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Conceptualisation 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

Objective

To develop a patient reported outcome measure (PROM) of active and passive function in the paretic lower limb.

Methods

Potential items for inclusion were identified through a) systematic review and analysis of existing measures and b) analysis of the primary goals for treatment in a spasticity service. Item reduction was achieved through consultation with a purposively-selected group of experienced physiotherapists and occupational therapists (n=16) in a 2-round Delphi process. This was followed by review of Delphi consultation findings by the Project Advisory Group (PAG) consisting of patients and carers.

Results

Development of the LegA included two rounds of Delphi consultation. Further rounds were not required due to the high degree (80%) of agreement between respondents in rounds one and two. 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 9 passive function sub-scale items and 15 active function sub-scale items. The Delphi consultation ensured content validity, due to the experience of the clinicians in this area of practice and therefore 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.

Conclusions

The LegA is designed to measure passive and active function following focal interventions for the paretic 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.

Word count 250

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 [1, 2], 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 [3].

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 [4], if no return of motor control is likely [5]. A comprehensive outcome measure therefore needs to assess both active and passive function to fully reflect the changes seen following therapeutic interventions [6]. 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 and 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 emphasised 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 meter walk test, reflect a patients' capacity to walk 10 meters, they may not reflect what 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 Measure [7-10]. 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:

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, and
2. To evaluate face and content validity by investigating item relevance for professionals, patients and carers.

Method

Development of the Leg Activity Measure (LegA) comprised a multistage process. Initially items were identified from a previously published systematic review of lower limb functional assessment tools [11] and a retrospective review of goals set for spasticity intervention. Duplicate items were then removed and the remaining items then presented to specialist clinicians through a Delphi consultation process. The project included a Project Advisory Group (PAG) consisting of patients and carers, who were then consulted on the findings from the Delphi process. See Figure 1 for the stages of LegA development.

Insert Figure 1 about here.

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

Goals Analysis

The retrospective goals analysis had two aims, firstly identification of new items by patients and carers, secondly confirmation and supporting identification of items from the systematic review for potential inclusion in the new measure. The methodology

used was based upon Ashford and colleagues work in using clinically set patient goals for PROM development [12].

Setting:

The goals analysed had been set during spasticity management intervention using botulinum toxin injection and physical therapy treatments. 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 specialist community service for patients with acquired brain injury and other complex neurological conditions.

Procedure:

Goals were set using the Goal attainment scaling (GAS) method, which 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 Kirusek and Sherman in the 1960s [13], GAS has been used in many areas of practice that warrant an individualised approach to outcome evaluation including rehabilitation [14, 15]. It is increasingly used as a person-centred outcome measure in research evaluations of outcome following spasticity intervention [16-20], and is recommended as a method of recording patient-reported outcomes in guidelines for management of spasticity with Botulinum toxin [21].

All goals are entered into the clinical database alongside intervention data. Goal statements were extracted from the database of routinely collected data. Goals were classified and mapped onto the WHO International Classification of Functioning (ICF) [22-24] .

Systematic review item classification

Active function items representing the same issue but from different measurement tools identified in the systematic review were collapsed into the same item for consideration. This followed the same method undertaken for the items identified in the goals analysis. Passive function items were not identified in the systematic review.

Delphi consultation

Item selection and reduction was conducted in a 2-round Delphi consultation process with a group of purposively-selected expert clinicians (see Figure 1). The Delphi consultation was therefore used to establish the 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
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 is similar, but evaluates that the instrument covers all the relevant concepts or domains (Streiner and Norman 2003).

Participants and setting

The purposive sample comprised expert clinicians, physiotherapists or occupational therapists, operating in 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. A requirement of inclusion was active involvement with spasticity management services or clinics both in providing

intervention (in the case of physiotherapists this included prescription and/or injection of botulinum toxin) and evaluating outcome.

Participating clinicians worked in neurorehabilitation units across England. An initial 39 clinicians were approached and 21 agreed to participate and were recruited to the study. However 5 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 collapsed items into single items from the goals analysis and systematic review 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 function in the leg, for use following lower limb 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:

(a) Rank the frequency the item was addressed as a goal in rehabilitation intervention;

(b) Rank the difficulty of the item (for patient achievement);

(c) List any items that were not already included which 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 then returned to the same experts for their further comment and verification, again asking them to identify items for inclusion and exclusion with stated reasons.

Item confirmation through PAG consultation:

The PAG was asked to review the results of the Delphi consultation. Four patient and carer dyads participated in the consultation meeting and commented on the findings. The PAG were given the questions that the Delphi participants had been presented with and were then asked to comment on:

(a) Deficiencies in the process

(b) Any items that had been missed and not considered

(c) Any items that had been excluded which they felt were not justified.

