADL and cognitive items	Turner-Stokes 1999 ²⁰
Berg Balance Scale	Walking	1	Stroke	14 static and dynamic balance tests, each rated from 0 (unable to perform task) to 4 (able to perform task)	Berg 1989 ²¹
Timed up-and-go	Walking	1	Frail elderly	Measures time taken to stand up from a chair and walk around a cone 3 m away and back to sit in the chair A standardised chair (with armrest and height of 44–47 cm) should be used Challenges balance, transfers and mobility 1 of 19 patients was able to complete on hospital discharge ¹⁰	Podsiadlo 1991 ²²
SF-36	QOL	1	Primary care	36-item self-completed questionnaire Covers all aspects of health including functional status, emotional and social wellbeing, and overall evaluation of health	Chrispin 1997 ²³
FSS-ICU	Mobility and walking	1	ICU	Developed for use in one ICU mobility trial Uses FIM scoring system, 7-point scale Five items to suit ICU mobility including ability to roll, move from lying to sitting, sit on edge of bed, move from sitting to standing, and ambulate Total score ranges from 5 (total dependence) to 35 (total independence)	Thrush 2012 ²⁴
6-minute walk test	Walking	1	Cardiorespiratory patients	Participant walks as far as possible in 6 minutes, with no external assistance Standardised feedback is given Standard corridor length (20–50 m) is used ATS recommends two tests completed > 1 hour apart ICU patients were not able to complete two tests due to fatigue ¹³	ATS statement 2002 ²⁵
2-minute walk test	Walking	1	Older adults	Participant walks as far as possible, with or without a gait aid, in 2 minutes, using a 50 m corridor Assessor is able to provide verbal encouragement but no physical assistance 1 of 19 patients was able to complete on hospital discharge ¹⁰	Brooks 2004 ²⁶
FAC	Walking	2	Stroke	Assesses ability to mobilise on indoor and outdoor terrains Performance rated on a scale from 1 (non-functional ambulatory) to 6 (independent ambulatory)	Pohl et al 2002 ²⁷

ADL = activities of daily living. ATS = American Thoracic Society. FAC = Functional Ambulation Classification. FIM = Functional Independence Measure. FSS-ICU = Functional Status Score for the ICU. ICU = intensive care unit. QOL = quality of life. SF-36 = Short Form 36. WHO = World Health Organization.

Table 5. Continued

Outcome measure	WHO domain ⁶	No. of studies	Original population	Description	Key reference
Functional mobility in PT and OT	Mobility and walking	3	ICU	Developed for use in three ICU mobility trials Records highest level of mobility using key categories including: no activity, passive range of motion, moving from lying to sitting, sitting on edge of bed, sitting to standing, sitting out of bed, and ambulation	Needham 2010 ¹¹ Bailey 2007 ¹⁷ Thompson 2008 ¹⁵
I-MOVE	Mobility and walking	1	Elderly acute inpatients	Sequential scale assessing ability to complete six basic tasks (rolling, sitting up, standing, sitting in a chair, walking in the room, walking in the hallway) and whether or not assistance is required Scale from 1 (requires assistance to roll) to 12 (independent walking in hallway)	Manning 2009 ²⁸
Days until first sit out of bed	Mobility	1	ICU	Numerical measure used to identify how quickly patients commence mobility (number of days)	Morris 2008 ¹⁴
Maximum distance ambulated	Walking	3	ICU	Used by three ICU mobility trials Numerical measure recording the distance ambulated (metres)	Schweickert 2009 ¹ Thompson 2008 ¹⁵ Zanni 2010 ¹²
Duration of unsupported sitting on edge of bed	Mobility	1	ICU	Recorded time able to sit unsupported on the edge of a bed Score ranges from 0 (unable) to 30 minutes	Zanni 2010 ¹²
Five-times sit-to-stand test	Mobility	1	Older people	Patient is required to rise from a chair five times as quickly as possible, with arms folded across chest Chair must be a standard height (43 cm) The time taken to perform the task is recorded	Lord 2002 ²⁹
MRC scale	Muscle function	5	War injuries and poliomyelitis	6-point scale from 0 (no muscle contraction) to 5 (full contraction through range against resistance) Can be used for all major upper and lower limb muscle groups	James 2007 ³⁰
Handheld dynamometer	Muscle function	3	Hand injuries	Used by one ICU mobility trial to measure quadriceps force (MicroFET 2) and one trial to measure hand grip strength (Jamar hand grip dynamometer) Quadriceps force: knee placed in 30° flex, dynamometer placed over anterior shin between malleoli, patient instructed to straighten knee Hand grip strength: arm adducted and elbow at 90°, patient instructed to squeeze hand and hold for 3–5 seconds	Schaubert 2005 ³¹

ICU = intensive care unit. I-MOVE = Independent Mobility Validation Examination. MRC = Medical Research Council. OT = occupational therapy. PT = physiotherapy. WHO = World Health Organization.

