Prosthetics and Orthotics International

Head-to-head Rasch comparison of the Prosthesis Evaluation Questionnaire-Mobility Section and the Prosthetic Mobility Questionnaire 2.0 in Italian lower-limb prosthesis users

--Manuscript Draft--

Manuscript Number:	
Full Title:	Head-to-head Rasch comparison of the Prosthesis Evaluation Questionnaire-Mobility Section and the Prosthetic Mobility Questionnaire 2.0 in Italian lower-limb prosthesis users
Article Type:	Original Research Report
Keywords:	lower-limb amputation; outcome assessment; psychometrics; rehabilitation; prosthetic mobility
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Abstract:	Introduction The Prosthesis-Evaluation-Questionnaire Mobility Section (PEQ-MS) and the Prosthetic Mobility Questionnaire (PMQ 2.0) are two validated self-report questionnaires assessing mobility in people with lower-limb amputation. The aim of this study was to assess and compare the psychometric properties of PEQ-MS and PMQ 2.0, in a sample of 100 Italian lower-limb prosthesis users. Material and Methods We conducted a secondary Rasch analysis of data from a prospective single-group observational study, comparing the PEQ-MS and PMQ 2.0 head-to-head and then co-calibrating them onto a common interval-scaled metric, through common-person equating, to compare their operational range. Results The PMQ 2.0 showed good measurement qualities. The PEQ-MS had acceptable psychometric properties, despite some weakness in item selection. Co-calibration of the two questionnaires indicated that they assess the same underlying construct (prosthetic mobility) but PMQ 2.0 items have a wider range of difficulty (by one logit). Finally, we created a nomogram allowing to ‘cross-walk’ between scores of the two questionnaires. Conclusions Comparison of the two questionnaires showed that the PMQ 2.0 has a better measurement performance and larger operational range than the PEQ-MS, making it more suitable for assessing lower-limb prosthesis users with a large range of locomotor abilities, in particular those with higher mobility levels.

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Suggested Reviewers:	
Opposed Reviewers:	
Manuscript Region of Origin:	ITALY

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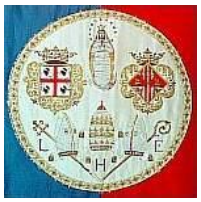

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PROSTHETICS AND ORTHOTICS INTERNATIONAL
Editorial office

February, 2022

Dear Editor,

I hereby submit our paper entitled "*Head-to-head Rasch comparison of the Prosthesis Evaluation Questionnaire-Mobility Section and the Prosthetic Mobility Questionnaire 2.0 in Italian lower-limb prosthesis users*" for your consideration for publication in "Prosthetics and Orthotics International".

The Prosthesis-Evaluation-Questionnaire Mobility Section (PEQ-MS) and Prosthetic Mobility Questionnaire (PMQ 2.0) are two validated self-report questionnaires assessing mobility in people with lower-limb amputation. We compared the psychometric properties of these two questionnaires head-to-head in a sample of 100 lower-limb prosthesis users. Our results show that the PMQ 2.0 has a better measurement performance and larger operational range than the PEQ-MS, making it more suitable for assessing lower-limb prosthesis users with a large range of locomotor abilities. We think that these findings will be of interest to the readers of your journal, in that understanding the psychometric strengths and weaknesses of measurement tools is important for selecting suitable outcome measures, addressing clinical and research issues, and informing healthcare policy decision-making.

I declare that this manuscript is original, has not been published before, and neither the manuscript nor any part of it is currently under consideration or published in another journal.

All authors have read and approved the manuscript and have contributed significantly to the paper; the requirements for authorship have been met and each author believes that the manuscript represents honest work.

No competing interests are at stake, and there is no conflict of interest with other people or organizations that could inappropriately influence or bias the content of the paper.

Given the observational nature of the study, we have included the STROBE checklist.

On behalf of all the co-authors.

Yours sincerely,
Marco Monticone, MD PhD

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Manuscript title:

Head-to-head Rasch comparison of the Prosthesis Evaluation Questionnaire-Mobility Section and the Prosthetic Mobility Questionnaire 2.0 in Italian lower-limb prosthesis users

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Source of Funding:

None.

Conflicts of Interest:

None.

Word count (exclusive of abstract and references): 2433

Number of references: 21

Number of tables: 2

Number of figures: 3

Running head: Rasch comparison of PEQ-MS and PMQ 2.0

Acknowledgments:

The Authors wish to thank all those who took part in the study.

Disclosures:

The Authors declare that this manuscript is original, has not been published before, and neither the manuscript nor any part of it is currently under consideration or published in another journal.

