7 Comparison of five instruments including a novel Upper Limb-Activity Monitor to determine functioning in complex regional pain syndrome type I

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7.1 Abstract

Objective: To study how five instruments that measure the functional consequences of diseases are related to each other in subjects with upper limb complex regional pain syndrome type I (CRPSI), with emphasis on a novel Upper Limb-Activity Monitor (ULAM). **Design:** Cross-sectional comparison study. **Setting:** Home environment. **Subjects:** Thirty patients with chronic CRPSI in one of the upper limbs. **Main measures:** The ULAM, which is based on ambulatory accelerometry. Two generic questionnaires; the 68-item Sickness Impact Profile (SIP68) and the RAND 36-item Health Survey (RAND36). Two body-part specific questionnaires; the Disabilities of Arm Shoulder and Hand questionnaire (DASH) and the Radboud Skills Questionnaire (RASQ). Statistics: Spearman rank correlations. **Results:** Of the inter-questionnaire correlations 87% were significant, whereas 39% of the correlations calculated between the ULAM and the questionnaires were significant. The number and strength of the correlations between the ULAM and questionnaires was dependent on the degree to which the same aspects of functioning were measured. **Conclusion:** All five instruments measure similar aspects of functioning to a certain extent; on the other hand, the ambiguous pattern of correlations demonstrates that the ULAM measures considerably different aspects of functioning than the questionnaires. It is concluded that the ULAM has a distinct place in the field of outcome assessment; it offers an alternative but important insight into the impact a disorder may have on a subject's functioning.

7.2 Introduction

For many medical disciplines, particularly for rehabilitation medicine, preferably objective instruments and quantifiable outcome measures that focus on the functional consequences of diseases are essential [1, 2]. In the International Classification of Functioning (ICF), activity limitations and participation restrictions are classified as two possible disease consequences on everyday life at the level of the person and society, respectively [3]. These functional consequences can be measured in different ways [4] but, until recently, objective, reliable and valid instruments were lacking [5]. To objectively measure activity limitations of subjects with upper limb disorders, an Upper Limb-Activity Monitor (ULAM) has been developed [6], based on a previously developed Activity Monitor (AM) that allows valid determination of limitations related to mobility [7-10]. The ULAM is based on long-term ambulatory monitoring and consists of body-fixed acceleration sensors connected to a recorder. Ambulatory accelerometry enables measurement of mobility-related activities and activity of upper limbs. The ULAM mainly measures at the ICF activity level, but some aspects of participation are also measured because what subjects actually do during everyday life in society is also determined. The ULAM has proven its ability to detect limitations of upper limb activity of subjects with upper limb complex regional pain syndrome type I (CRPSI) when compared to healthy subjects [11].

CRPSI is a disorder that may comprise sensory, trophic, autonomic and motor impairments. When it occurs, it usually follows surgery or trauma and is generally expressed in the limbs [12]. The pathophysiology of CRPSI remains controversial [13-16] and it may lead to activity limitations and participation restrictions [17-33]. Up to now, only scales and questionnaires (both generic and body-part specific) have been applied to determine functioning in CRPSI [34]. Knowledge of the relationships between the ULAM and these other instruments, and mutual relationships between questionnaires and scales, is important in the assessment of the characteristics and added value of both the ULAM and other instruments. On the one hand, relationships can be expected because all these instruments generally aim at measuring the same functional levels or concepts; on the other hand, differences (related to characteristics of the technique, the aspects that are measured, and methodological quality) will also exist [4]. For example, questionnaires measure functioning as perceived and recalled by the subjects, whereas the ULAM measures what subjects actually do; questionnaires have standardised response options and retrospective data collection, whereas the ULAM measures *during* everyday life. Within the “same functional level” two or more sub-levels can be distinguished, and instruments may differ in their sub-levels. In addition, questionnaires sometimes measure a mixture of aspects (i.e. both capacity and performance items, or both simple skills and complex motor tasks). Furthermore, instruments will differ in displaying ceiling or floor effects, or in their reliability and validity. Thus, these differences may affect the strength of relationships or may even result in an absence of relationships.

Therefore this study aimed to explore and describe how instruments with outcome measures at functional levels were inter-related in upper limb CRPSI, with emphasis on the ULAM. To structure the study, two main assumptions were made. First, we assumed that some relationship will exist between ULAM outcome measures and questionnaires, but this relationship will be weak, and certainly weaker than the mutual relationships between the questionnaires. Second, we assumed that the relationships will be stronger between outcome measures that are aimed at the same aspect of activity limitations or participation restrictions.

