Association Between Physiotherapy Outcome Measures and the Functional Independence Measure: A Retrospective Analysis

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Objective: To assess the association between change scores in the Functional Independence Measure (FIM) with evaluative measures used in physiotherapy to objectively show that use of the FIM in isolation is limited.

Design: Retrospective observational study.

Setting: Five rehabilitation inpatient wards from 1 public local health district in NSW Australia.

Participants: Patient data over a 5-year time frame (2015 to 2019) were reviewed (N = 2378). The patient data from the 3 most prevalent impairment groups (Australasian Rehabilitation Outcome Centre classification) were identified for inclusion in this study: Reconditioning (n = 742, mean age 76.88 years); Orthopedic Fracture (n = 585, mean age 77.46 years); and Orthopedic Replacement (n = 377, mean age 73.84 years).

Measurements: The difference between the admission and discharge scores were calculated for each measure. Kruskal-Wallis and χ^2 tests were used to analyze the data.

Results: Pearson correlation (*r*) coefficients between FIM Motor change to the de Morton's Mobility Index (DEMMI) change was $r = 0.396$, FIM Motor change to the Timed Up and Go (TUG) change was $r = -0.217$, and the FIM Motor change to the Ten Meter Walk Test (10MWT) change was .194.

Conclusion: The FIM Motor change scores showed a weak positive association to the DEMMI change and no association to the TUG and 10MWT change, demonstrating that the outcome measures do not measure the same attributes. To review rehabilitation effectiveness from a management perspective, it is recommended that all measures are reviewed to assess the burden of care, functional mobility, and dynamic balance.

Keywords: physiotherapy; rehabilitation; clinical outcome measures.

Patients receive interdisciplinary inpatient rehabilitation treatment after they have sustained a lower limb fracture, a lower limb joint replacement, or have generalized deconditioning (muscle wasting and disuse atrophy) following hospitalization for surgery or illness. The degree of a patient's impairment or loss of functional capacity, as well as their ability to manage at home safely, is assessed using standardized outcome measures during their recovery and rehabilitation.[1,2]

Physiotherapists routinely use validated outcome measures to assess patient progress and to measure goal attainment through assessment of functional independence, dynamic balance performance, and ambulatory ability. These objective assessments provide clinicians with information about the effectiveness of the rehabilitation program, as well as the patient's ability to manage in their home environment, to determine the need for assistive devices, level of caregiver support, future level of autonomy, and strategies for falls prevention.[3-7]

There is a view among service providers that rehabilitation decisions can be based on a singular measure of function known as the Functional Independence Measure (FIM). This is an understandable position because not only is the FIM an internationally recognized, valid, and reliable tool, but, as a singular measure, it also means

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measurement consistency across rehabilitation sites is more likely. However, rehabilitation is complex, and it is risky to base decisions on a single measure, which might not capture the results of rehabilitation treatment ingredients on individual patient targets.[8,9]

The patient's progress is objectively assessed using functional outcome measures such as the FIM. Other measures used typically in our service include the de Morton's Mobility Index (DEMMI), Timed Up and Go (TUG), and the Ten Meter Walk Test (10MWT), which measure patient mobility, balance during directional changes, and walking ability, respectively. Additional measures include patient progression to a less supportive level of assistance (ie, number of persons required to assist or level of supervision) or the selection of a walking aid (eg, forearm support frame, crutches). This progression—or lack thereof—assists in decision-making regarding the individual's future once they are discharged from rehabilitation. Such considerations would include the need to modify the home environment, selection of assistive devices, community access (walking indoors, outdoors, and shopping), personal care needs, and age-appropriate care facility recommendations (ie, level of care). The use of outcome measures also indicates the need for further referrals to other care providers upon discharge from the rehabilitation facility.

There is widespread support in the literature for the use of the FIM, DEMMI, TUG, and 10MWT in rehabilitation population groups. For example, DEMMI has been validated in hip fracture patients during rehabilitation,[10] as well as among older people hospitalized for medical illness.[11-13] It has also been shown to be a predictor of discharge destination for patients living with frailty in geriatric rehabilitation settings,[14] and to have moderate predictive validity for functional independence after 4 weeks of rehabilitation.[15] Similarly, TUG has been validated for use among hospitalized and community-dwelling individuals,[16-18] and for patients after joint arthroplasty[19,20] or hip fracture.[21] It has also been shown to be an indicator of fall risk,[22-24] as well as a predictor of fracture incidence.[25] Furthermore, TUG has been identified as an indicator of a patient's ability to walk in the community without the need for a walking device.[26] It has also been shown to be an early identifier of patients in need of rehabilitation.[27] Normative values for TUG have been reported, and the association with gait time established.[28]

Gait speed has been shown to predict adverse outcomes in community-dwelling older people.[29] In fact, the 10MWT has been established as a powerful tool to benchmark rehabilitation recovery after a medical event.[30] Results of the test relate to overall quality of walking, health status, morbidity, and the rate of mortality.[31-33] Meaningful improvement, minimum detectable change (0.19-0.34 m/s), and responsiveness in common physical performance in older adults has been reported.[26,34,36]

Structural and functional impairment has been used to define rehabilitation classes by the Australasian Rehabilitation Outcome Centre (AROC) in the Australian National Sub-Acute and Non-Acute Patient Classification (AN-SNAP) Version 4.[37-43] Variables used for grouping are age, care type, function, and impairment for rehabilitation. FIM was developed in order to assess patients' outcomes after inpatient multidisciplinary care, and is an internationally accepted measure of functioning.[44] It is a holistic outcome measure, which can be used to determine the patient's level of disability and burden of care, and is widely used in both public and private inpatient rehabilitation settings. Each patient classification is reported separately within the case mix structure.[45] Inpatient rehabilitation centers are evaluated and compared by the AROC,[46] with an emphasis on length of stay and the FIM change. The most successful centers demonstrate shorter length of stay and greater FIM improvement. Although the FIM is a valuable measure, it does not provide a complete picture of the individual patient's rehabilitation gain: ie, the specific attributes of patients' mobility, walking ability, or balance during directional changes.