Head-to-head Rasch comparison of the Prosthesis Evaluation Questionnaire-Mobility Section and the Prosthetic Mobility Questionnaire 2.0 in Italian lower-limb prosthesis users

ABSTRACT

Introduction – The Prosthesis-Evaluation-Questionnaire Mobility Section (PEQ-MS) and the Prosthetic Mobility Questionnaire (PMQ 2.0) are two validated self-report questionnaires assessing mobility in people with lower-limb amputation. The aim of this study was to assess and compare the psychometric properties of PEQ-MS and PMQ 2.0, in a sample of 100 Italian lower-limb prosthesis users.

Material and Methods. We conducted a secondary Rasch analysis of data from a prospective single-group observational study, comparing the PEQ-MS and PMQ 2.0 head-to-head and then co-calibrating them onto a common interval-scaled metric, through common-person equating, to compare their operational range.

Results – The PMQ 2.0 showed good measurement qualities. The PEQ-MS had acceptable psychometric properties, despite some weakness in item selection. Co-calibration of the two questionnaires indicated that they assess the same underlying construct (prosthetic mobility) but PMQ 2.0 items have a wider range of difficulty (by one logit). Finally, we created a nomogram allowing to 'cross-walk' between scores of the two questionnaires.

Conclusions - Comparison of the two questionnaires showed that the PMQ 2.0 has a better measurement performance and larger operational range than the PEQ-MS, making it more suitable for assessing lower-limb prosthesis users with a large range of locomotor abilities, in particular those with higher mobility levels.

Keywords: lower-limb amputation**;** outcome assessment; psychometrics; rehabilitation; prosthetic mobility.

INTRODUCTION

Rehabilitation professionals are showing increasing interest today in the psychometric properties of patient-reported outcome measures, to ensure that they monitor accurately the impact of therapeutic interventions (1). The assessment of mobility in people with lower-limb amputation (PwLLA) is no exception to this trend (2), particularly with regard to assessing the effects of prosthetic trials (3,4).

The Mobility Section of the Prosthesis Evaluation Questionnaire (PEQ-MS) was validated through Rasch analysis in 2007 as a tool to assess the perceived mobility capabilities of PwLLA when using their prosthetic device (5). The 12-item PEQ-MS is a subsection of the larger PEQ questionnaire that comprehensively evaluates prosthesis use and prosthesis-related quality of life in PwLLA (6).

In 2015, a study on the PEQ-MS was carried out that modified the wording of two of its items and added two new items of higher difficulty, selected from the modified Lower Extremity Functional Status module of the Orthotics and Prosthetics Users' Survey (7). The aim of the study was to provide a more accurate assessment of lower-limb prosthesis users with high mobility skills. The preliminary 14-item set underwent a Rasch analysis that led to the selection of a parsimonious 12-item set (10 from PEQ-MS plus the 2 new items) with good psychometric qualities, favourably comparing with those of the original PEQ-MS. The new tool was dubbed the Prosthetic Mobility Questionnaire (PMQ) (8).

A subsequent Slovene study confirmed the sound psychometric properties of the PMQ but proposed a further improvement of its metric performance to solve the local dependence between two pairs of items. This new version – PMQ 2.0 (9) – was positively used in other validation studies (10,11). A German team performed a head-to-head Rasch validation of the PMQ 2.0 and the Locomotor Capabilities Index (LCI-5) in PwLLA, confirming the good measurement quality of the PMQ 2.0 and showing that its operational range is more suitable than the LCI-5 for assessing people with advanced locomotor abilities (12).

However, a head-to-head comparison between PMQ 2.0 and its precursor, PEQ-MS, is still lacking. Such analysis would be useful for a more informed choice about which tool is better to use in terms of metric and target group characteristics. Therefore, the aim of this study was, in a sample of Italian lower-limb prosthesis users, to assess the psychometric properties of the PEQ-MS and PMQ 2.0 by Rasch analysis and to compare their operational range, after co-calibration onto a common interval-scaled metric.

METHODS

Participants

We conducted a secondary analysis of data from a prospective single-group observational study (8) with the aim to examine mobility in 100 adults using a modular prosthesis after unilateral lower limb amputation (LLA) at any level. The subjects were consecutive outpatients at a free-standing rehabilitation center. The main exclusion criteria were the presence of cognitive or language function deficits and bilateral LLA. Of 125 individuals who were invited to participate in the study, 18 declined and 7 did not return the questionnaire: the remaining 100 formed the study cohort (8). The study was approved by the local ethics committee (n. 10/2010) and was undertaken in compliance with the Declaration of Helsinki. All participants gave their written informed consent before enrolment and completed all parts of the questionnaires (no missing data).