7.3 Methods

Design and subjects

Thirty subjects with CRPSI in one upper limb volunteered for this cross-sectional comparison study. Their average age was 55.1 (sd ± 14.9, range 20-81) years and the majority was female (n= 29). In 15 subjects the dominant side was involved and in the other 15 the non-dominant side was involved. Mean duration of CRPSI was 33 months. Inclusion criteria were: 1) presence of Veldman´s criteria [35] at diagnosis, which do not substantially differ from the official IASP criteria [12, 16] and 2) presence of CRPSI-related complaints at enrolment. Subjects were excluded if they had co-morbidities that might influence functioning.

Instruments and outcome measures

Two generic questionnaires, two body-part specific questionnaires, and the ULAM were used. The generic Sickness Impact Profile (SIP) measures the impact of a disease on everyday functioning [36]. The SIP68 is a reliable and valid short version [37, 38] of the original SIP; both have been applied in CRPSI [39-42]. The body-part specific Radboud Skills Questionnaire (RASQ) [19] reliably scores the effort certain activities cost compared to pre-CRPSI; it has only been used in upper limb CRPSI [41]. The body-part specific Disabilities of Arm Shoulder and Hand Questionnaire (DASH) has been developed to determine limitations of the entire upper limb [43, 44]; the Dutch version [45] has not been used in CRPSI. The generic RAND36 Health Survey [46] is a valid Dutch version of the Short Form 36 [47, 48] but with different scoring rules [49]; the RAND36 has been used in CRPSI research [21, 22].

The ULAM consists of acceleration sensors (Analog devices, ADXL202, uni-axial piezo-resistive, size 1x1x0.5cm) on forearms, thighs and trunk connected to a waist-worn recorder (TEMEC Instruments BV, Kerkrade, the Netherlands, see Figure 7.1). The raw signals are a combination of gravitational acceleration and accelerations due to activity [50]. Data were stored on a PCMCIA card and downloaded onto a PC for automatic post-measurement kinematic analysis using signal processing and inferencing language (SPIL) routines [51]. Briefly, the accelerometer signals from the thighs and the trunk allow mobility-related activities (such as lying, sitting, standing, walking, cycling and general movement) to be automatically detected. Two of the generic ULAM outcome measures used in the present study were the percentage of

the measurement period that a person was “dynamic” (i.e. walked, walked stairs, cycled, moved without cyclic movements) (ULAM-%dyn), and body motility (the intensity of body movement measured with accelerometry) (ULAM-body). The addition of accelerometers on the forearms allowed to calculate four body-part specific ULAM measures: the intensity of upper limb movement during sitting (ULAM-isit) and during standing (ULAM-istand), and the percentage of the time that the upper limb was used during sitting (ULAM-%sit) and during standing (ULAM-%stand). A more extensive description is given in earlier studies [6-9, 11, 52].

Figure 7.1: A woman wearing the ULAM that was fitted in her home environment.

Instruments can be assessed according to measurement technique, type of instrument, health related quality of life domain, ICF level, performance of capacity aspect, and on their possibility to compare populations with upper limb disorders (table 7.1). Although specific terminology is not consciously applied in literature [44], we consider capacity to be a subject’s capability, ability or potential to carry out activities (can do), and performance to be a subject’s actual execution of activities (do do). Concerning the possibility to compare upper limb populations, intra-subject comparability refers to the possibility to compare the activity of one upper limb relative to the activity of the other upper limb in one subject (e.g. involved side relative to non-involved side for a patient). Inter-subject comparability refers to the possibility to compare outcome measures between subjects across one population. Intra-group comparability refers to comparison of outcome measures between one or more subgroups within one specific population (e.g. comparing scores between the subgroup with dominant side involvement and the subgroup with non-dominant side involvement, or between chronic and acute subgroups). Inter-group comparability refers to the possibility to compare outcome measures between various populations (e.g. comparing scores between CRPSI and other patient groups or a healthy population). Finally, norm score comparison refers to whether population norm scores were available.

Table 7. 1: Overview of several characteristics of the ULAM and four questionnaires. If an instrument partly measured other aspects in addition to the main aspect, this is indicated by 'partly' between brackets. It was not possible to classify ULAM outcome measures according to health-related quality of life (HRQoL) domains because these domains represent functioning as subjectively perceived by the study population.