Quality assessment

Search Strategy 2 identified 77 articles, of which six were assessed in full (Table 6).^{23,32-36} Three of the functional outcome measures in the ICU population — the Medical Research Council (MRC) scale score,^{32-34,37} the handheld dynamometer,^{33,35,38} and the Short Form 36 (SF-36)²³ for health-related QOL — have been reported to have good to excellent reliability. The Independent Mobility Validation Examination (I-MOVE) has been assessed for inter-rater reliability and face validity and shown to have excellent reliability in the acute hospital setting,²⁸ but no studies were identified in the ICU setting.

The Barthel Index has been extensively assessed and found to have very good measurement properties, including responsiveness, inter-rater reliability and face validity, in

stroke and geriatric populations.³⁹⁻⁴² No studies were found that assess the measurement properties of the Barthel Index in the ICU. Measures of physical function including the FIM scale,⁴³ Functional Ambulation Classification (FAC),⁴⁴ Berg Balance Scale^{21,45} and the five-times sit-to-stand test²⁹ have been shown to have excellent reliability and validity in non-ICU patient populations.

The 6MWT has very good responsiveness, inter-rater reliability and content validity in patients with heart failure,⁴⁶ community-dwelling adults, older adults,⁴⁷ and cardiac and pulmonary rehabilitation settings.^{48,49} However, its use may not be appropriate in the critical care population during the ICU stay, because of the high level of patient acuity. The 6MWT may provide valuable information at hospital discharge, as it showed a response to change with

Table 6. Reliability and validity of physical function outcome measures in the intensive care unit

Outcome measure	Study	Population	<i>n</i>	Method	Outcome	Statistic	Result	Main result
SF-36	Chrispin 1997 ²³	ICU	166	Patient completed with nursing staff		Reliability coefficient	>0.75	Good reliability
				Differences in scores with age and sex	Construct validity			Confirmed
				Broad distribution of scores	Content validity			Confirmed
MRC scale	Fan 2010 ³²	Recovering from critical illness	19	Various professionals	Inter-rater reliability	ICC	0.98	Excellent reliability
	Hough 2011 ³⁴	ICU	34	Doctors	Inter-rater reliability	ICC	0.83	Good reliability
	Hermans 2012 ³³	ICU	75	Physiotherapy	Inter-rater reliability	ICC	0.95	Excellent reliability
Handheld dynamometer	Hermans 2012 ³³	ICU	46	Physiotherapy	Inter-rater reliability	ICC	0.97	Excellent reliability
	Baldwin 2012 ³⁶	ICU	17	Physiotherapy	Inter-rater reliability	ICC	0.782–0.946	Good reliability
					Intra-rater reliability	ICC	0.819–0.918	Good reliability
	Vanpee 2011 ³⁵	ICU	12	Physiotherapy	Test–retest reliability	<i>P</i>	0.4	No significant difference
39			Physiotherapy	Inter-rater reliability	ICC	0.76–0.96	Good reliability	

FIM = Functional Independence Measure. ICC = interclass correlation coefficient. MRC = Medical Research Council. SF-36 = Short Form 36.

a clinically significant difference between two groups in a single-centre RCT of intensive care rehabilitation.¹³ However, this study was not blinded, did not use intention-to-treat analysis, and had some loss to follow-up (Table 3).

From articles evaluating reliability and validity, two additional measures of physical function — the Physical Function ICU Test (PFIT)⁵⁰ and the de Morton Mobility Index^{51–53} — were identified as having good reliability in the ICU or acute hospital setting. We did not include them in this review as they had not been published as an outcome in an ICU clinical trial, but they may be of future interest in Phase II or III studies of critically ill patients.

Discussion

Key findings

The main findings of this systematic review were that the most commonly used measurements of physical function were mobility, such as the highest functional mobility (eg, rolling, sitting, standing, walking) measured during physiotherapy or occupational therapy in the ICU,^{11,15,17} and walking, such as the maximum distance ambulated, measured at ICU or hospital discharge.^{1,12} As no studies have investigated the measurement properties of these measures, including inter-rater or intra-rater reliability, construct or population validity, in critically ill patients, the results

relating to efficacy that are based on these end points may need to be interpreted with caution.

