RESEARCH ARTICLE

Conceptualization and Development of the Leg Activity Measure (LegA) for Patient and Carer Reported Assessment of Activity in the Paretic Leg

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Abstract

Background and Purpose. The purpose of the paper is to develop a patient-reported outcome measure of active and passive function in the paretic lower limb with associated spasticity. Methods. Potential items for inclusion were identified through (1) systematic review and analysis of existing measures and (2) analysis of the primary goals for treatment in a spasticity service. Ethical approval for re-evaluation of routinely collected data was received. Item reduction was achieved through consultation with a purposively selected group of experienced physiotherapists and occupational therapists (n = 16) in a two-round Delphi process. This was followed by a review of Delphi consultation findings by the Project Advisory Group consisting of patients and carers. Results. Development of the leg activity measure (LegA) included two rounds of Delphi consultation, which resulted in a high degree of agreement (80% in round 2) between respondents in rounds 1 and 2. From an initial shortlist of 126 items, 29 items were initially identified for inclusion in LegA and subsequently refined to a 24-item (two sub-scales) tool consisting of nine passive function and 15 active function items. Discussion. The Delphi consultation with clinicians experienced in this area of practice ensured content validity and appropriate reduction of items. In common with previous work in the upper limb, a 5-point ordinal scaling structure was chosen, with ratings based on activity over the preceding 7 days. The LegA is designed to measure passive and active function following focal interventions associated with spasticity in the lower limb. Content and face validity have initially been addressed within the development process. The next phase of development will involve formal evaluation of psychometric properties. Copyright © 2016 John Wiley & Sons, Ltd.

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Keywords

outcome measurement; outcome measures; stroke; traumatic brain injury

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Implications for Physiotherapy Practice

• This study describes the systematic development of the leg activity measure (LegA), the first measure of active and passive function in the paretic lower limb with associated spasticity.

• The LegA demonstrated face and content validity.

• The LegA is theoretically appropriate for clinical application and is undergoing psychometric testing to demonstrate this.
Introduction

In patients with acquired brain injury such as stroke or head injury, or other long-term neurological conditions such as multiple sclerosis, lower-limb spasticity (involuntary over-activity of muscle) can cause a diverse range of problems. Its prevalence varies but has been reported in 19–38% of patients after stroke (Watkins et al., 2002; Sommerfeld et al., 2004), and it has been highlighted as having a negative effect on both patients’ functional abilities, and on the ease with which others can care for them (Royal College Of Physicians, National Council For Palliative Care, and British Society Of Rehabilitation Medicine, 2008).

Goals for the rehabilitation of patients with lower-limb spasticity may therefore be to restore active function, for example, balance, walking speed and gait pattern/quality, if there is return of motor control, or to improve passive function and make it easier to care for the limb, for example, maintaining perineal hygiene or assisting with dressing (Moore et al., 2008), if no return of motor control is likely (Shean, 2001). A comprehensive outcome measure therefore needs to assess both active and passive function to fully reflect the changes seen following therapeutic interventions (Shaw et al., 2010). The goals for treatment are therefore highly diverse but are mostly contained within the domains of active and passive function.

Interventions to manage lower-limb spasticity are similarly complex and diverse. They include various combinations of medical treatments (systemic medications or botulinum toxin injections to relax muscles) and physical treatments (e.g. stretching, splinting, muscle strengthening, exercise etc.). In order to establish what types of intervention are most effective and cost-efficient for which patients, we need to record both inputs (the type and amount of physiotherapy or other physical interventions) and outcomes (functional and other benefits for patients).

The importance of measuring the impact of treatments on functional activity from the perspective of patients and their carers has been emphasized in Department of Health Guidance on the routine collection of patient-reported outcome measures (PROMs). Tools used in clinical practice need to be feasible for use in busy clinical settings and reflect performance in the real-life context as closely as possible. PROMs reflect what patients actually do in their normal environment. They therefore have advantages over clinic-based tools. For example, although tools such as the 10-m walk test reflect a patients’ capacity to walk 10 m, they may not reflect what that individual actually does outside test conditions. However, there is currently no comprehensive instrument to measure function in the context of the spastic lower limb, which may range from passive caring for the limb in severely disabled patients to using the limb for active mobility in more able patients.