Characteristic / Instrument	ULAM	RASQ	DASH	RAND-36	SIP-68
Measurement technique	Ambulatory monitoring	Questionnaire	Questionnaire	Questionnaire	Questionnaire
Type of instrument: Generic (G), body-part specific (BPS), condition specific (CS)	G, BPS	BPS, CS (partly)	BPS, G (partly) CS (partly)	G, BPS (partly)	G, BPS (partly)
Health-related quality of life (HRQoL) domain: physical & occupational function (POF), psychological state (PS), social interaction (SI), somatic sensation (SS)	POF, SI (partly)	POF	POF, PS (partly), SI (partly), SS (partly)	POF, PS, SI, SS	POF, PS, SI
International Classification of Functioning (ICF) level: function & structure (FS), activity (A), participation (P)	A, P (partly)	A	A, FS (partly), P (partly)	A, P, FS (partly)	A, P
Performance (P), capacity (C)	P	P, C (partly)	C	C, P (partly)	P, C (partly)
Possibility to compare in upper limb population: intrasubject (intraS), intersubject (interS) intragroup (intraG), intergroup (interG), norm scores (Nscores)	intraS, interS, intraG, interG, Nscores	InterS, intraG	interS, intraG, interG	interS, intraG, interG, Nscores	interS, intraG, interG

Protocol

The study was approved by the local Ethical Committee and all subjects gave informed consent. All measurements took place in the subjects' home environment. On the first day, the ULAM was fitted and subsequently worn for 24 hours. Subjects were instructed to continue their usual everyday life, but not to swim, bath or shower. The next day, the ULAM was removed and the exact measurement technique was explained. Then, the four questionnaires were administered.

Data-analysis and statistics

Descriptive statistics and Spearman rank correlations were calculated (significance level $p \leq 0.05$). First, correlations were calculated between the ULAM outcome measures and the questionnaire sum and total scores to determine the degree of relationship between the instruments. Then, inter-questionnaire correlations were calculated between the mutual questionnaire sum and total scores to determine the relationship between the four questionnaires. In addition, correlations between the mutual ULAM outcome measures were calculated. Finally, because the ULAM mainly measures at the ICF activity level, the questionnaire outcome measures were classified according to the ICF level and correlations were calculated between these classified questionnaire outcome measures and the ULAM outcome measures to establish whether relationships differed depending on the ICF level.

7.4 Results

Descriptive statistics (table 7.2) showed that the results of the generic questionnaires tended to show better functioning (i.e. absence of activity limitations and participation restrictions) rather than worse functioning. The body-part specific questionnaire scores indicated worse functioning than the generic questionnaires. The RASQ-ra, RASQ-w and RASQ-da, RAND36-prl, RAND36-bp and RAND36-pf, SIP68-mc and SIP68-sb scores were the worst. The SIP68-psss sum score expressed worse functioning than the SIP68-phss sum score.

Table 7.2: Descriptive statistics for all five instruments and their outcome measures.

*^ The possible range is not specified for ULAM scores because the theoretical range for outcome measures involving percentages is from 100 to 0%, whereas this range is from ∞ to 0 g for outcome measures involving intensity. For each ULAM outcome measure, a higher score refers to better functioning. # An unweighted mean across all eight RAND36 outcome measure scores was used as additional outcome measure. However, the RAND36 'change in health' score was not taken into account in this chronic CRPSI population which explains the 35 items for RAND36-tot. * These are the population mean norm scores of a Dutch population for the RAND36 outcome measures [58].*

