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Development of a measure of therapy provision for spasticity management in the paretic lower limb - the Leg Therapy recording Schedule (LegTS).

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Abstract

Purpose

In rehabilitation studies, it is critical to understand the constituents of interventions. Firstly, to enable replication of the work and secondly, to identify what treatments work best. The development of a tool to describe and quantify therapy interventions in the context of focal spasticity management is presented.

Methods

Potential intervention categories were identified from; a)retrospective analysis of prospectively collected data from a cohort of patients(n=62) receiving physical interventions in the context of botulinum toxin (BoNT) injection for leg spasticity and b)cognitive de-briefing with Patient and Carer Advisory Group (PCAG) of patient and carer dyads(n=8). Item reduction was achieved through consultation with a purposively-selected group of physiotherapists and occupational therapists(n=16) in a 2-round Delphi process. This was followed by review of findings by PCAG members.

Results

A list of 24 possible therapy categories were identified and then reduced, resulting in a tool with two domains: 1) postural management; four categories and 2)Exercise and retraining; four categories. The LegTS wording and presentation were refined for clinical and research use.

Conclusions

The LegTS is designed to record therapy interventions for the paretic lower limb in the context of spasticity intervention. Content and face validity have initially been addressed within the development process.

Word count 200

Keywords: Patient experience, lower limb, physiotherapy, Delphi, exercise

Introduction

Following neurological illness or injury, lower limb spasticity (involuntary over-activity of muscle) can cause a range of problems and severely limit function. Data on the prevalence of spasticity are varied but it has been reported in 19 to 38% of patients after stroke [1,2]. In the most disabled patients, problems with passive function include difficulty for carers in maintaining perineal hygiene or assisting with dressing [3]. In more able patients, spasticity may restrict active function, resulting in limited mobility, balance and walking speed or quality. The goals for treatment are therefore highly diverse.

Interventions to manage lower limb spasticity are similarly complex and diverse. They include various combinations of medical treatments (systemic medications, intrathecal medications at a spinal level or botulinum toxin injections (BoNT) to relax muscles) and physical treatments, for example; stretching, splinting, muscle strengthening and exercise to inhibit spasticity and prevent the secondary problems associated with it. The majority of interventions used are theoretically applied with an aim of managing the secondary consequences of spasticity, rather than directly impacting on the spasticity itself. 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, other physical interventions as well as pharmacological interventions) and outcomes of this treatment (functional and other benefits for patients).

As yet there is no comprehensive tool to quantify and describe therapy interventions used in this context [4]. The Leg Therapy recording Schedule (LegTS) was built on our previous work to develop a patient-reported tool for the recording of therapy intervention

for upper limb spasticity.[5-8] The Upper Limb Spasticity Therapy Recording tool (ULSTR) is currently being tested within the International Upper Limb Spasticity study (ULIS III) [9]. The LegTS was designed to record therapy intervention provided to patients and reported by them to the spasticity clinic team.

We describe the development the LegTS, which is designed for use with the Leg Activity measure (LegA), for evaluating function outcome.

Aims

The aim was to develop the LegTS - a practical patient reported measure to record the therapy interventions applied for spasticity and physical management in the paretic lower limb. The development process was designed in four stages to confer face and content validity by investigating intervention relevance for professionals, patients and carers.

Method

Development of the LegTS was undertaken in four stages:

1. Initial identification of intervention categories from secondary analysis of cohort data from an integrated care pathway for spasticity management
2. Cognitive de-briefing with a Patient & Carer Advisory Group to confirm the interventions and ensure they were understood by patients/carers
3. Category selection using a Delphi methodology.
4. Re-consultation with members of the Patient & Carer Advisory Group.

The project team included a Patient & Carer Advisory Group (PCAG) consisting of patients and carers with relevant experience, who were involved in identifying interventions and who were consulted on findings from the Delphi process. See Figure 1 for the stages of LegA development.

Insert Figure 1 about here

Ethical approval for 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.