A large-scale analysis of the association between the holistic disability measure of the FIM and the more mobility- and ambulation-focused physiotherapy outcomes has not been documented.

The well-documented DEMMI accumulates points for the patient's mobility in a similar fashion to the FIM, but with more mobility detail. These 2 outcome measures allow for the full range of patients, from the very dependent up to and including the independently ambulant patients. The DEMMI may show a positive relationship to the FIM, yet the association is unknown. The association of the TUG to the

10MWT has been established[28]; however, their relationship to the FIM is unknown.

Current practice in the participating public health inpatient rehabilitation wards is to use the DEMMI, TUG, 10MWT, and FIM to ensure physiotherapy and allow the wider multidisciplinary team to more effectively evaluate patient mobility outcomes. The 3 most frequent patient groups identified within the current patient population are expected to present clinical differences and will be analyzed for comparison. If an association is found between the outcome measures in question, clinical efficiency could be improved.

The aim of the current study is to assess the association between change scores in the FIM with evaluative measures of outcomes typically used in physiotherapy to objectively show that use of the FIM in isolation is limited in our population of patients.

Table 1. **AROC Impairment Groups**

Impairment group[48]	Australian National Sub-Acute and Non-Admitted Patient Classification[46]
Reconditioning	• Reconditioning following illness
	• Reconditioning following surgery
	• Reconditioning following cancer rehabilitation
Orthopedic fracture	• Ortho fracture hip bilateral
	• Ortho fracture knee
	• Ortho fracture leg ankle foot
	• Ortho fracture multiple sites
	• Ortho fracture pelvis
	• Ortho fracture shaft femur
	• Ortho fracture other
	• Ortho other surgery
Orthopedic replacement	• Ortho bilateral knee replacement
	• Ortho unilateral knee replacement
	• Ortho bilateral hip replacement
	• Ortho unilateral hip replacement

AROC, Australasian Rehabilitation Outcome Centre.

Methods

Study design and setting

This retrospective descriptive observational study complied with the STROBE-RECORD guidance and checklist (available at mdedge.com/jcomjournal) and analyzed the routinely collected data from rehabilitation patients who were admitted to 5 different rehabilitation wards in 4 different public hospitals from 1 regional local health district (20-24 beds per ward) from 2015 to 2019. As this study conducted secondary analyses using existing de-identified data from a public health facility and did not involve interaction with any human subjects, ethical approval was not required.[46] Approval to conduct this study was granted by the health district's institutional review committee, as per the National Statement on Ethical Conduct in Human Research 2015.

Participants

Patient data over a 5-year time frame were reviewed (N = 2378). The patient data from the 3 most prevalent impairment groups were identified for inclusion in this study: reconditioning, orthopedic fracture, and orthopedic replacement. (See **Table 1** for the specific AN-SNAP impairment groups used in this study.)

Patient data from the less-frequent impairment groups were excluded (n = 673, 28.19%), including stroke (n = 343), brain dysfunction (n = 45), amputation of limb (n = 45), spinal cord dysfunction (n = 36), neurological dysfunction (n = 34), cardiac (n = 24), and others (n = 25) who may have benefitted from other outcome measures due to their medical condition. Ten patient data sets were excluded for missing discharge outcome measure data, from when the patient became ill and returned to acute services or was discharged at short notice. To be included in the study, both the admission and discharge scores from the FIM and the admission and discharge scores from at least 1 of the physiotherapy outcome measures were required for each patient (n = 1704, 71.39%): Reconditioning (n = 742), Orthopedic Fracture (n = 585), and Orthopedic Replacement (n = 377). Information regarding the type of walking aid and the amount of assistance required for safe ambulation was also recorded. These items were included in the study's descriptive analysis. Only 1.7% of these descriptors were missing.

Outcome measures

DEMMI tasks of bed mobility, sitting balance, transfers, walking, and balance were scored with an assigned

Table 2. **Patient Demographic Information (N=1704)**

Units	Reconditioning patients (n=742)	Orthopedic fracture patients (n=585)	Orthopedic replacement patients (n=377)
Site, n (%)			
Site 1	145 (19.54)	139 (23.76)	76 (20.16)
Site 2	170 (22.91)	147 (25.13)	84 (22.28)
Site 3	170 (22.91)	140 (23.93)	103 (27.32)
Site 4	159 (21.43)	101 (17.26)	82 (21.75)
Site 5	98 (13.21)	58 (9.91)	32 (8.49)
Mean (SD) length of stay, d	23.87 (22.37)	26.46 (16.44)	18.03 (13.62)
Age, y			
Mean (SD)	76.88 (11.58)	77.46 (11.60)	73.84 (9.70)
Range, y	48-101	45-93	29-98
Discharge destination, n (%)[a]			
Hospital	24 (3.25)	12 (2.07)	2 (0.54)
Home	645 (87.40)	502 (86.40)	356 (97.00)
High-level care	40 (5.42)	34 (5.85)	4 (1.09)
Low-level care	26 (3.52)	25 (4.30)	2 (0.54)
Family	3 (0.41)	8 (1.38)	3 (0.82)
Aid improvement, n (%)[b]			
No	426 (58.20)	176 (30.66)	91 (24.73)
Yes	306 (41.80)	398 (69.34)	277 (75.27)
Assist improvement, n (%)[c]			
No	193 (26.26)	103 (17.85)	94 (25.20)
Yes	542 (73.74)	474 (82.15)	279 (74.80)

[a]Data missing for 4 reconditioning patients, 4 orthopedic fracture patients, and 10 orthopedic replacement patients.
[b]Data missing for 10 reconditioning patients, 11 orthopedic fracture patients, and 9 orthopedic replacement patients.
[c]Data missing for 7 reconditioning patients, 8 orthopedic fracture patients, and 4 orthopedic replacement patients.

value according to the patient's performance. This was then tallied and the results scaled, to provide an overall score out of 100 available points. The total score from admission and discharge was then compared. Improvement (change) was identified by the increase in scores.