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

Pilot testing:

The LegA was then plot tested in routine clinical practice with individuals undergoing focal spasticity intervention, including botulinum toxin administration and physical interventions.

Results

Goals Analysis

In the analysis 125 goals were identified from the records of 62 patients who had received focal spasticity intervention and six distinct categories of goal were identified.

These were: pain, involuntary movement, range of movement, mobility, passive function and active function as shown in figure 2 and table 1.

Insert Figure 2 about here.

Insert Table 1 about here

Identified goals were then 'mapped' to ICF codes [22, 24], after the method applied by Turner-Stokes [18] (See table 2.

Insert Table 2 about here

Systematic review item classification

The systematic review initially identified 111 possible active function items, taken from 7 measurement tools. These initial items were then collapsed into categories (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 PROM's is presented in table 3.

Insert Table 3 about here

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.

Insert Table 4 about here

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.

Insert Table 5 about here

In table 5 the items removed have also been indicated (marked with *) as well as those added from round 1 (indicated in **'bold'**). Four items were removed in round 2 Delphi consultation, these were: 'cleaning the foot', 'cutting toe nails', 'catheterisation', and 'spasms impacting on comfort or sleep'. 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.

Project Advisory Group (PAG) 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 which were then included in the final list of items (see Figure 3).

Insert Figure 3 about here

They included suggestions for wording questions in a manner more easily understood by patients and carers. 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 developed.

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 LegA was pilot tested by 16 patients (and their carers when relevant) undergoing rehabilitation intervention for lower limb activity limitations requiring the management of spasticity. Passive function sub-scale scores ranged from 1 to 23 and active function scores ranged from 11 to 60. Five patients had repeated measurement after intervention and showed changes on both sub-scales. In general the pilot group had significant functional impairment reflected in the active function limitation recorded by LegA.

The scale structure for the LegA is taken from that used in the previously developed ArmA and also used in other patient reported tools. The application of the same scale presentation maintains consistency of the tools and should aid clinicians in the application of LegA. The final measure, which now warrants formal psychometric testing, consists of two domains, active and passive function. Passive function contains 9 items. Active function contains 15 items. A summary of the changes to items through the different stages of development can be seen in Figure 1.

Discussion

This project and process of development built on our previous and on-going work in developing a patient reported measure of arm activity, the Arm Activity (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 utilising experts in an unbiased manner throughout the entire process of development [25]. Finger and colleagues 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 [26]. 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 due to the high degree of agreement between respondents in rounds one and two. The resulting 24-item (two sub-scales) tool consists of 9 passive function sub-scale items and 15 active function sub-scale items. 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 address 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 the advantages of providing anonymity to participants and reducing personality based influences such as the impact of socially dominant individuals on the consensus process [26, 27]. The literature provides no definitive recommendation on panel size, which have ranged greatly in different studies between 10 and 1685 [28] and in the rehabilitation literature from 15 [29] to 263 [26]. Raine suggests that good results can be obtained with 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 [29]. 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 was a reflective sample of the population of interest.

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 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 LegA is unique in addressing these constructs and, being patient reported, evaluates 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 which 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.

Declarations of interest

This paper presents independent research funded by the National Institute for Health Research (NIHR). The views expressed are those of the authors and not necessarily those of the NHS, the NIHR or the Department for Health.

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Clinical Messages

- 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.
- The Leg Activity (LegA) measure has been developed with demonstrated face and content validity.
- The LegA is theoretically appropriate for clinical application and is undergoing psychometric testing to demonstrate this.

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Table 1: Breakdown of goals set for all patients (125 goals in 62 patients) in each goal area

Goal Domain	Goal area	No. of goals set	Percentage of goals set
Body structure and function N=45 goals (32 %)	Spasticity-related pain or discomfort	10	8
	Range of movement, prevention of contractures/ deformity	32	25.6
	Involuntary movements during use of other limbs (associated reactions) or spasms	3	2.4
Activities and participation N=80 goals (64 %)	Passive function - Ease of caring for the affected limb (e.g. maintaining hygiene, skin integrity, dressing the limb, resting splint use and application)	51	40.8
	Active function - Using the limb in an active function task (e.g. functional splint use and application)	15	12
	Improved mobility (e.g. transfers, standing, walking, balance, confidence, avoiding falls)	12	9.6
	Therapy facilitation	2	1.6

Table 2: Mapping of main goal categories onto the relevant World Health Organisation ICF codes according to Turner-Stokes et al 2010