Stage 1: Identifying intervention categories

Categories for inclusion were initially identified from retrospective analysis of intervention used in conjunction with botulinum toxin administration in a prospectively collected cohort of patients undergoing treatment for lower limb spasticity.

Participants and setting

Patients referred to a regional specialist spasticity service for focal spasticity management.

Procedure

In the context of an integrated care pathway (ICP) for spasticity management, we interrogated a database of routinely collected focal spasticity intervention (including administration of botulinum toxin) from 02/01/2009 to 02/01/2013. The aim was to initially identify patients receiving intervention for lower limb spasticity. Following case identification, the 'therapeutic' interventions received alongside botulinum toxin intervention were extracted and categorised. In many cases patients were also receiving systemic anti-spasticity medications (e.g. Baclofen) which were recorded, but are not presented in this analysis. Information captured in free text in the database was supplemented by hand searching and further extraction of interventions from the paper integrated care pathway document.

Stage 2: Cognitive debriefing with an established Patient and Carer Advisory Group (PCAG)

The PCAG consisted of four patient and carer dyads (n=16). Patient members of the PCAG had all:

- Suffered an acquired brain injury (traumatic brain injury or stroke).
- Gone through an inpatient rehabilitation programme followed by community input.
- Had treatment for spasticity.

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

Procedure

The PCAG were asked to review the extracted intervention categories to confirm their understanding of those identified, or to indicate if they did not and why. They were additionally asked to report any additional categories if they felt key aspects had not been covered. Cognitive debriefing was then used to explore their mutual understanding of the terms and categories identified to ensure that they were of relevance to patients and carers.

Stage 3: Delphi consultation

Item category reduction was achieved through consultation with a purposively-selected group of experienced physiotherapists and occupational therapists (n=16) in a two-round Delphi process. They all had specialist skills and experience in spasticity management. See Figure 1 for the stages of LegTS development.

This was followed by review of Delphi consultation findings by the same PCAG members and one of the researchers who was a 'patient expert' to the study.

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 [Botulinum Toxin] Injectors in spasticity' and from the contacts of these professionals. Inclusion criteria were:

- 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 were senior experienced clinicians in rehabilitation practice in general.

Procedure

Delphi Consultation Round 1: The list of categories was presented to the expert clinicians by e-mail. The consultation exercise required respondents to judge the importance of possible items for inclusion in the tool.

Respondents were asked to:

- (a) Identify categories representing the same issue;
- (b) Rank the frequency of intervention from their own experience;
- (c) List any interventions 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 short list of items for inclusion was produced for round 2.

Delphi Consultation Round 2: The shortlist was then returned to the same 16 experts for their further comment and verification, again asking them to identify categories for inclusion and exclusion with stated reasons. Clinicians also commented on the likely duration of intervention of different types and this information was used in the final tool to produce intervention duration classifications.

Stage 4: PCAG re-consultation:

Four patient and carer dyads participated in the PCAG consultation group and were asked to review the findings from the Delphi study. When reviewing the Delphi results, the PCAG were given the same questions to consider as Delphi participants, but were also presented with the items that had been excluded to confirm their agreement. They were asked to comment on:

- (a) Deficiencies in the process
- (b) Any interventions that had been missed and not considered

Responses from the PCAG were then considered by the lead researcher (SA) and discussed further with the group to identify solutions or additions. The PCAG commented on the final tool to refine presentation.

Results

Stage 1: Identification of intervention categories

A total of 165 patients received focal spasticity intervention including BoNT injection, between 1st January 2009 and 1st January 2013. Among this group, 62 received interventions for lower limb spasticity and were used in this analysis. A total of 215 intervention categories were identified following review of these cases.

Stage 2: Cognitive debriefing with the Patient Carer Advisory Group

After initial intervention category identification (215), consultation with PCAG members was undertaken. No additional items were identified, but the initial categories were collapsed from 215 to 25, as agreed by the PCAG members. Further classification of domains then linked categories addressing related interventions. The categories and initial domains are presented in in table 1.