The TUG assesses a patient's dynamic balance performance.[47] The number of seconds it took the patient to complete the procedure was recorded at admission and discharge. Improvement (change) was identified by the reduction in time taken at discharge from the admission score.

The 10MWT measures the unidirectional walking speed of a person over 10 meters and is recorded in seconds and reported in meters per second. Improvement (change) was identified by the reduction in the time taken to increase walking speed.

Concurrent to the physiotherapy measures were the FIM scores, recorded by the accredited nursing staff from each rehabilitation ward. Improvement is demonstrated by the accumulation of points on the ordinal scale of the FIM Total, including mobility, dressing, bladder and bowel care, cognition, and social interaction, and is represented as a score between 18 and 126. The FIM Motor category is reported as a score between 13 and 91.

The 2 data sets were matched by unique identifier and admission dates, then de-identified for analysis.

Statistical analysis

Patient demographic information was analyzed using descriptive statistics (mean, SD, frequencies, percentages) for each impairment group (orthopedic fracture, orthopedic replacement, reconditioning). Differences in continuous demographic variables for each impairment group were assessed using Kruskal-Wallis tests and χ^2 tests for categorical variables. Functional outcome scores were compared at admission, discharge, and change between the impairment groups. Association of the functional outcome change scores was determined with the Pearson correlation coefficient (*r*) between the FIM and the DEMMI, TUG, and 10MWT. Graphs were plotted for each of these (**Figure** available online at mdedge.com/jcomjournal). A strong, moderate, and weak association was described as >0.6, >0.4, and >0.2, respectively.[46] Statistical significance was set at $P<.05$. Analyses were conducted using Stata (StataCorp LLC, USA).

Results

The patient descriptive data (site from which data were collected, admission length of stay, age at admission, discharge destination, walk aid improvement, and walk assistance improvement) from the 3 impairment groups are reported in **Table 2**. The functional outcomes for DEMMI, TUG, 10MWT, FIM Motor, FIM Total at admission, discharge, and the change scores are presented in **Table 3**.

Orthopedic fracture patients had the greatest improvement in their functional outcomes, with a DEMMI improvement of 18 points, TUG score change of 23.49 seconds (s), 10MWT change of 0.30 meters/second (m/s), FIM Motor change of 20.62, and a FIM Total change of 21.9 points. The outcome measures exceeded the minimum detectable change as reported in the literature for DEMMI (8.8 points[48]), TUG (2.08 s[26]), walking speed 0.19 m/s[26], and FIM Motor (14.6 points[49]).

Association of functional outcomes (change scores)

There was a significant weak positive correlation between DEMMI change score and both the FIM Motor ($r=0.396$) and FIM Total change scores ($r=0.373$). When viewing the specific items within the FIM Motor labelled FIM Walk change, FIM MobilityBedChair change, and FIM stairs change, *r* values were 0.100, 0.379, and 0.126, respectively. In addition, there was a weak negative correlation between TUG change scores and both FIM Motor ($r=-0.217$) and FIM Total change scores ($r=-0.207$). There was a very weak positive correlation between 10MWT (m/s) change scores and both FIM Motor ($r=0.194$) and FIM Total change scores ($r=0.187$) (**Table 4**, Figure). There was a moderate correlation between 10MWT change (s) and TUG change (s) ($r=0.72$, $P<.001$).

Discussion

The purpose of this study was to ascertain the association between the DEMMI, TUG, 10MWT, and FIM measures using retrospective data collected from 5 public hospital inpatient rehabilitation wards. The results of this retrospective analysis demonstrate that a variety of objective outcome measures are required for the multidisciplinary team to accurately measure a patient's functional improvement during their inpatient rehabilitation stay. No single outcome measure in this study fully reported all mobility attributes, and we note the risk of basing decisions on a single measure evaluating rehabilitation outcomes. Although the internationally used FIM has a strong place in rehabilitation reporting and benchmarking, it does not predict change nor provide a proxy for the patient's whole-body motor control as they extend their mobility, dynamic balance, and ambulatory ability. Multiple objective outcome measures should therefore be required to evaluate the patient's progress and functional performance toward discharge planning.