In previous work, we have developed a measure of upper limb passive and active function, the arm activity (ArmA) measure (Ashford et al., 2014b; Ashford et al., 2013a; Ashford et al., 2013b; Ashford and Turner-Stokes, 2013). The ArmA was developed to evaluate outcome following upper limb rehabilitation interventions with a particular focus on spasticity. The current project was set up to develop and test an equivalent patient-reported measure, the leg activity measure (LegA), for evaluating lower-limb function, particularly following focal spasticity intervention.

The objectives were as follows:

1. To develop the LegA: a self-report measure for the assessment of both active and passive function in the paretic lower limb before and after rehabilitation interventions (including spasticity management) and
2. To evaluate initial face and content validity by investigating item relevance for professionals, patients and carers.

Method

Development of the LegA comprised a multistage process incorporating the following:

1. Item identification from a systematic review of lower-limb functional assessment tools (Ashford et al., 2014a).
2. A retrospective review of goals set for rehabilitation input, including focal spasticity intervention with botulinum toxin.
3. Duplicate items were then removed, and the remaining items were then presented to specialist clinicians through a two-round Delphi consultation process.

The project team included a Project Advisory Group (PAG) consisting of patients and carers with relevant experience, who were consulted on the findings from the Delphi process. See Figure 1 for the stages of LegA development.

Ethical approval for re-evaluation of routinely collected data was granted by Harrow Research Ethics Committee (REC 04/Q0405/81). Confirmation that National Health Service (NHS) UK Research Ethics Approval was not
required for the Delphi consultation with professionals was received.

**Systematic review item classification**

The systematic review was performed by the authors in three stages, according to the methodology described previously (Ashford et al., 2008). The review methodology, specific to this review, has been published and registered on the international database of prospectively registered systematic reviews in health and social care (PROSPERO) registry (CRD42013005046), Centre for Reviews and Dissemination, University of York. The Preferred Reporting Items for Systematic Reviews and Meta-Analyses principles were used in the systematic review (Moher et al., 2009).
Measure selection criteria were as follows: (1) application of the PROM in acquired brain injury (including stroke and traumatic brain injury). The stage 1 systematic search was used to identify measures applied in this area of practice. Studies were therefore not excluded on the basis of methodological design. (2) Measures were retained at stage 3 provided they addressed psychometric properties included in the COnsensus-based Standards for the selection of health Measurement INstruments (COSMIN) criteria (Mokkink et al. 2010). Psychometric evaluation using COSMIN was undertaken on all the retained measures. Passive function items were not identified in the systematic review. Its full methods and findings have been published (Ashford et al., 2014a).

All items identified in measures meeting the final selection criteria for the systematic review were considered for inclusion. Equivalent active function items identified across different measurement tools were grouped together for consideration. This replicated the method used for items identified in the goals analysis.

Goals analysis

The retrospective goals analysis had two aims, firstly, identification of new items relating to passive and active function by the patients and carers who had participated in setting the goals and secondly, confirmation and supporting identification of items from the systematic review for potential inclusion in the new measure. The methodology was based on work carried out by Ashford et al. (2015) using clinically set patient goals for PROM development.

Participants and setting

To capture a broad range of patient experience, the intervention and goal setting took place within a specialist hyper-acute/sub-acute rehabilitation service and related a specialist community service for patients with acquired brain injury and other complex neurological conditions. A total of 165 patients received spasticity intervention between 1 January 2009 and 1 January 2013. Of those treated with spasticity management intervention, 62 were specifically for lower-limb spasticity and were used in this analysis.

Procedure

Goals relating to passive and active function were set during spasticity management intervention using botulinum toxin injection and physical therapy treatments. The goal attainment scaling method was used. This scores the extent to which a patient’s individual goals are achieved in the course of intervention, so that diverse outcomes may be captured by a single system. Originally described by Kiresuk and Sherman (1968) in the 1960s, goal attainment scaling has been used in many areas of practice that warrant an individualized approach to outcome evaluation including rehabilitation (Hurn et al., 2006; Turner-Stokes et al., 2009a). It is increasingly used as a person-centred outcome measure in research evaluations of outcome following spasticity intervention (Ashford and Turner-Stokes, 2006; McCrory et al., 2009; Borg et al., 2011; Turner-Stokes et al., 2013; Turner-Stokes et al., 2013) and is recommended as a method of recording patient-reported outcomes in guidelines for management of spasticity with botulinum toxin (Royal College Of Physicians, British Society Of Rehabilitation Medicine, Chartered Society Of Physiotherapy, and Association Of Chartered Physiotherapist Interested In Neurology, 2009).