Insert Table 1 about here

Based on consideration of these findings, the categories were condensed into:

1. Positioning the lower limb
2. Splinting
3. Orthotic use
4. Serial casting
5. Standing
6. Task practice
7. Strengthening
8. Transfer practice
9. Passive stretch (manually applied)
10. Neuro-muscular Electrical Stimulation
11. Walking aid provision

These categories were then presented to participants in the Delphi consultation.

Stage 3: Delphi Consultation

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

Table 2 presents the rank frequency of intervention, based on the clinicians' own clinical practice experience. The ranking presented is that generated from round one of Delphi consultation. The ranking did not change in round two, but some additional items were suggested and are recorded at the bottom of the table.

Insert Table 2 about here

Additional items suggested, did not represent entirely new categories and were further examples of interventions that could be included in the current categorisation. No further categories of intervention were therefore added at this stage.

Stage 4: Project Advisory Group (PCAG) consultation

The results of the Delphi consultation were reported to the PCAG, consisting of 8 patient and carer dyads (n=16). No changes to intervention category were suggested, but some comments were made on intervention descriptions and presentation of the tool.

Classification of the categories into domains was then re considered and domains of 1) postural management and 2) exercise and retraining were identified. Within the categories, 'walking aid provision' was removed because this represented a therapy process item and did not conform to either the postural management nor the exercise and retraining domains, though walking aid provision may enable gait or transfer training to take place. The resulting domains and categories are presented in Table 3.

Insert Table 3 about here

Subsequently, balance as a separate category was combined with strength training, both of which may ultimately be prerequisites to task practice intervention.

Insert Table 4 about here

Table 4 presents the finalised intervention category list incorporated into a recording system to form the tool, following the inclusion of final comments by the PCAG. The final tool is designed for use as a structured interview for completion by the clinician, through consultation with the patient, carers and other clinicians. Overall therapeutic

activity in terms of time is captured and an estimate of time spent on each intervention is also recorded including self-practice by the patient (supported by a carer as appropriate). The time frames used in the tool are based on the recommendations of the clinician participants in the Delphi consultation.

Discussion

In this study we set out to develop a practical patient and carer-reported, clinician recorded tool to capture therapy interventions in the course of management of lower limb spasticity management. The four-stage development process incorporated a sizeable cohort analysis of patients following an integrated care pathway in routine clinical practice, and included input from 16 experienced clinicians as well as patients and their carers. This process was designed to confer face and content validity. From 24 interventions initially identified, the final LegTS tool has 9 items.

Development of the LegTS included two rounds of Delphi consultation. Further rounds were not required due to the high degree of agreement between respondents in rounds one and two. The resulting tool has been subdivided into two sections based on the identified domains. The likely duration of application of the therapy interventions differs between domains and this is reflected in the tool. Clinician and PCAG comments on presentation of the new tool, ensuring ease of completion in clinical settings, have been incorporated.

Initial identification of items from treatment applied in practice was fundamental to ensuring the content of the resulting tool. Cognitive de-briefing with the PCAG ensured that descriptions of interventions were accessible and understandable for clinicians as well as patients and carers. The PCAG also identified possible items for inclusion during development, offering a comprehensive selection of intervention categories. Identified

items are primarily selected from practice and by expert clinicians, all have some evidential support, but the evidence for some interventions is stronger than others.

Delphi consultation was used for LegTS development because of its strengths in utilising experts in an unbiased manner throughout the entire process of development [10]. 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 category selection); and informed input from expert participants [11]. These characteristics were particularly relevant when using expert clinicians to develop a tool to capture therapy intervention.

Delphi consultation also provides anonymity to participants and reduces personality based influences such as the impact of dominant individuals on the consensus process [11,12]. The literature provides no absolute recommendation on panel size. Panel sizes have ranged in different studies between 10 and 1685 [13] and in the rehabilitation literature from 15 [14] to 263 [11]. Raine recommends that robust results can be obtained with between 10 and 15 panel participants where the group is homogenous, and that smaller groups are also more likely to retain group members [14].