The FIM is a measure of disability or care needs, incorporating cognitive, social, and physical components of disability. It is a valid, holistic measure of an individual's functional ability at a given time. Rehabilitation sites internationally utilize this assessment tool to evaluate a patient's progress and the efficacy of intervention. The strength of this measure is its widespread use and the inclusion of the personal activities of daily living to provide an overall evaluation encompassing all aspects of a person's ability to function independently. However, as our study results suggest, patient improvement measured by the FIM Motor components were not correlated to other widely used physiotherapy measures of ambulation and balance, such as the 10MWT or TUG. This is perhaps largely because the FIM Motor components only consider the level of assistance (eg, physical assistance, assistive

Table 3. **Functional Outcomes (N = 1704)**

	Unit	Reconditioning patients (n = 742)	Orthopedic fracture patients (n = 585)	Orthopedic replacement patients (n = 377)	*P* value[a]
DEMMI (n = 979)					
Mean (SD)	Out of 100 points				
Admission		35.59 (14.88)	31.00 (11.72)	34.63 (12.01)	< .001
Range		0.00-100.00	0.00-85.00	2.00-67.00	
Discharge		50.49 (15.38)	48.93 (11.94)	52.39 (10.18)	.004
Range		8.00-100.00	0.00-100.00	27.00-100.00	
Change		14.91 (11.81)	18.01 (11.47)	18.03 (11.14)	< .001
Range		-12.00-67.00	-39.00-56.00	-5.00-54.00	
TUG (n = 1180)					
Mean (SD)	Seconds				
Admission		33.72 (20.39)	45.93 (28.09)	42.40 (23.95)	< .001
Range		7.6-190.00	8.81-230.00	13.00-144.00	
Discharge		23.58 (14.94)	23.45 (10.20)	22.70 (11.32)	.008
Range		6.20-120.00	7.53-95.00	8.50-102.00	
Change		-11.23 (16.41)	-23.49 (26.71)	-21.03 (21.97)	< .001
Range		-162.6-49.53	-206.69-31.00	-126.32-26.62	
10MWT (n = 1476)					
Mean (SD)	Meters per second				
Admission		0.52 (0.22)	0.38 (0.19)	0.39 (0.18)	< .001
Range		0.05-1.25	0.04-1.00	0.05-0.95	
Discharge		0.69 (0.28)	0.66 (0.24)	0.64 (0.22)	.052
Range		0.09-1.61	0.09-1.59	0.10-1.33	
Change		0.20 (0.21)	0.30 (0.24)	0.27 (0.21)	< .001
Range		-0.37-0.98	-0.33-1.35	-0.31-0.89	
FIM Motor (n = 1704)					
Mean (SD)	13 to 91 points				
Admission		53.79 (15.48)	51.91 (13.76)	58.78 (13.28)	< .001
Range		13.00-89.00	15.00-85.00	13.00-91.00	
Discharge		71.27 (15.14)	72.52 (13.72)	78.52 (9.90)	< .001
Range		13.00-91.00	15.00-91.00	28.00-91.00	
Change		17.45 (12.83)	20.62 (13.48)	19.75 (11.94)	< .001
Range		-63.00-67.00	-24.00-61.00	-13.00-69.00	
FIM Total (n = 1704)					
Mean (SD)	19 to 126 points				
Admission		81.57 (19.52)	80.15 (17.31)	89.35 (16.49)	< .001
Range		0.00-124	21.00-120.00	27.00-126.00	
Discharge		99.86 (19.51)	102.03 (17.44)	110.29 (12.41)	< .001
Range		0.00-126.00	21.00-126.00	52.00-126.00	
Change		18.29 (14.23)	21.88 (14.64)	20.94 (12.99)	< .001
Range		-80.00-71.00	-34.00-66.00	-13.00-89.00	

DEMMI, de Morton's Mobility Index; FIM, Functional Independence Measure; TUG, Timed Up and Go; 10MWT; Ten Meter Walk Test.
[a]Kruskal-Wallis tests were used to compare admission, discharge, and change score between impairment groups.

Table 4. **Correlation of Functional Outcomes**

	Correlation with DEMMI change (Pearson *r*)	Correlation with TUG change (Pearson *r*)	Correlation with 10MWT change (Pearson *r*)
FIM Motor change	0.396	-0.217	0.194
FIM Total change	0.373	-0.207	0.187
FIM Walk change	0.100	-0.02	0.188
FIM MobilityBedChair change	0.379	-0.223	0.192
FIM Stairs change	0.126	0.05	0.073

DEMMI, de Morton's Mobility Index; FIM, Functional Independence Measure; TUG, Timed Up and Go; 10MWT, Ten Meter Walk Test.

device, independence) and do not consider assessment of balance and gait ability as assessed in the 10MWT and TUG. The 10MWT and TUG provide assessment of velocity and dynamic balance during walking, which have been shown to predict an individual's risk of falling.[22,23] This is a pertinent issue in the rehabilitation and geriatric population.[29] Furthermore, the use of the FIM as a benchmarking tool to compare facility efficiency may not provide a complete assessment of all outcomes achieved on the inpatient rehabilitation ward, such as reduced falls risk or improved ambulatory ability and balance.

Of the objective measures evaluated in our paper, the DEMMI assessment has the most similar components to those of the FIM Motor. It includes evaluating independence with bed mobility, standing up, and ambulation. In addition, the DEMMI includes assessment of both static and dynamic balance. As a result of these commonalities, there was only a weak positive correlation between the change in DEMMI and the change in FIM Motor and FIM Total. However, this correlation is not statistically significant. Therefore, the FIM is not recommended as a replacement of the DEMMI, nor can one be used to predict the other.

It has previously been confirmed that there is a significant positive correlation between the 10MWT and the TUG.[27] This retrospective analysis has also supported these findings. This is possibly due to the similarity in the assessments, as they both incorporate ambulation ability and dynamic movement.

Each of the 4 outcome measures assess different yet vital aspects of an individual's functional mobility and ambulation ability during their subacute rehabilitation journey. The diversity of patient age, functional impairment, and mobility level needs a range of outcomes to provide baselines, targets, and goal attainment for discharge home.