All goals are entered into the database of routinely collected clinical data alongside intervention data. Goal statements were extracted from this database, classified and mapped onto the World Health Organisation International Classification of Functioning (ICF) codes (Moriello et al., 2008; Roorda et al., 2005; WHO, 2002), after the method applied by Turner-Stokes (Turner-Stokes et al., 2013).

Delphi consultation

Item selection and reduction were conducted in a two-round Delphi consultation process with a group of purposely selected expert clinicians (Figure 1) in order to establish face and content validity for the LegA. Face validity is important because

1. it increases cooperation and motivation among respondents,
2. attracts respondents,
3. reduces dissatisfaction among respondents and
4. makes it more likely that policy-makers and funders will accept findings

(Nevo 1985).

A closely related concept to face validity is content validity, which establishes that the instrument covers all the relevant concepts or domains (Streiner and Norman 2003).
Participants and setting
The purposive sample comprised expert clinicians who were physiotherapists or occupational therapists working in neurorehabilitation units across England that operated specialist services offering spasticity management and botulinum toxin injection with concurrent therapy intervention. They were identified from the 'UK Adult Spasticity Forum', the 'UK Physiotherapy Injectors in Spasticity' and from the contacts of these professionals. Inclusion criteria were as follows:

- Active involvement in specialist spasticity management services or clinics providing intervention (for physiotherapists, this included prescription and/or injection of botulinum toxin).
- Providing concurrent therapy or physical interventions and evaluating outcome.
- To have been undertaking clinical practice in this area for a minimum of 2 years.

All clinicians were experienced in rehabilitation practice in general and were senior clinicians.

An initial 39 clinicians were approached, and 21 agreed to participate and were recruited to the study. However, five clinicians did not respond to the first round of consultation and were then excluded. The remaining 16 clinicians participated in both rounds of consultation.

Procedure
Delphi consultation round 1
Categorisation of items from the systematic review and goals analysis was confirmed with Delphi participants in round 1. The consultation exercise then required respondents to judge the importance of possible items for inclusion in a PROM of leg function, for use following lower-limb rehabilitation incorporating spasticity intervention (including botulinum toxin administration). The items were presented in two separate sections of active function and passive function.

Respondents were then asked to

1. rank the frequency the item was addressed as a goal in rehabilitation intervention;
2. rank the difficulty of the item (for patient achievement) and
3. list any items that were not already included that they considered to be of particular importance, explaining their reasons for inclusion.

After the comments had been returned, and participants contacted if necessary to clarify any points, the initial list of items was revised, and a short list of items was produced for round 2.

Delphi consultation round 2
The short list was returned to the same experts for further comment and verification, again asking them to identify items for inclusion and exclusion with stated reasons.

Item confirmation through Project Advisory Group consultation
Patient members of the PAG had all

- suffered an acquired brain injury (traumatic brain injury or stroke),
- gone through an inpatient rehabilitation programme followed by community input and
- had treatment for spasticity.

The associated carer members of the PAG also had experience of these settings and spasticity intervention from their own perspective.

Project Advisory Group members were asked to review the Delphi consultation results for their clarity, relevance, completeness and ease of scoring. Four patient and carer dyads participated in the consultation meeting and commented on the findings. They were given the questions that Delphi participants had been presented with and asked to comment on:

1. deficiencies in the process,
2. any items that had been missed and not considered and
3. any items that had been included that they felt were not justified and should not be.

Responses from the PAG were then discussed with the lead researcher (SA), and solutions or additions were identified.

Pilot testing
The LegA was then pilot tested to confirm its initial feasibility for routine clinical application with individuals undergoing focal spasticity intervention, including botulinum toxin administration and physical interventions.
Participants and setting

Participants all had an acquired brain injury and were receiving spasticity management, including botulinum toxin injection and physical therapy treatments. They were either inpatients within a specialist hyper-acute rehabilitation service or were receiving neurological rehabilitation from community services.

Procedure

Patients completed the draft LegA prior to intervention for spasticity. They were asked to complete the tool, either individually, or with their carer if passive function involved both patient and carer. Following completion of both sub-scales, they were asked to rate how long completion took (under 5, 5–10, 11–15, 16–20 or over 20 min), and how relevant the questionnaire was to them (very, relevant, moderately, little or not relevant). Finally, they were asked how easy the questionnaire was to complete (very, easy, moderate, difficult or very difficult).