Selection of participants has also received some attention in the literature. Hsu and Sandford (2007) consider selection of participants as one of the most important components of the whole Delphi process [10]. The selection of participants is important because it influences the of results obtained [10] and dictates to a great extent the utility of those results in future application. Selection was undertaken in a purposive manner in this study with a requirement that participants had knowledge and experience of the area

of clinical practice to be included. The rigorous process of selection has resulted in consensus between group members despite lack of direct interaction. A similarly focused approach to recruitment for Delphi consultation has been applied in other rehabilitation work [15]. Philp and colleagues (2013) used purposive selection of participants for a Delphi consultation developing a checklist for standardised post stroke follow-up care. Although differences were present between participants, for example the country in which they worked, they were still a relatively homogeneous group. The post stroke follow-up checklist developed also required only two rounds of Delphi consultation indicating a high degree of agreement between that group, as in this study.

The homogeneity of a set of participants has been criticised in not fully representing the range of possible opinion on the selected topic [10]. However in the current study this was not considered a major limitation, because the starting point of category selection was clinical practice, the findings from which were then reviewed by patients and carers.

Some limitations to the current work are however apparent. The review of interventions used in practice was taken from one service, and ideally other services, and indeed services in other health systems and countries, providing input to this patient group would have been helpful to include. Differences in patient severity and therefore some pharmacological interventions, were not addressed in initial item selection because all patients included were appropriate for focal spasticity management. In many instances focal spasticity intervention was provided on a background of systemic antispastic medication. No participants were receiving intrathecal interventions. Selection bias for item categories could be a theoretical limitation for patients with the most severe spasticity requiring intrathecal interventions. Additionally, physical interventions

carried out may not have all been recorded in the integrated care pathway (ICP) document. The ICP is a clinical document and as such, recording of intervention was not undertaken with the express aim of this analysis. 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 the research team consider this to be unlikely, given the consistency of findings and the need for only two rounds of consultation.

The content and face validity of the LegTS have been addressed within the development process through initial identification of items from practice and selection by expert clinicians. The LegTS is not a measure as such, but a classification system, nevertheless, it would be appropriate to consider further psychometric properties as appropriate. Evaluation of the reliability of the LegTS in capturing intervention appropriately would be valuable going forward. In addition, considering its application in different health systems and other countries would also strengthen its future use, as is currently being undertaken for the upper limb version of this tool.

In conclusion, the LegTS has been developed as a systematic method of recording therapy intervention in clinical practice and research. In the management of focal spasticity, botulinum toxin injection is often considered. However, in the majority of cases injection is carried out in the context of physical interventions, such as splinting, which are important in meeting patient identified goals. The LegTS will therefore ensure, that clinical intervention is captured for focal spasticity intervention.

Implications for rehabilitation

- Clinicians need to understand intervention effectiveness, and to do so, it is critical to capture all the components of a complex intervention.
- In clinical practice or research, patient experience measures are required to capture the complexity of intervention provided and monitor intervention effectiveness on a case by case basis.
- Clinicians involved in rehabilitation and management of focal spasticity in the leg can use the Leg Therapy recording Schedule (LegTS) to enable an understanding of the entirety of the intervention package provided.

Declarations of interest

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Table 1 Therapy intervention categories from secondary analysis and cognitive debriefing (n=62)

Therapy Intervention Category	Frequency identified (secondary analysis)
Orthotic (provision and application)	
Ankle Foot Orthosis (AFO) provision/splinting/orthotic	43
AFO provision (Soft/scotch)/serial casting/splinting	20
AFO revision	26
Dynamic insole	4
Calliper provision	6
Training of carers - AFO application	10
Positioning	
Positioning of the lower limb (bed or wheelchair)	4
'T' roll (lower limb bed positioning aid)/positioning	78
Wheelchair modification/positioning	8
Wheelchair pommel	1
Training of carers - positioning bed	38
Training of carers - positioning chair	11
Electrical stimulation	
Functional (Neuro-muscular) Electrical Stimulation	4
Task practice, balance, strengthening	
Gait training	47
Standing frame/standing	14
Standing frame/standing	14
Tilt table standing	2
Balance training	3
Strength training	3
Training of carers - transfers	10
Transfer training/Task practice	10
Walking task practice/Task practice	1
Stretching	
Passive self-stretching	10
Passive stretch during care	24
Provision of aids	
Walking aid provision (Quad stick/stick/frame)	1
Grand Total	215