The study cohort (males, 46%) had a median age of 58 years (interquartile range 48-65). The cause of amputation was peripheral vascular disease and/or diabetes in 71% and trauma in 29%. The level of amputation was above the knee in 58%, and below the knee in 42%. Further details of the sociodemographic and clinical characteristics of participants are available elsewhere (8).

In this study, we considered data coming from both the admission to rehabilitation for prosthetic training and the 6-month follow-up. We randomly selected patients across the two time points in

such a way that each patient figured only once in the dataset and both time points were equally represented. We selected these two time points in order to widen the spectrum of locomotor abilities examined in the study.

Outcome measures

PEQ-MS – This is a 12-item patient-reported outcome measure assessing the ability to perform mobility tasks when using a lower-limb prosthesis (5). It was developed by combining the two mobility scales of the Prosthesis Evaluation Questionnaire (PEQ) (6), an 82-item self-administered tool subdivided into 10 scales that comprehensive evaluate prosthesis use and function and health-related quality of life in PwLLA.

PMQ 2.0 – This is a Rasch-validated self-administered questionnaire that examines different tasks of varying difficulty related to mobility in lower-limb prosthesis users (8,9). The starting point for this tool was the PEQ-MS (5). The wording of two items of the PEQ-MS was modified and two new items of higher difficulty added ('Walk up to two hours' and 'Run one block', selected from the modified Lower Extremity Functional Status module of the Orthotics and Prosthetics Users' Survey) (7). Then, the 14-item set underwent Rasch analysis, after which two PEQ-MS items were deleted - 'Walk on slippery surfaces' (misfitting) and 'Sit down and get up from the toilet' (local dependence). The remaining 12 items form the PMQ 2.0. All 12 items are scored but in PMQ 2.0 the total score is calculated on 10 of them, using only the worst performance in two pairs of locally-dependent items representing the same task performed in opposite directions ('Walk upstairs' and 'Walk downstairs'; 'Walk up a steep hill' and 'Walk down a steep hill') (9).

In both PEQ-MS and PMQ 2.0, individuals are asked to rate their mobility skills using a 5-level rating scale (0= unable; 1= high difficulty; 2= moderate difficulty; 3= little difficulty; 4= no problems). Thus, higher scores indicate greater prosthetic mobility. Raw scores range from 0 to 48 in

PEQ-MS and from 0 to 40 in PMQ 2.0. Patients were administered the validated Italian versions of the PEQ-MS (5) and PMQ 2.0 (8).

Statistical analysis

Rasch analysis was performed using Winsteps® software v. 4.8.0 (Winsteps.com, Beaverton, OR, USA), adopting the partial credit model for both scales (13). An introduction to Rasch analysis and related measurement concepts is available in dedicated textbooks (14,15).

Initially, the two questionnaires were separately assessed according to the following multi-stage approach (the analysis was rerun each time a modification was made, in an iterative process).

First, the correct functioning of rating scale categories was assessed verifying the ordered set of response thresholds for each item (a threshold being the transition point between adjacent categories) (16). Then, we performed a principal component analysis on the standardized residuals (PCAr) to investigate: i) the scale's unidimensionality, calculating the unexplained variance after extracting the main construct that the scale intended to measure (the so-called Rasch factor). Additional factors are likely to be present if the eigenvalue of the first residual factor (first contrast) is >2.0 (15); ii) the local independence of the items. Any residual correlation for 2 items >0.30 above the average observed residual correlation is considered as an indicator of potential local dependence (17,18).

The internal construct validity of the scale was assessed by checking how well data fit the Rasch model in terms of goodness-of-fit. Chi-square fit statistics (expressed as infit and outfit mean-square statistics, MnSq; expectation 1, range 0 to infinity) were calculated for each item in each scale. Considering our sample size, we defined acceptable fit as mean-square values from 0.7 to 1.3 (19), associated with standardized z values (ZStd) less than 2.0 (14,15). Items with larger fit values were considered underfitting (i.e. showing responses more erratic than expected by the Rasch model), while items with smaller values were considered overfitting (i.e. showing a too predictable pattern of responses) (14). Reliability was assessed in terms of the separation reliability, indicating the degree of replicability of the estimates across other samples (coefficients >0.80 are considered good) (15).

After these analyses, the two scales were co-calibrated onto a common interval-scaled metric, using the common-person equating method (13,14). The person-item map thus formed allowed a quick comparison between the distribution of the (common) person parameter estimates and that of the item difficulty calibrations for each of the two scales.

A sample size of 100 participants was deemed sufficient to allow a stable calibration of item difficulty within ±0.5 logits with 95% confidence (19).