Domain	Goal area	Chapter	Primary ICF Code	Associated ICF codes
Body structure and function				
	Pain	2 - Sensory& Pain	b280 - Pain	b735
	Passive range of movement	7- Neuro-musculoskeletal	b735 - Muscle tone	b710
	Reducing associated reactions	7- Neuro-musculoskeletal	b755 - Involuntary movement reactions to position/balance	b735
Activity and participation				
	Maintaining postures	4- Mobility	d415 - Maintaining body position	d445
	Improved walking / gait pattern	4- Mobility	d450 - Walking	d420
	Transferring	4- Mobility	d420 - Transferring	d410, d415
	Changing position	4- Mobility	d410 – Changing body position	d415, d420
	General Independence	5- Self care	d500 - General Independence	b510-washing
	Hygiene /skin integrity	5- Self care	d520 - Caring for body parts	b735, b710, b510
	Caring for the leg	5- Self care	d520 - Caring for body parts	b735, b710, b510
	Dressing	5- Self care	d540 - Dressing	d440, b735, d710

ICF: International classification of functioning disability and heal

Table 3 Items identified through the systematic review following categorisation and the tools from which they originated.

Active Function	BICRO	CSQ	HAP	LEFS	N-ADL	RMI	SIS
Turning in bed				✓		✓	
Lying to sitting						✓	
Sitting						✓	
Transfer (bed to chair)	✓					✓	✓
Transfer (Bath or car)				✓	✓		
Sit to stand						✓	
Standing			✓			✓	✓
Walking indoors	✓		✓	✓		✓	✓
Stairs		✓	✓		✓	✓	
Picking object off floor						✓	
Walking outdoors (even ground)	✓		✓	✓	✓	✓	
Walking outdoors (uneven ground)						✓	
Running				✓	✓	✓	
Jumping / hopping				✓			
Endurance (Walking half a mile)			✓	✓			
Endurance (running half a mile)			✓	✓			

Brain Injury Community Rehabilitation Outcome Scales (BICRO), Climbing Stairs Questionnaire (CSQ), Human Activity Profile (HAP), Lower Extremity Functional Scale (LEFS), Nottingham Extended ADL Index (N-ADL), Rivermead Mobility Index (RMI), Stroke Impact Scale (SIS).

Table 4 Round 1 Delphi consultation initial item short list and rankings

Frequency item addressed in practice – Relevance of item				
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, 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

Active Function items not included in ranking and removed: up and down 4 steps, picking (object) off the floor, bicycling, fluidity of walking (gait pattern) and hopping.

Table 5 Round 2 Delphi consultation item assignment

Mean rank: Difficulty of item	
Passive Function	
1	Perineal hygiene
2	Splint application (AFO or Knee splint)
3	Wheelchair positioning
4	Lower limb dressing (e.g. putting limb through trouser leg)
5	**Enable hoist transfer (including sling insertion)**
6	Catheterisation*
7	Putting on underwear or continence pads
8	Bed positioning (including positioning legs using pillow or positioning aid)
9	Cleaning behind the knee
10	**Putting on shoes**
11	**Spasms impacting on comfort or sleep***
Active Function	
1	Turning in bed
2	Lying to sitting
3	Transfer (bed to chair)
4	Sitting
5	Transfer (Bath or car)
6	Sit to stand
7	Standing
8	Walking indoors
9	**Turning around**
10	Balance (standing, walking, turning)**Modified, balance included in other items*
11	Stairs
12	Walking around obstacles
13	Walking over carpet
14	Walking outdoors
15	Walking outdoors over uneven ground
16	Jumping / hopping*
17	Running*
18	Endurance (Walking half a mile)
19	Endurance (running half a mile)*

Items in 'bold' were added after round 1. Items with * were removed after round 2.