Table 2 Delphi category evaluation

Frequency of application in practice (Most frequent ranked 1 and least ranked 11)				
Category	Mean Rank	SD	Mode	Median
Used in final tool				
Positioning of lower limb	2.5	1.4	1	2.5
Splinting	3.4	2.6	2	2
Orthotic use	4.7	2.8	7	5
Serial casting	5	3.5	1	4
Standing	5.8	2.8	9	5
Task practice	6.2	2.8	6	6
Strengthening	6.2	2.0	6	6
Transfer practice	7.1	2.4	10	6.5
Passive stretch (manually applied)	7.2	3.1	10	7.5
Neuro-Muscular Electrical Stimulation	8.4	2.4	11	9
Walking aid provision	8.6	2.2	11	9
Proposed and considered during Delphi consultation				
Myofascial Release Techniques				
Continuous passive ranging (CPM)				
Sling suspension				
Functional Electrical Stimulation combined with static bike				

Table 3: Project Advisory Group confirmed domains and categories

Postural management domain
1. Splinting (static including circumferential) Static including circumferential splints with an aim of maintaining range of movement (resting splints).
2. Orthotic provision Supply and assessment for an orthotic device other than a serial cast.
3. Serial Casting Static or adjustable (often circumferential) splints with an aim of increasing range of movement (serially applied).
4. Positioning (therapeutic or stretching position) Therapeutic positioning often carried out by therapists, patients and/or carers (for example to maintain muscle length). Including application of positioning aids e.g. 'T-roll' application.
Exercise and retaining domain
5. Passive Stretch (manually applied) Short duration manually applied passive stretch.
6. Electrical Stimulation Electrical stimulation to: 1) strengthen muscle, 2) to incorporate in functional activity 3) for pain.
7. Strength training Exercise programmes specifically designed to increase muscle strength
9. Task Practice (incorporating augmented practice using robotics and gaming technologies) All aspects of gait retaining, treadmill training with/without partial body weight support
10. Balance Specific intervention targeting the re-education of balance to then be incorporated into the task.

Table 4: Summary of the Leg Therapy recording Schedule (Leg TS)

A. Postural management domain						
Interventions are recorded over the preceding week. 0 = None; 1 = less than daily; 2 = up to 1 hour daily; 3 = up to 3 hours daily; 4 = up to 6 hours daily; 5 = over 6 hours daily						
1. Splinting (static including circumferential) Static including circumferential splints with an aim of maintaining range of movement (resting splints).	0	1	2	3	4	5
2. Orthotic Any orthotic device (excluding a serial cast)	0	1	2	3	4	5
3. Serial Casting Static or adjustable (often circumferential) splints with an aim of increasing range of movement (serially applied).	0	1	2	3	4	5
4. Positioning of leg (therapeutic or stretching position) Therapeutic positioning often carried out by patients and carers (for example to maintain muscle length).	0	1	2	3	4	5
B. Exercise and retraining domain						
Interventions are recorded over the preceding week. 0 = None; 1 = less than daily; 2 = up to 15 minutes daily; 3 = up to 30 minutes daily; 4 = up to 1 hour daily; 5 = over 1 hour daily						
5. Passive Stretch (manually applied) Short duration manually applied passive stretch.	0	1	2	3	4	5
6. Electrical Stimulation Electrical stimulation to the injected muscle, to strengthen muscle or to incorporate in functional activity.	0	1	2	3	4	5
7. Strength and balance training Exercise programmes specifically designed to increase muscle strength and/or balance	0	1	2	3	4	5
8. Task Practice Gait retraining (e.g. free walking, pulpit frame walking, treadmill training)	0	1	2	3	4	5
9. Other (please detail below)	0	1	2	3	4	5

The LegTS tool is available from: <http://www.csi.kcl.ac.uk/tools.html>

Figure 1 Summary of item reduction for the LegTS