RESULTS

The mean PEQ-MS score was 21.3 (standard deviation, SD: 8.1), while that of the PMQ 2.0 was 15.8 (SD: 6,1). The main Rasch analysis results were as follows. The performance of the five response options of both scales complied with the pre-set criterion for appropriate functioning: there were no disordered thresholds. Table 1 reports for each scale: i) the person ability (i.e. perceived prosthetic mobility level) and item difficulty levels; ii) reliability indices; iii) the variance explained by the Rasch factor and the eigenvalue of the first residual factor. Table 2 shows the goodness-of-fit results for each item of PEQ-MS and PMQ 2.0. All items fit the Rasch model, except PEQ-MS item #8 'Walk on slippery surfaces' (Infit MnSq 1.48 with ZStd 3.01; Outfit MnSq 1.45 with ZStd 2.70). In addition, the residual correlation between items #11 'Sit down and get up from a low, soft chair' and #12 'Sit down and get up from the toilet' was 0.30 above the average residual correlation.

Figure 1 plots the correlation between the two scales (logit measures), obtained through common-person equating. The trend line of our sample was parallel to the identity line and all person ability estimates lay within the 95% confidence intervals (the two external dotted lines), indicating that the two scales were assessing the same underlying construct (prosthetic mobility) in a statistically equivalent way. Based on the common-person equating results, we constructed a Wright map co-calibrating the PEQ-MS and PMQ 2.0 items (Figure 2), which it showed the PMQ 2.0 items to have a wider range of difficulty (by one logit). In addition, we created a nomogram allowing one to

calculate the global raw score of one scale from the other, and from it estimate the corresponding ability level of the subject (Figure 3).

DISCUSSION

A careful scrutiny of the measurement assumptions and properties of an outcome tool by means of advanced psychometric methods represents a key step in determining if the scores it provides are meaningful in clinical practice and research (14,20). Rasch analysis is an authoritative method for testing if the properties of a questionnaire comply with several psychometric requirements that classical test theory techniques do not analyze (15). In addition, the Rasch co-calibration procedure enables the data coming from the two scales (which share several items) to be analyzed together and easily compared.

Our examination of the psychometric characteristics of the PEQ-MS and PMQ 2.0 (two self-report questionnaires measuring mobility in people with LLA wearing a prosthesis) showed that both scales performed reasonably well in our sample from a psychometric point of view. Data related to all items of both scales were consistent with the Rasch model expectations, except for the item 'Walk on slippery surfaces' in PEQ-MS. The perceived ability related to this task is subject to personal and environmental factors, and thus some individuals may respond in an idiosyncratic way. However, according to Linacre's criteria (13), the item is still able to provide productive information for measurement in PEQ-MS. The unexpectedly high variability of responses we found to this item had already emerged in our previous study (8). There, the statistical analysis was carried out on both admission and follow-up data (100 patients × 2 times), while in the present analysis a random sample of 100 patients was selected so that each patient figured only once in the data-set, and both time points were equally represented.

Further evidence of the internal construct validity of both questionnaires was the hierarchical arrangement we obtained by Rasch item calibration, which was in line with clinical expectations and results of previous studies (6,8,9,12). The two easiest items (common to both scales) were 'walking indoors' and 'walking in a confined space', while the most difficult items were those assessing sustained walking ('walk 2 hours'), and running ability ('run one block') in PMQ 2.0, and that examining 'walk on slippery surfaces' in PEQ-MS.

Also the local dependence we found between item #11 'Sit down and get up from a low, soft chair' and #12 'Sit down and get up from the toilet' of the PEQ-MS was quite predictable (the two tasks require a similar change of position) and replicated the finding of the previous paper on this outcome measure (5). In our study, we considered this violation of the Rasch assumptions as borderline and negligible for our ongoing analyses (the shared variance being about 10%). However, one should bear in mind that the partial redundancy of information provided by these two items (response dependence) could have influenced –although to a limited extent– item location parameters and increased the reliability indexes of PEQ-MS (16).

The results of the co-calibration of the two scales onto a single interval-scaled metric, using the common-person equating method (15), provides a clear visual comparison of the item difficulty calibrations between each scale, as shown in Figure 2. As expected, the range of PMQ 2.0 items is wider (by one logit) than those in PEQ-MS, due to the presence in the former of the two items hardest to endorse: 'walk two hours' and 'run one block'. This means that the PMQ 2.0 appears more appropriate for assessing individuals with high locomotor performance (e.g. young persons with trauma-related lower limb amputation). At the same time, the procedure confirmed that the two questionnaires measure the same construct and yield scores that can be compared thanks to the conversion nomogram in Figure 3.