Consistent with the AROC AN-SNAP reporting of Length of Stay and FIM change separated into the weighted impairment groups, the data analysis of this study demonstrated significant differences between the Reconditioning, Orthopedic Fracture, and Orthopedic Replacement patient data. Tables 2 and 3 describe the differences between the groups. The fracture population in this study improved the most across each outcome measure. In contrast, the reconditioning population showed the least improvement. This may be expected due to the pathophysiological differences between the groups. Furthermore, for the elderly who sustain fractures because of a fall, rehabilitation will be required to address not only the presenting injury but also the premorbid falls risk factors which may include polypharmacy or impaired balance.

Any conclusions drawn from the findings of this study need to take into consideration that it has focused on patients from 1 local health district and therefore may not be generalizable to a wider national or international context. As this study was a retrospective study, controlling for data collection quality, measurement bias due to nonblinding and missing data is a limitation. However, clinicians regularly completed these outcome assessments and recorded this information as part of their standard care practices within this health district. There may have been slight differences in definitions of practice between the 5 rehabilitation sites. To ensure reliability, each individual site's protocols for the FIM, DEMMI, TUG, and 10MWT were reviewed and confirmed to be consistent.

It is important, too, to consider the ceiling effect for the FIM scores. For patients requiring a walking aid well after discharge, the highest level of independence from the walking aid will not be achieved. It is acknowledged that the floor effect of the 10MWT and TUG may also influence the outcomes of this study. In addition, data were not collected on preadmission functional measures to enable further evaluation of the population groups. The proportion of variance in change from admission to discharge for TUG and 10MWT to FIM was less than 5%, so the correlation interpretation from this type of scaling is limited. Further research into outcome measures for inpatient rehabilitation in respect to variables such as patient age, length of stay, discharge destination, and efficacy of intervention is warranted.

Conclusion

The FIM Motor change scores showed a weak positive association to the DEMMI change, and no association to the TUG and 10MWT change, demonstrating that the outcome measures do not measure the same attributes. Thorough reporting of clinical outcomes is much more meaningful to assess and guide the physiotherapy component of rehabilitation. To review rehabilitation effectiveness from a management perspective, it is recommended that all measures are reviewed to assess the burden of care, mobility, functional capacity, and dynamic balance.

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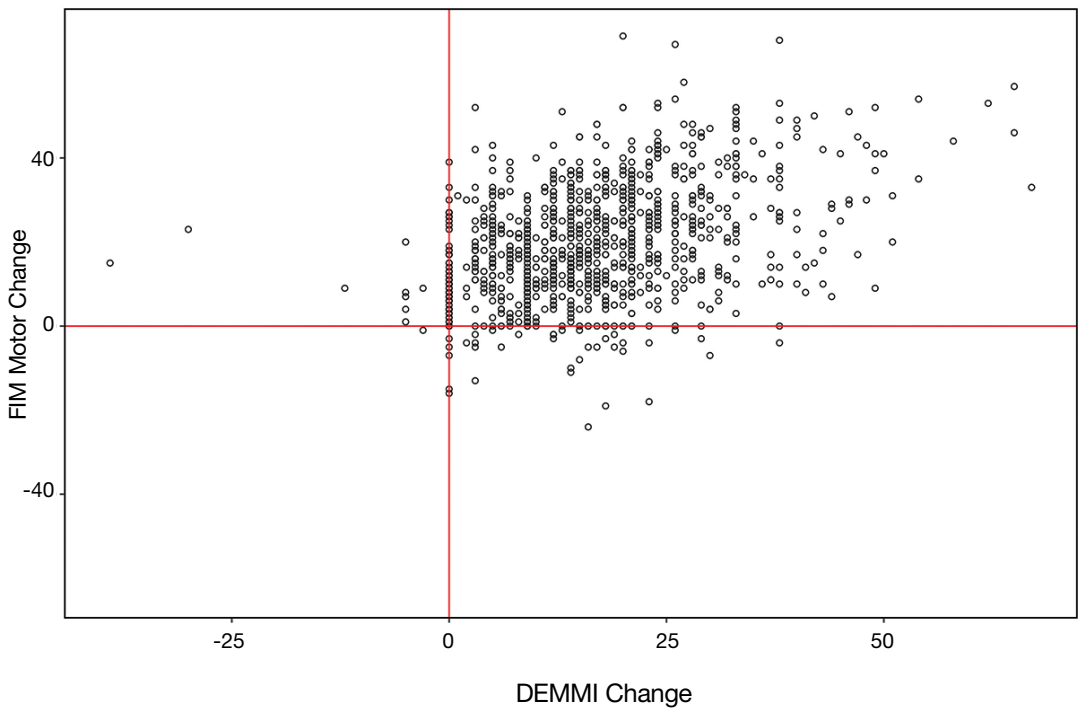