Five participants repeated the LegA after spasticity intervention including botulinum toxin administration and physical interventions. These participants were reviewed from 6 to 8 weeks post-botulinum toxin injection.

The scale structure for the LegA is taken from that used in the previously developed ArmA and also used in other patient-reported tools (Figure 2). The application of the same scale presentation maintains consistency with other similar tools. Participants were asked to indicate if they found the completion of the scale specifically problematic in any way.

Results

Goals analysis

The records of 62 patients were included, of these, 44 had a diagnosis of acquired brain injury (traumatic, hypoxic or stroke), five were spinal cord injury (all traumatic) and 13 were multiple sclerosis (progressive condition). The mean age for patients seen through this service between 1 January 2009 and 1 January 2013 was 56 (SD 16.7). In the analysis, 125 goals were identified from the 62 patients who had all received focal spasticity intervention, and six distinct categories of goal were identified. The categories identified were as follows: pain, involuntary movement, range of movement, mobility, passive function and active function as shown in Table 1.

Identified goals ‘mapped’ to ICF codes are presented in Table 2.

Systematic review item classification

The systematic review initially identified 111 possible active function items, taken from seven measurement tools. These initial items were then collapsed into categories representing the same function (with duplicate items also removed) resulting in 16 possible new items.

The resultant list of active function items and their representation in the systematic review identified pre-existing PROMs is presented in Table 3.

Delphi consultation

Round 1 Delphi consultation resulted in an initial selection of measurement items within the domains of active and passive function only as per the study aims. There was no disagreement with the categorisation of passive or active function items taken from the goals analysis and systematic review. Table 4 shows the initial items selected after round 1 of consultation.

Table 4 presents the rank frequency with which an item had been addressed or set as an intervention goal in practice by respondents, and the rank ‘difficulty’ of the item for patients to perform.

In Table 5, the items removed are marked with *, and those added from round 1 are indicated in ‘bold’. Four items were removed in round 2 Delphi consultation; these were the following: ‘cleaning the foot’, ‘cutting toenails’, ‘catheterisation’ and ‘spasms impacting on comfort or sleep’. A minimum of 13 respondents (80%) recommended removal of each of these items. The items ‘positioning the legs’ and ‘bed positioning’ were combined into a single item. Given the consistency of respondents’ responses and the consensus identified, further rounds of consultation were not undertaken. All items included in LegA were from the activity and participation domain of the ICF.

Project Advisory Group consultation

The results of the Delphi consultation were reported to the PAG, consisting of four patient and carer dyads. No changes to items were suggested, but some comments were made on question wording that were then included in the final list of items (Figure 2).

They included suggestions for wording questions in a manner more easily understood by patients and carers.
Difficulty for each item is scored over the preceding 7 days as follows:

0 = no difficulty
1 = mild
2 = moderate
3 = severe difficulty
4 = Unable to do activity

Section A

1. Cleaning and washing the area between your legs
2. Putting on a splint (If never done circle 0)
3. Positioning legs in a wheelchair (If never done circle 0)
4. Putting your leg(s) through a trouser leg(s) (If never done circle 0)
5. Transfer using a hoist, including positioning sling
   (If never done circle 0)
6. Putting on underwear or continence pads
7. Positioning your leg(s) in bed using a positioning aid or
   pillow (If never done circle 0)
8. Cleaning behind your knee (knees)
9. Putting on your footwear

Section B

1. Turning in bed
2. Moving from lying to sitting
3. Being able to sit (including balance)
4. Transferring from bed to chair or wheelchair
5. Transferring from wheelchair to car
6. Moving from sitting to standing (including balance)
7. Standing (including balance)
8. Walking indoors (including balance)
9. Turning around (including balance)
10. Walking up stairs
11. Walking around obstacles or objects (including balance)
12. Walking over carpet
13. Walking outdoors
14. Walking over rough or uneven ground outdoors
15. Walking for half a mile or more

- The LegA tool is available from: http://www.csi.kcl.ac.uk/tools.html

Figure 2. Leg activity measure items
For example, the question about perineal hygiene was modified to ‘cleaning and washing the area between your legs’. It is anticipated that these small modifications to the wording and presentation of questions will aid consistency of responses when undertaking the psychometric evaluation of the measure.

Involvement of patients and carers in the PAG played an important part in measure development and was highly valued, as expressed by one member: ‘Having participated in a pilot for the Leg Activity measure, I have observed how straightforward, simple and seamless it was to contribute to as a patient with experience. I am convinced this pioneering measurement will provide an important development in the consistent assessment of spastic lower limbs; it will have a valuable impact on guidance in respect of rehabilitation input, thus improving function in daily life.’