Care should be taken in interpreting our data. The study investigated middle-aged adults with unilateral lower limb amputation and a low-to-medium level of locomotor abilities. Thus, it is uncertain whether the results can be generalized to individuals with different clinical characteristics. Nevertheless, our participants seem reasonably representative of adults after lower-limb amputation, in terms of sex distribution, motor performance, amputation causes and level. Moreover, our findings are in line with other studies using the same instruments, but carried out in different contexts (5,9,10,12).

In summary, this Rasch study demonstrated the good measurement quality of the PMQ 2.0, in line with other studies performed using Italian (8), Slovene (9-11) and German (12) versions. It also confirmed acceptable psychometric properties of the PEQ-MS (5,21), despite some weakness in its item selection. Overall, this head-to-head comparison of the two questionnaires provides further evidence pointing to the PMQ 2.0 as the better tool in terms of measurement performance and larger operational range, and more suitable than the PEQ-MS for assessing lower-limb prosthesis users with a large range of locomotor abilities, in particular with higher mobility levels.

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Figure captions

Figure 1 – Results of the common-person equating procedure between Prosthetic Mobility Questionnaire (PMQ 2.0, x axis) and Prosthesis Evaluation Questionnaire-Mobility Section (PEQ-MS, y axis) (Measures, in logits). The dashed line indicates the identity line, the solid line the "best fit" trend line of our sample. The two lines are parallel and the trend line is about -0.5 logits to the left of the identity line.

Figure 2 – The so-called Wright map, showing estimates of patient-ability and item-difficulty (expressed in logit units, in the leftmost column) based on the results of the common-person equating procedure. Zero logits represents the mean item difficulty, while positive values indicate higher difficulty for that item.

Figure 3 – Nomogram for PEQ-MS and PMQ 2.0, designed to rapidly calculate the global raw score of one scale based on the other, as well as estimate the corresponding ability level (expressed in logit units) of an individual with that score.

Figure 1

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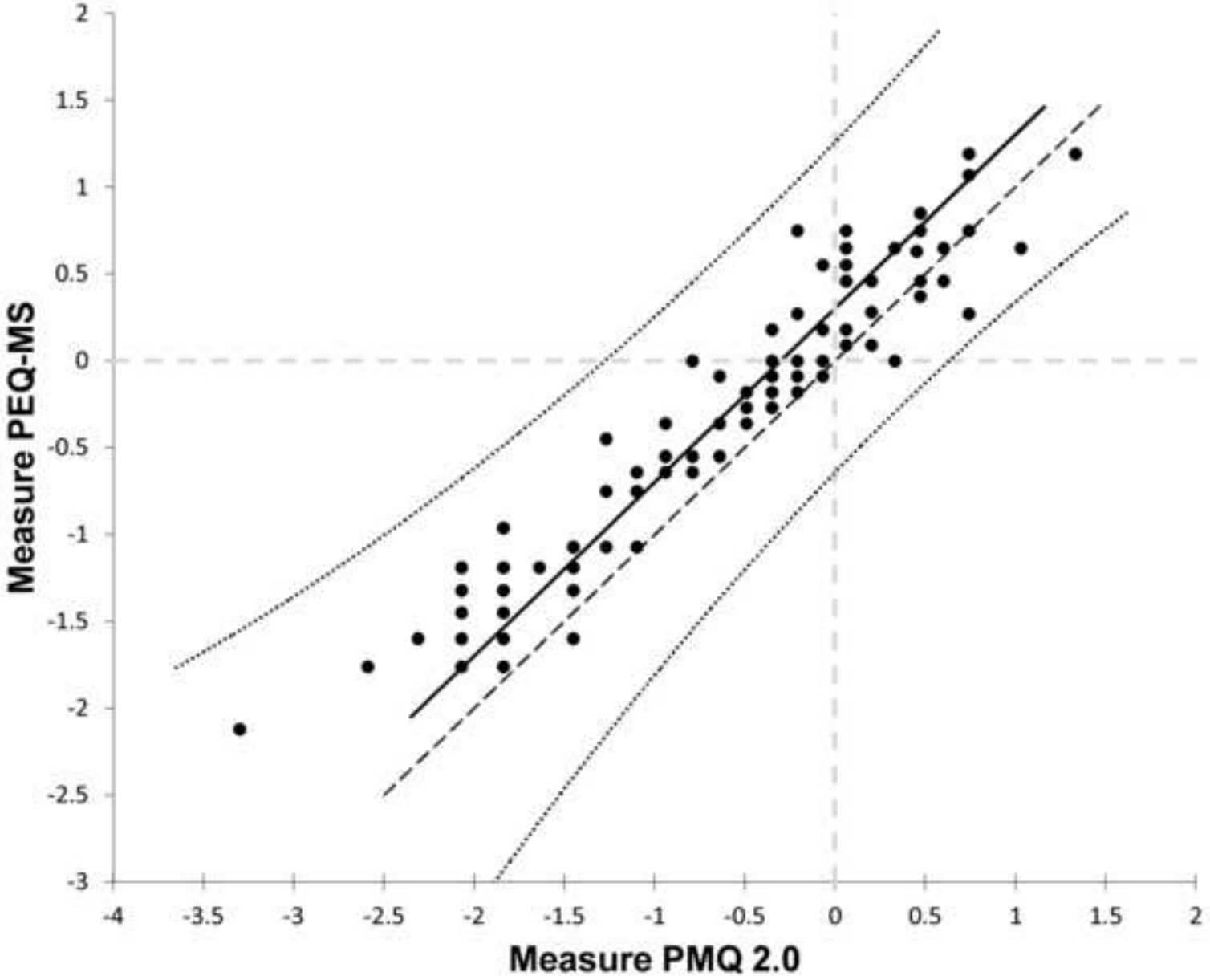