Figure 1 Summary of item reduction for the LegA

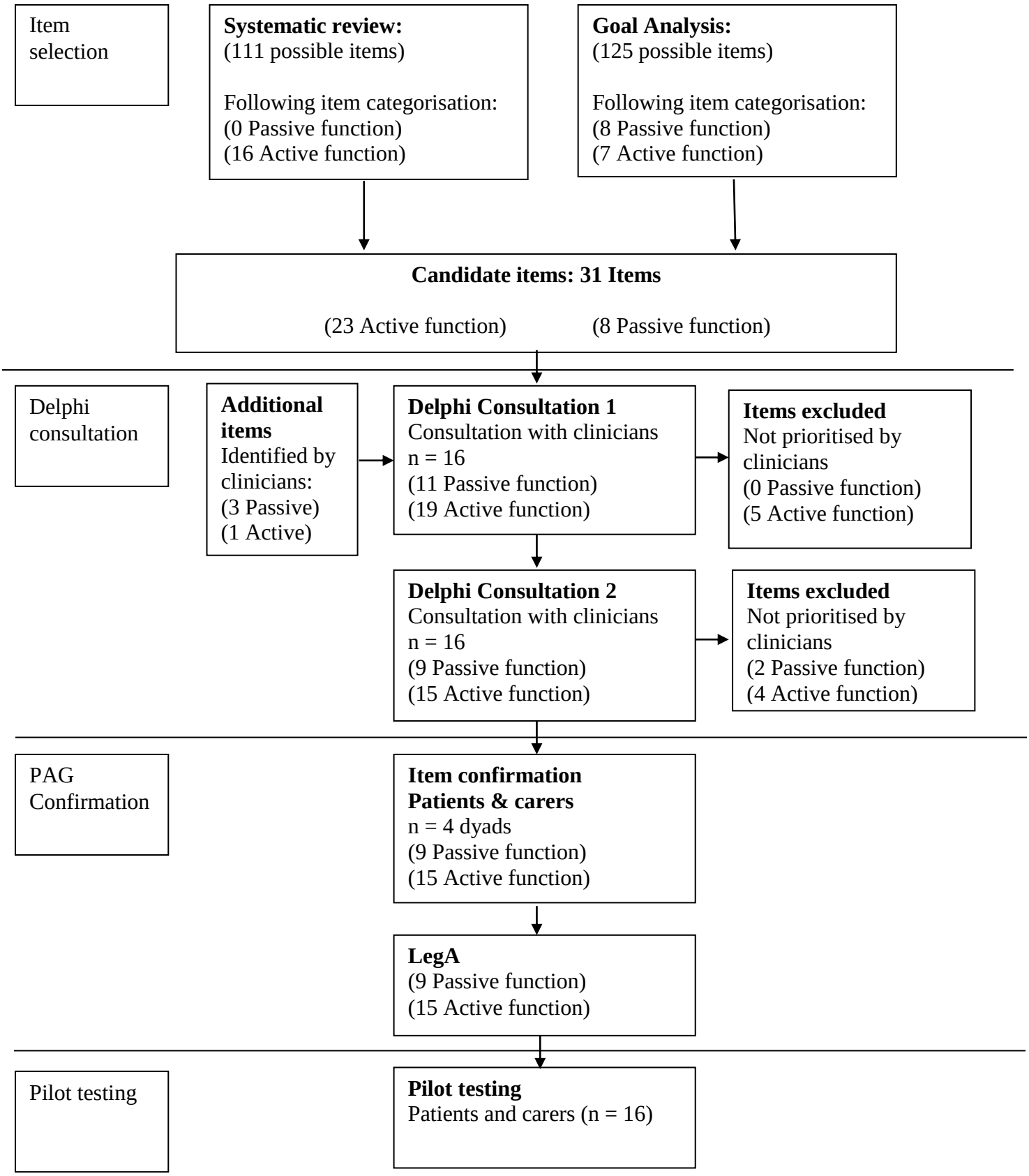

Figure 2 Categories of goal set and achieved

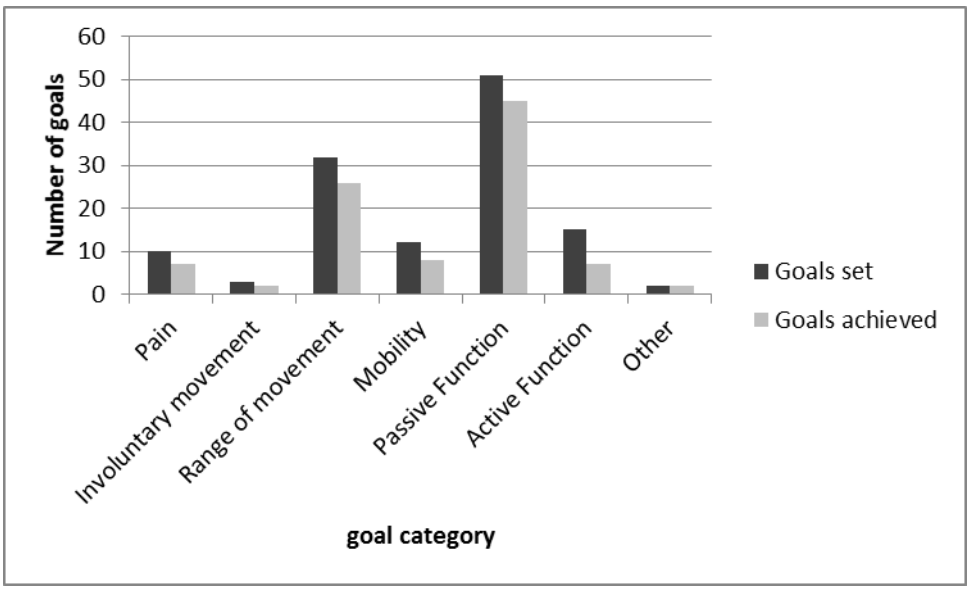

Figure 3: Leg Activity measure items

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**