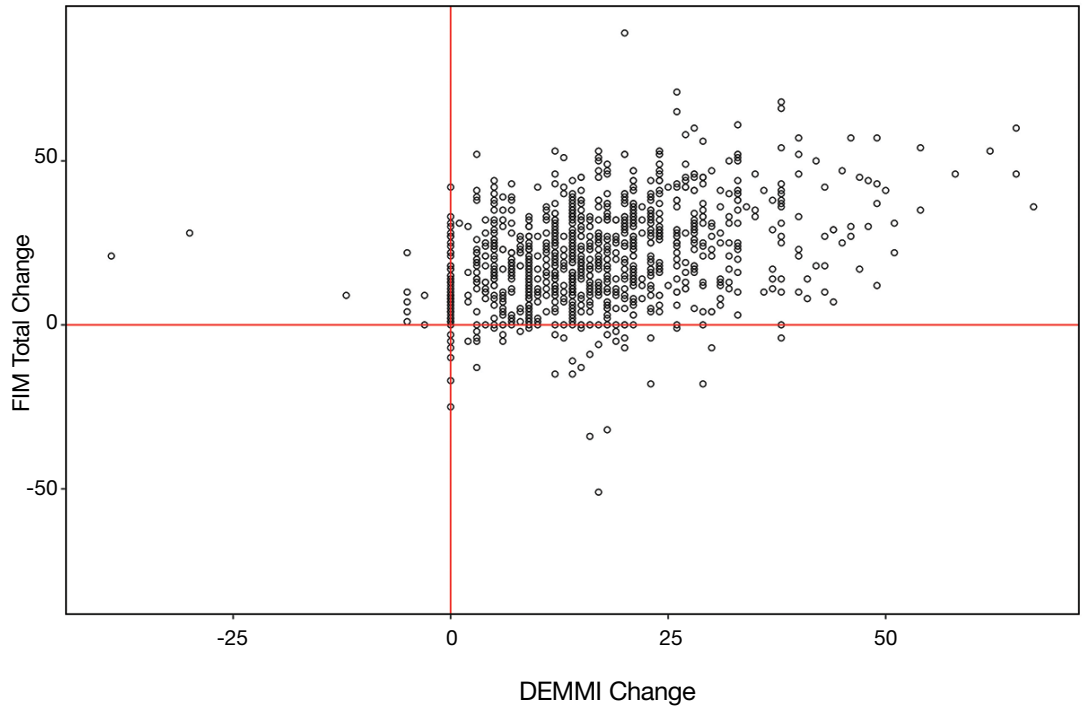
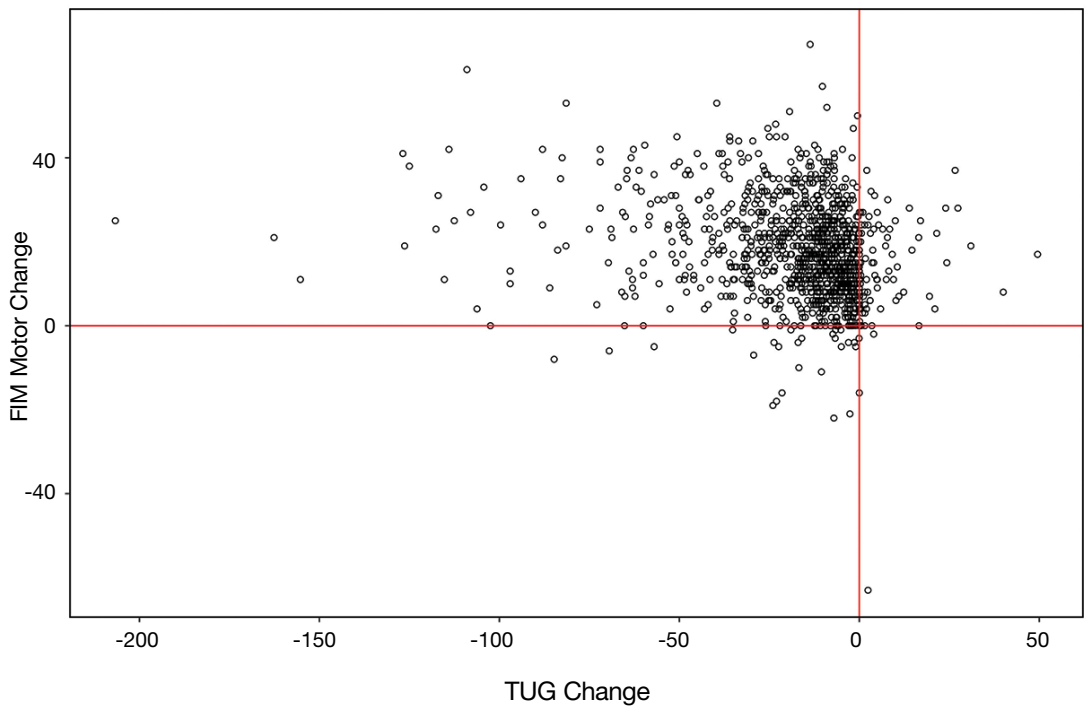


Figure. Correlation Between Change Scores (DEMMI, TUG, 10MWT [m/s], and FIM Motor, FIM Total).