Figure 2

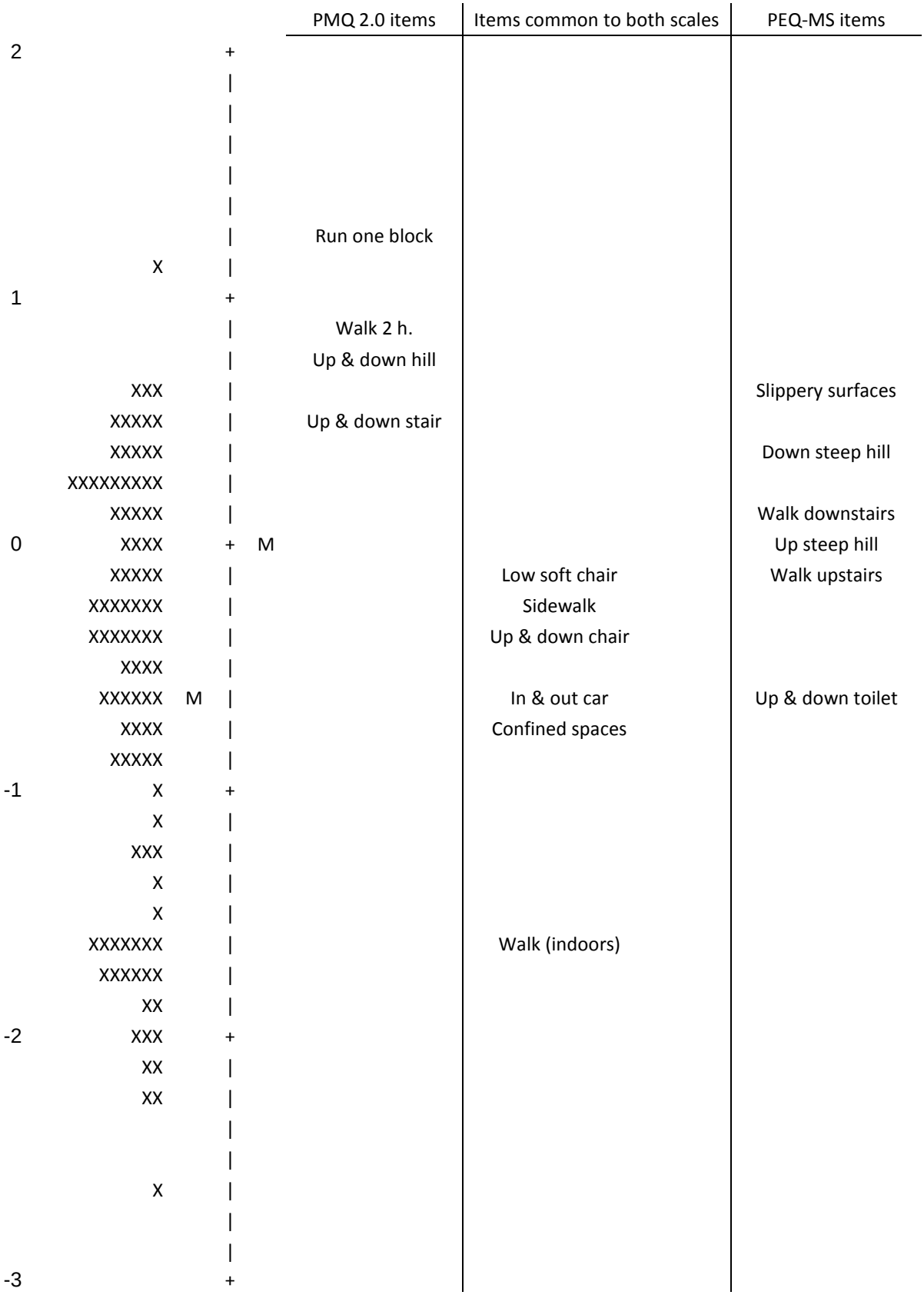
PMQ 2.0 items
Items common to both scales
PEQ-MS items
2
1
0
-1
-2
-3
Run one block
Walk 2 h.
Up & down hill
Up & down stair
Low soft chair
Sidewalk
Up & down chair
In & out car
Confined spaces
Walk (indoors)
Slippery surfaces
Down steep hill
Walk downstairs
Up steep hill
Walk upstairs
Up & down toilet
M