Reliability, validity and responsiveness have been established for the SF-36²³ as a measure of health-related QOL in critically ill patients,⁵⁴ and for the MRC scale score and handheld dynamometer scores as measures of strength.^{23,32–34,36} The Functional Status Score for the ICU (FSS-ICU) was the only end point identified in the included studies that was specifically designed for use in the ICU.¹² It has demonstrated clinical responsiveness in the ICU setting, but further evaluation is required to assess its construct validity, reliability and predictive ability.²⁴

Clinical implications and significance

The lack of data on measurement properties, including responsiveness, face validity, content validity, cross-cultural validity and inter-rater and intra-rater reliability, of the most commonly used end points in contemporary studies requires further comment. Measures that generate discrete numerical scores, such as strength of specific muscle groups (MRC scale score and handheld dynamometry), may be pragmatically attractive, but may not enable an intuitive translation into an understanding of functional ability, such as ability to sit on the edge of a bed and maintain posture, or to walk or dress. We therefore suggest that measures of physical function should be categorised into four types of

end point that could broadly reflect whether they are being used for proof-of-concept (Phase II) studies or potential practice-changing (Phase III) studies. The four categories are:

1. A single numerical score that evaluates a specific physical function or muscle function, such as strength or walking distance
2. A hierarchical scale that measures some aspect of physical function (eg, for mobility: sit, stand, walk, or highest physical mobility)
3. A “composite measure” that measures the ability to perform multidimensional physical activities (such as the WHO classification of self-care⁶)
 - a. Short- to medium-term end points: FIM, FSS-ICU, PFIT
 - b. Long-term end points: Barthel Index and Katz ADL scale
4. A measure of the patient’s perception of his or her physical function (SF-36).

In the context of the observational studies that have explored the feasibility of delivering early mobilisation interventions, the research agenda now needs to focus on identifying candidate end points for Phase II and Phase III RCTs, and establishing their measurement properties. This may require consensus opinions augmented by input from clinicians, patients and caregivers. End points from our categories 1 and 2 may be suited to evaluating proof-of-concept of efficacy in Phase II RCTs, to assess whether a candidate intervention has a measurable effect in the short term (ie, at or before hospital discharge). End points from categories 3 and 4 may be more suited to Phase III RCTs, as they could be used to evaluate the effect of candidate interventions on complex multidimensional activities that are more relevant to medium- or long-term outcomes (ie, at or after hospital discharge). Some end points (eg, the 6MWT) may be suited for use in both Phase II and III studies.

The potential for change to be quantified in patients with a wide range of physical function may be limited when using a single outcome measure. For example, many patients may be too unwell to perform the 6MWT during their ICU stay, but this test may provide valuable information at hospital discharge and beyond. Therefore, it may be appropriate to use a combination of outcome measures, to allow appropriate, valuable and diverse patient information to be collected throughout the ICU and hospital stay.

There are other considerations with studies of early mobilisation that measure physical function. First, the difficulty with blinding participants and therapists highlights the importance of ensuring the blinding of assessors to increase the study quality. Second, the level of sedation or arousal in critically ill patients may be an important factor when

determining the inter-rater and test–retest reliability of functional end points.^{33,55}

Novel measures of function in the ICU

One article described the PFIT as a functional measure designed for the ICU population.⁵⁰ It measures strength, endurance, cardiovascular capacity and functional level. The PFIT was shown to have good reliability and is responsive to change in the ICU population.⁵⁰ The de Morton Mobility Index was specially designed for use in the acute hospital and is valid in this setting, but it has also been extended for use in subacute settings.^{51,52}

Strengths and limitations

The strengths of this systematic review include the extensive search strategy, the rigorous approach to reviewing the data, and the multidisciplinary team of researchers. However, it does have some limitations. First, the search strategy may not have captured all of the studies of measurement properties of these outcome measures in an ICU population, although every attempt was made to search for these and to contact appropriate authors. Second, measures of physical function may be used in studies unrelated to early mobilisation and rehabilitation. Third, studies that measured these outcomes with undesirable results may not have been published (publication bias). Fourth, we included the SF-36 health-related QOL as a measure of physical function, as several studies have reported the “physical function” component separately to the entire survey. Fifth, we did not include studies that investigated functional status in a rehabilitation setting after discharge from the ICU, and this is a growing area of research in patients who have been critically ill. Finally, there is no information about the relationship between functional status at ICU or hospital discharge and functional status at 3, 6 or 12 months’ follow-up. This is the key question that needs to be addressed in future studies.

Future directions

Good functional survival is a key theme in intensive care medicine, and the growth of research in this area reflects this.² However, there is a scarcity of measures of physical function that are validated and reliable in this setting, and there is a clear imperative for these. Some new measures of physical function that have been developed for use within the ICU, including the PFIT and the FSS-ICU, are of interest.

Conclusion

The feasibility of early mobilisation has been established.⁵⁶ We identified 19 measures of physical function that have been used in clinical studies, and the choice of end point

will depend on whether the aim of a study is proof of concept (Phase II) or practice-changing (Phase III). Future studies of early mobilisation and rehabilitation conducted in the ICU need to ensure that measures of physical function are practical, responsive, valid and reliable in this unique setting. Where the goal is to return the patient to his or her previous level of both physical function and QOL, global measures of physical function that include self-care or activities of daily living (Barthel Index, I-MOVE or the Katz ADL scale), or QOL measures, may be more informative than simple measures of strength, mobility or best level of activity during the day.

Competing interests

None declared.

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