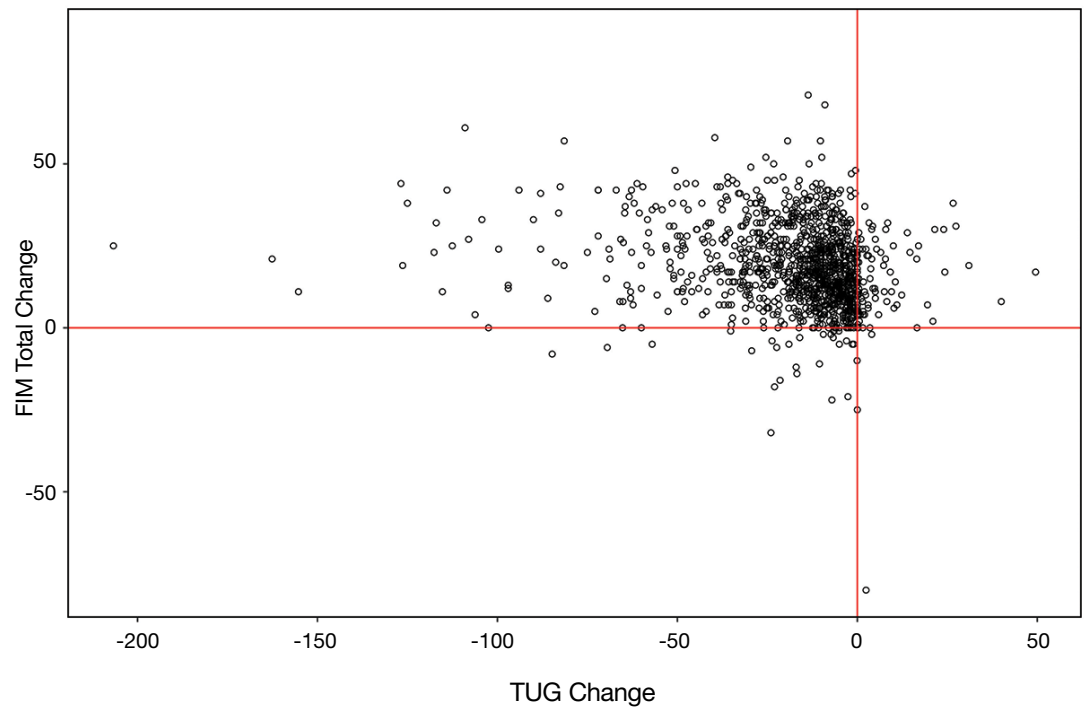
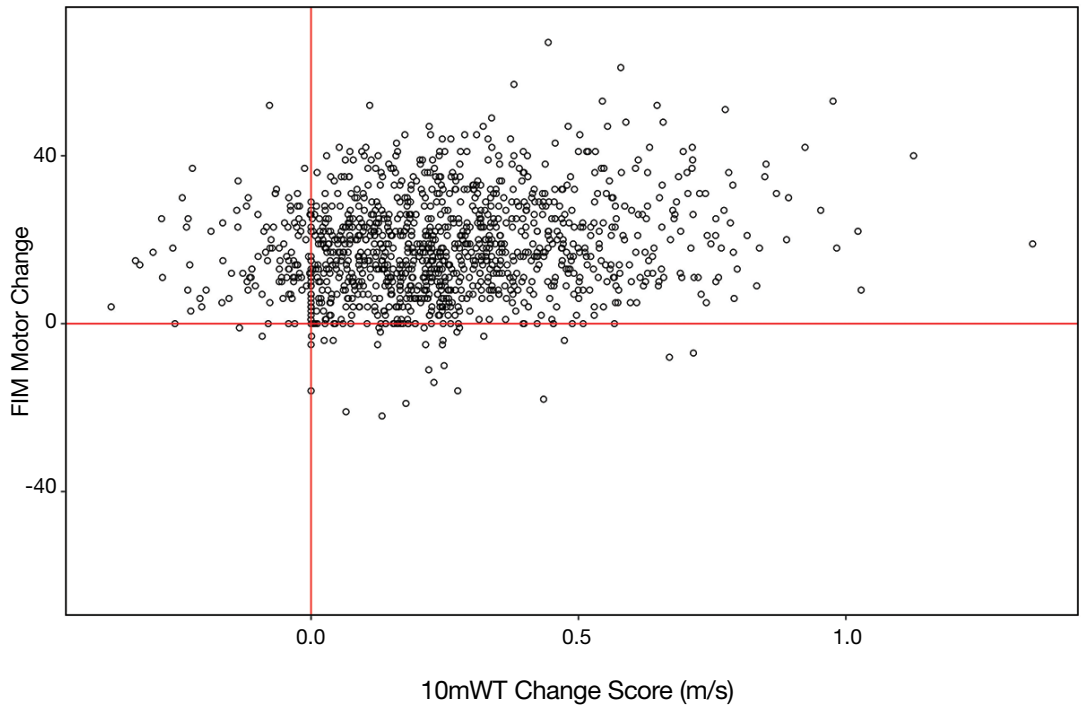


Figure. Correlation Between Change Scores (DEMMI, TUG, 10MWT [m/s], and FIM Motor, FIM Total). continued