Figure 3

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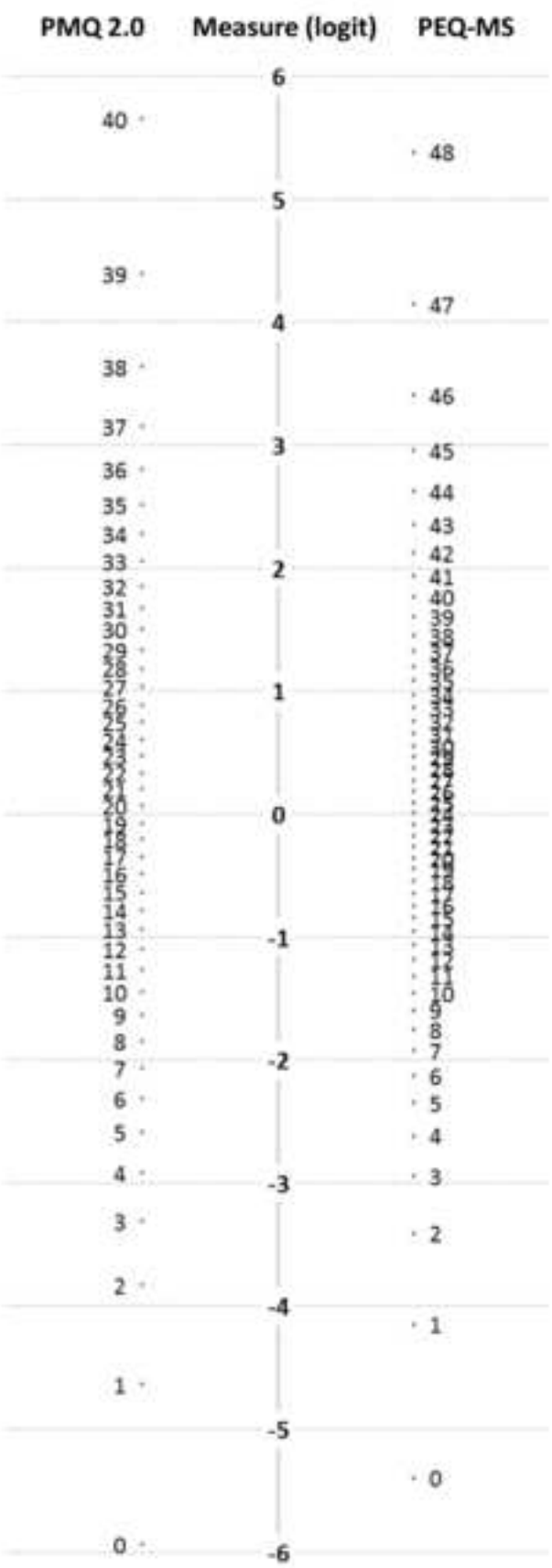

Table 1 – Person locomotor ability and item difficulty levels, reliability indices, and Rasch dimensionality (according to principal component analysis of the standardized residuals) of PEQ-MS and PMQ 2.0, calculated with separate analysis on the same population (n=100).

	PEQ-MS	**PMQ 2.0**
Person ability, mean (and range)	-0.29 (-2.12 to 1.19)	-0.63 (-3.30 to 1.32)
Item difficulty calibration, range	-1.36 to 0.92	-1.88 to 1.47
Person separation reliability	0.81	0.79
Cronbach's alpha	0.83	0.80
Item separation reliability	0.95	0.98
Variance explained by the Rasch factor	43.9%	54.1%
Eigenvalue of the first residual factor	2.0	1.6

Table 2- Results of Rasch goodness-of-fit analysis for each item of PEQ-MS and PMQ 2.0, regarding infit and outfit mean square (MnSq) and z standardized statistics (ZStd).