**Pilot testing**

The final version of LegA was pilot tested by 16 patients and their carers, undergoing rehabilitation intervention for lower limb activity limitations requiring spasticity management. Passive function sub-scale scores ranged from 1 to 23 (sub-scale range 0 to 36), and active function scores ranged from 11 to 60 (sub-scale range 0 to 60). No ceiling or floor effects were identified in the passive function sub-scale. Floor effects were not identified
in the active function sub-scale, but ceiling effects were. The ceiling effect (representing task difficulty) reflects the significant functional impairment of some patients included in the pilot group, some of whom were unable to perform any active function (i.e. wheelchair and hoist transfer dependent). Five patients had repeated measurement after intervention and showed changes on both sub-scales.

All participants \( (n = 16) \) were able to complete the LegA in under 15 min. In rating the relevance of LegA to them, 14 rated it as ‘very relevant’ or ‘moderately relevant’ to them (one ‘little relevance’ and one missing). When asked how easy it was to complete, all participants rated LegA as ‘very easy’ to ‘moderately easy’. No problems were identified by participants with the scale structure applied to completion of LegA.

### Discussion

This project and process of development built on our previous and ongoing work in developing a patient reported measure ArmA for evaluating spasticity intervention in the upper limb (Ashford et al. 2013; Ashford et al. 2013c; Ashford and Turner-Stokes 2013d; Ashford et al. 2014). The model of development for ArmA was modified to develop the LegA. Delphi consultation was used again for LegA development because of its strengths in utilizing experts in an unbiased manner throughout the entire process of development (Hsu and Sandford, 2007). Finger et al. (2006) consider the Delphi method to have four key characteristics: anonymity for those participating, iteration of concepts, statistical group response based on frequency of selections (in this instance, item selection) and informed input from expert participants. These characteristics are particularly relevant in using expert clinicians to develop a measure of functional outcome.

The development of the LegA included two rounds of Delphi consultation. Further rounds of consultation were not required because of the high degree of agreement between respondents in rounds 1 and 2. The Delphi consultation ensured content validity, due to the experience of the clinicians in this area of practice and therefore appropriate reduction of items. This was in addition to the initial process of item selection and input in the process of development and review of findings by the PAG. Face validity was addressed through selection of goal-based items by patients and carers, Delphi consultation with clinicians and confirmed by the review of patient and carer members of the PAG.

Delphi consultation has advantages in providing anonymity to participants and reducing personality-based influences such as the impact of socially dominant individuals on the consensus process (Burns et al., 2003; Finger et al., 2006). The literature provides no definitive recommendation on panel size, which have ranged greatly in different studies between 10 and 1685 (Reid, 2007).
and in the rehabilitation literature from 15 (Raine, 2006) to 263 (Finger et al., 2006). Raine (2006) suggests that good results can be obtained between 10 and 15 panel participants where the group is homogenous and that smaller groups such as this are also more likely to retain group members. Hsu and Sandford (2007) recommend that approximately 15 subjects maybe an appropriate number where again the participants are homogenous.

Some limitations to the current work are however apparent. Firstly, the selection of the measurement items was primarily based on the judgement of clinical experts and not patients and carers. Patient-selected items were included alongside the literature at the start of the process, and the PAG reviewed the outcomes of the Delphi consultation at the end of the process. Nevertheless, direct involvement of patients and carers in item selection could have been considered further. Secondly, the size of the Delphi panel, though within the range of recommendations by other authors, could still be considered quite small. There is a possibility that had the group been larger, different results may have been obtained. However, this is unlikely given the consistency of findings and the need for only two rounds of consultation. Sample size was also a potential limitation for the goals analysis but reflected the population of interest.