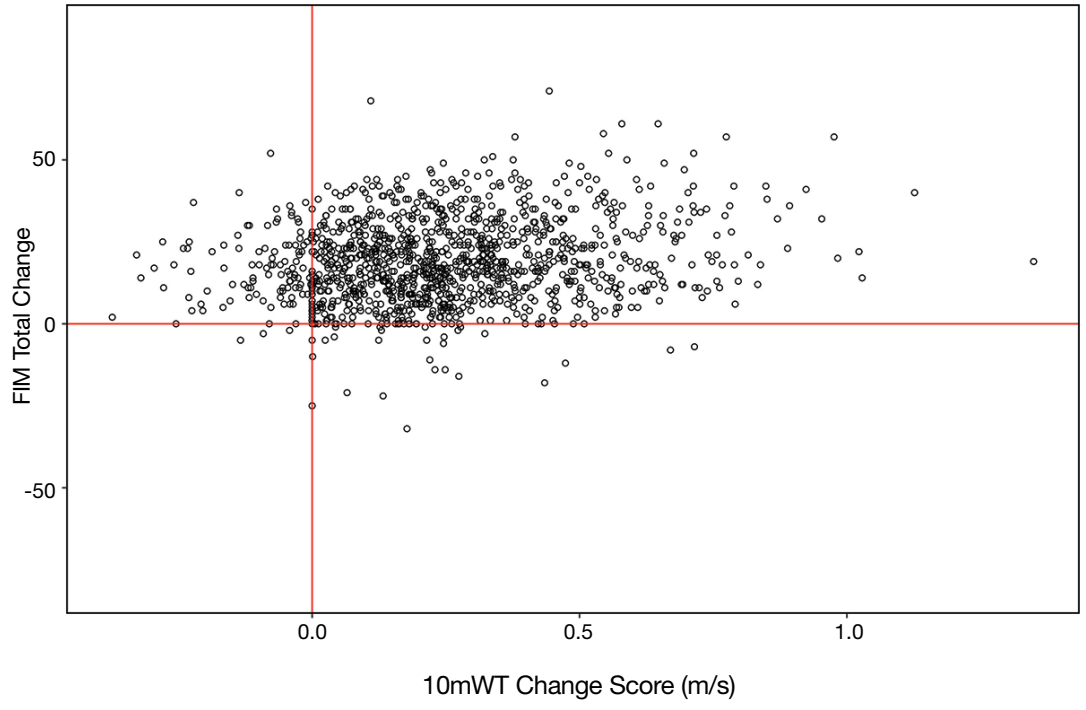


Figure. Correlation Between Change Scores (DEMMI, TUG, 10MWT [m/s], and FIM Motor, FIM Total). continued

STROBE Statement—checklist of items that should be included in reports of observational studies

	Item No	Recommendation	
Title and abstract	1	(*a*) Indicate the study's design with a commonly used term in the title or the abstract	☑
		(*b*) Provide in the abstract an informative and balanced summary of what was done and what was found	☑
Introduction			
Background/rationale	2	Explain the scientific background and rationale for the investigation being reported	☑
Objectives	3	State specific objectives, including any prespecified hypotheses	☑
Methods			
Study design	4	Present key elements of study design early in the paper	☑
Setting	5	Describe the setting, locations, and relevant dates, including periods of recruitment, exposure, follow-up, and data collection	☑
Participants	6	(*a*) *Cohort study*—Give the eligibility criteria, and the sources and methods of selection of participants. Describe methods of follow-up *Case-control study*—Give the eligibility criteria, and the sources and methods of case ascertainment and control selection. Give the rationale for the choice of cases and controls *Cross-sectional study*—Give the eligibility criteria, and the sources and methods of selection of participants	☑
		(*b*) *Cohort study*—For matched studies, give matching criteria and number of exposed and unexposed *Case-control study*—For matched studies, give matching criteria and the number of controls per case	
Variables	7	Clearly define all outcomes, exposures, predictors, potential confounders, and effect modifiers. Give diagnostic criteria, if applicable	☑
Data sources/ measurement	8*	For each variable of interest, give sources of data and details of methods of assessment (measurement). Describe comparability of assessment methods if there is more than one group	☑
Bias	9	Describe any efforts to address potential sources of bias	☑
Study size	10	Explain how the study size was arrived at	☑
Quantitative variables	11	Explain how quantitative variables were handled in the analyses. If applicable, describe which groupings were chosen and why	☑
Statistical methods	12	(*a*) Describe all statistical methods, including those used to control for confounding	☑
		(*b*) Describe any methods used to examine subgroups and interactions	☑
		(*c*) Explain how missing data were addressed	☑
		(*d*) *Cohort study*—If applicable, explain how loss to follow-up was addressed *Case-control study*—If applicable, explain how matching of cases and controls was addressed *Cross-sectional study*—If applicable, describe analytical methods taking account of sampling strategy	N/A
		(*e*) Describe any sensitivity analyses	

Continued on next page

Results			
Participants	13*	(a) Report numbers of individuals at each stage of study—eg numbers potentially eligible, examined for eligibility, confirmed eligible, included in the study, completing follow-up, and analysed	☑
		(b) Give reasons for non-participation at each stage	N/A
		(c) Consider use of a flow diagram	N/A
Descriptive data	14*	(a) Give characteristics of study participants (eg demographic, clinical, social) and information on exposures and potential confounders	☑
		(b) Indicate number of participants with missing data for each variable of interest	☑
		(c) *Cohort study*—Summarise follow-up time (eg, average and total amount)	☑
Outcome data	15*	*Cohort study*—Report numbers of outcome events or summary measures over time	☑
		Case-control study—Report numbers in each exposure category, or summary measures of exposure	
		Cross-sectional study—Report numbers of outcome events or summary measures	
Main results	16	(*a*) Give unadjusted estimates and, if applicable, confounder-adjusted estimates and their precision (eg, 95% confidence interval). Make clear which confounders were adjusted for and why they were included	☑
		(*b*) Report category boundaries when continuous variables were categorized	☑
		(*c*) If relevant, consider translating estimates of relative risk into absolute risk for a meaningful time period	N/A
Other analyses	17	Report other analyses done—eg analyses of subgroups and interactions, and sensitivity analyses	☑
Discussion			
Key results	18	Summarise key results with reference to study objectives	☑
Limitations	19	Discuss limitations of the study, taking into account sources of potential bias or imprecision. Discuss both direction and magnitude of any potential bias	☑
Interpretation	20	Give a cautious overall interpretation of results considering objectives, limitations, multiplicity of analyses, results from similar studies, and other relevant evidence	☑
Generalisability	21	Discuss the generalisability (external validity) of the study results	☑
Other information			
Funding	22	Give the source of funding and the role of the funders for the present study and, if applicable, for the original study on which the present article is based	☑

*Give information separately for cases and controls in case-control studies and, if applicable, for exposed and unexposed groups in cohort and cross-sectional studies.

Note: An Explanation and Elaboration article discusses each checklist item and gives methodological background and published examples of transparent reporting. The STROBE checklist is best used in conjunction with this article (freely available on the Web sites of PLoS Medicine at http://www.plosmedicine.org/, Annals of Internal Medicine at http://www.annals.org/, and Epidemiology at http://www.epidem.com/). Information on the STROBE Initiative is available at www.strobe-statement.org.