PEQ-MS			**PMQ 2.0**		
Item number and label	**Infit MnSq (ZStd)**	**Outfit MnSq (ZStd)**	**Item number and label**	**Infit MnSq (ZStd)**	**Outfit MnSq (ZStd)**
1. Walk	0.73 (-2.05)	0.77 (-1.66)	1. Walk indoors	0.86 (-1.03)	0.87 (-0.91)
2. Walk in confined spaces	1.15 (1.13)	1.16 (1.18)	2. Walk in confined spaces	1.23 (1.66)	1.21 (1.54)
3. Walk upstairs	0.93 (-0.52)	0.94 (-0.44)	3. Walk upstairs / 4. Walk downstairs	0.86 (-0.97)	0.82 (-1.29)
4. Walk downstairs	1.03 (0.28)	1.07 (0.52)			
5. Walk up a steep hill	1.22 (1.59)	1.19 (1.38)	5. Walk up a steep hill / 6. Walk down a steep hill	0.97 (-0.14)	0.91 (-0.56)
6. Walk down a steep hill	0.84 (-1.19)	0.79 (-1.53)			
7. Walk on sidewalks and streets	0.93 (-0.50)	0.92 (-0.56)	7. Walk on sidewalks and streets	0.97 (-0.18)	0.98 (-0.09)
8. To walk on slippery surfaces	**1.48 (3.01)**	**1.45 (2.70)**	//		
9. Get in and out of a car	0.89 (-0.82)	0.90 (-0.73)	8. Get in and out of a car	1.03 (0.27)	1.02 (0.22)
10. To sit down and get up from a chair with a high seat	0.76 (-2.0)	0.79 (-1.69)	9. Sit down and get up from a common chair w/o armrests	0.93 (-0.48)	0.97 (-0.18)
11. Sit down & get up from a low soft chair	0.98 (-0.09)	0.95 (-0.38)	10. Sit down & get up from a low soft chair	1.10 (0.75)	1.06 (0.49)
12. To sit down and get up from the toilet of regular height (no aids)	1.10 (0.77)	1.09 (0.74)	//		
//			11. Walk up to two hours	1.08 (0.57)	1.17 (1.11)
//			12. Run one block	0.96 (-0.19)	0.90 (-0.54)

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

	Item No	Recommendation	Pag
Title and abstract	1	(*a*) Indicate the study's design with a commonly used term in the title or the abstract	1
		(*b*) Provide in the abstract an informative and balanced summary of what was done and what was found	1
Introduction			
Background/rationale	2	Explain the scientific background and rationale for the investigation being reported	2-3
Objectives	3	State specific objectives, including any pre-specified hypotheses	3
Methods			
Study design	4	Present key elements of study design early in the paper	3
Setting	5	Describe the setting, locations, and relevant dates, including periods of recruitment, exposure, follow-up, and data collection	3
Participants	6	*Cohort study*—Give the eligibility criteria, and the sources and methods of selection of participants	3
Variables	7	Clearly define all outcomes, exposures, predictors, potential confounders, and effect modifiers. Give diagnostic criteria, if applicable	3-5
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	3-5
Bias	9	Describe any efforts to address potential sources of bias	5-6
Study size	10	Explain how the study size was arrived at	5-6
Quantitative variables	11	Explain how quantitative variables were handled in the analyses. If applicable, describe which groupings were chosen and why	5-6
Statisticalmethods	12	(*a*) Describe all statistical methods, including those used to control for confounding	5-6
		(*b*) Describe any methods used to examine subgroups and interactions	n.a.
		(*c*) Explain how missing data were addressed	n.a.
		(*d*) *Cross-sectional study*—If applicable, describe analytical methods taking account of sampling strategy	n.a.
		(*e*) Describe any sensitivity analyses	n.a.

Continued on next page

Results			**Pag**
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	3
		(b) Give reasons for non-participation at each stage	3
		(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	3
		(b) Indicate number of participants with missing data for each variable of interest	3
Outcome data	15*	Cohort study—Report numbers of outcome events or summary measures over time	n.a.
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	6-7
		(*b*) Report category boundaries when continuous variables were categorized	n.a.
		(*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	7
Discussion			
Key results	18	Summarise key results with reference to study objectives	7-9
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	9
Interpretation	20	Give a cautious overall interpretation of results considering objectives, limitations, multiplicity of analyses, results from similar studies, and other relevant evidence	7-9
Generalisability	21	Discuss the generalisability (external validity) of the study results	9
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	None