| Table 4. Round 1 Delphi consultation initial-item short list and rankings (n = 16) |
|-----------------------------------------|---------|---------|---------|---------|
| Frequency item addressed in practice — relevance of item | Mean | SD | Mode | Median |
| **Passive function** | | | | |
| Bed positioning | 2.3 | 1.9 | 1 | 1.5 |
| Cleaning the foot | 9.6 | 1.8 | 10 | 10 |
| Cutting toe nails | 10.3 | 0.7 | 11 | 10 |
| Cleaning behind the knee | 8.2 | 2.0 | 9 | 9 |
| Wheelchair positioning | 2.7 | 1.6 | 3 | 2.5 |
| Catheterisation | 7.2 | 2.1 | 6 | 7 |
| Perineal hygiene | 3.8 | 1.7 | 3 | 3.5 |
| Splint application (AFO or knee splint) | 5.2 | 2.6 | 9 | 5.5 |
| Positioning the legs (using pillow or positioning aid) | 3.4 | 1.4 | 4 | 4 |
| Putting on underwear or continence pads | 6.2 | 1.9 | 7 | 7 |
| Lower limb dressing (e.g. putting limb through trouser leg) | 6.9 | 1.6 | 8 | 7.5 |
| **Active function** | | | | |
| Turning in bed | 6.2 | 4.5 | 1 | 6 |
| Lying to sitting | 6.8 | 3.4 | 7 | 7 |
| Sitting | 5.6 | 4.6 | 3 | 3.5 |
| Transfer (bed to chair) | 3.7 | 1.9 | 4 | 4 |
| Transfer (bath or car) | 8.6 | 2.1 | 10 | 8.5 |
| Sit to stand | 3.6 | 2.4 | 1 | 3 |
| Standing | 4.3 | 4.1 | 2 | 3 |
| Walking indoors | 6 | 3.6 | 4 | 5.5 |
| Balance (standing, walking and turning) | 6.6 | 3.0 | 5 | 7 |
| Stairs | 9.4 | 2.2 | 9 | 9.5 |
| Walking around obstacles | 12.1 | 1.1 | 12 | 12 |
| Walking over carpet | 10.7 | 3.4 | 12 | 11 |
| Walking outdoors | 10.9 | 2.8 | 13 | 11.5 |
| Walking outdoors over uneven ground | 12 | 3.1 | 14 | 14 |
| Running | 15.2 | 1.8 | 16 | 16 |
| Jumping/hopping | 16.3 | 1.9 | 17 | 17 |
| Endurance (walking half a mile) | 15.4 | 1.5 | 15 | 15 |
| Endurance (running half a mile) | 17.4 | 1.0 | 18 | 18 |

Table 4 presents the rank frequency with which an item had been addressed or set as an intervention goal in practice by respondents. Active function items are not included in ranking and removed: up and down four steps, picking (object) on the floor, bicycling, fluidity of walking (gait pattern) and hopping.

AFO = Ankle Foot Orthosis.

1988) and in the rehabilitation literature from 15 (Raine, 2006) to 263 (Finger et al., 2006). Raine (2006) suggests that good results can be obtained between 10 and 15 panel participants where the group is homogenous and that smaller groups such as this are also more likely to retain group members. Hsu and Sandford (2007) recommend that approximately 15 subjects maybe an appropriate number where again the participants are homogenous.
The LegA is a measure of difficulty in passive and active function for application following focal therapy intervention and in particular for spasticity (botulinum toxin and physical) interventions. The active and passive sub-scales of the tool are treated as separate constructs, which nevertheless are related and are both important to the achievement of clinically relevant goals. The ceiling effect (representing task difficulty) seen in the pilot testing reflects the significant functional impairment of the pilot group. The fact that some participants were unable to perform any active function items emphasizes the need for the passive function sub-scale to capture ease of care improvements when active function improvement is not possible. The LegA is therefore likely to have utility in practice for evaluation of spasticity intervention (often for passive function) and possibly other focal interventions such as task practice training for active function improvement. The items of the active function scale are included in many other lower limb or mobility-related measures (as evidenced in the item selection from the systematic review), most of which are self-reported, which supports the potential for wider utility than spasticity intervention alone. Nevertheless, application for evaluation of spasticity intervention and other possible areas of application will need to be tested prior to recommending application for wider clinical and research use. The LegA is unique in addressing both of these constructs in a single tool and in addressing passive function in the lower limb. In being patient reported, the LegA is also able to evaluate function in a ‘real-life’ context.

In conclusion, (1) a measure for lower-limb active and passive function was developed, and (2) the Delphi method confirmed the content and face validity of the LegA. This has resulted in a measure that now warrants psychometric testing. The process of item selection, reduction and confirmation was comprehensive, and while limitations to the methodology are present, the overall process had a high degree of rigour, ensuring confidence in the content validity of the LegA measure. Its psychometric properties (construct validity, internal consistency, unidimensionality, reproducibility and feasibility) will now undergo preliminary evaluation.

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