Instrument & Outcome measures (number of items)		Abbreviation	Possible range [best – worst functioning]	Mean score	Actual range
RASQ					
RASQ-total (45)		RASQ-tot	1-5	2.8	1.7-4.0
Personal care (13)		RASQ-pc	1-5	2.3	1.0-3.5
Domestic activities (19)		RASQ-da	1-5	3.2	1.8-4.2
Recreational activities (2)		RASQ-ra	1-5	4.1	1.0-5.0
Social activities (3)		RASQ-sa	1-5	2.4	1.0-5.0
Other items (7)		RASQ-oi	1-5	2.6	1.0-4.7
Work (1)		RASQ-w	1-5	3.8	2.0-5.0
DASH					
Function Symptoms Score (30)		DASH-fss	0-100	43.3	16.7-68.3
RAND-36 / SF-36					
RAND-36 total score (35#)	Nscores: *	RAND36-tot	100-0	67.2	95.3-34.9
Physical functioning (10)	81.9	RAND36-pf	100-0	67.7	90.0-20.0
Social functioning (2)	86.9	RAND36-sf	100-0	85.0	100.0-25.0
Physical role limitations (4)	79.4	RAND36-prl	100-0	32.5	100.0-0.0
Emotional role limitations (3)	84.1	RAND36-erl	100-0	81.1	100.0-0.0
Mental health (5)	76.8	RAND36-mh	100-0	79.6	100.0-36.0
Vitality (4)	67.4	RAND36-vit	100-0	68.8	100.0-10.0
Bodily Pain (2)	79.5	RAND36-bp	100-0	54.5	100.0-22.4
General health perception (5)	72.7	RAND36-ghp	100-0	68.7	90.0-20.0
SIP68					
SIP68-total (68)		SIP68-tot	0-68	9.1	1-22
Somatic autonomy (17)		SIP68-sa	0-17	0.8	0-5
Mobility control (12)		SIP68-mc	0-12	2.8	1-8
Psychological autonomy and communication (11)		SIP68-pa	0-11	1.1	0-10
Social behaviour (12)		SIP68-sb	0-12	3.2	0-7
Emotional stability (6)		SIP68-es	0-6	0.7	0-4
Mobility range (10)		SIP68-mr	0-10	0.6	0-4
Physical sum score (39)		SIP68-phss	0-39	4.1	1-14
Psychosocial sum score (29)		SIP68-psss	0-29	5.0	0-17
ULAM					
Percentage spent in dynamic mobility-related activities		ULAM-%dyn	^	11.3	3.1-24.0
Mean intensity of body activity		ULAM-body	^	2.3	0.8-4.5
Mean activity intensity involved limb during sitting		ULAM-isit	^	3.1	1.5-5.2
Mean activity intensity involved limb during standing		ULAM-istand	^	10.0	4.5-17.4
Percentage of activity involved limb during sitting		ULAM-%sit	^	29.2	13.3-46.6
Percentage of activity involved limb during standing		ULAM-%stand	^	73.0	40.1-89.1

Appendix for Table 7.2:

ULAM:

The generic ULAM outcome measure ULAM-%dyn represents the percentage of the 24-hour measurement period spent in dynamic mobility-related activities (i.e. walking, cycling, general non-cyclic movement) and ULAM-body describes the mean intensity of body activity (in g, ms^{-2}), which can be regarded as a general measure for the intensity of everyday physical activity. The body-part specific ULAM outcome measures ULAM-isit and ULAM-istand represent the mean intensity of upper limb activity of the involved side, expressed in mean (scaled) motility values during the time the involved upper limb was active while the subjects were sitting and standing, respectively. ULAM-%sit and ULAM-%stand represent the percentage of upper limb activity of the involved side, expressed as the percentage of the time that the involved upper limb was active (i.e. exceeding a certain threshold in the motility value) while the subjects were sitting and standing, respectively. The lower the scores, the worse the functioning.

RASQ:

The RASQ outcome measure RASQ-pc describes items related to personal hygiene, getting dressed and eating/drinking [19]. RASQ-da describes items related to housekeeping, meal preparation and taking care of clothes. RASQ-ra contains items related to sports and hobbies and RASQ-sa items related to going out, on holiday/vacation and playing with children or pets. The RASQ-oi score describes items related to communication (e.g. writing and typing) and transportation (bicycle, car, public). The RASQ-w score refers to performing occupation (excluding household activities). For each item, subjects score from 1 (normal) to 5 (not done anymore) and for each outcome measure a mean across the various items is calculated, with a lower mean score representing better functioning.

DASH:

The DASH function symptoms score (DASH-fss) includes 21 activity items (e.g. prepare a meal, lock a door, similar to RASQ items), 6 body structure and function items (e.g. pain, tingling) and 3 participation items (e.g. undertaking activities with friends and family) [48]. Scores are transformed into a score ranging from 0-100, with a lower score indicating better functioning.

RAND36:

The RAND36-pf score contains items such as walking (stairs), washing up, getting dressed, lifting a heavy bag. The RAND36-sf score describes the influence of physical and/or emotional problems on undertaking activities with friends and family. The RAND36-prl score refers to whether physical problems interfere with the amount of time spent with (specific kinds of) work or other engagements, satisfaction with what is accomplished and the effort it costs, while the RAND36-erl score refers to whether emotional problems due to the disorder interfere with the amount of time spent with and careful execution of work or other engagements, and satisfaction with what is accomplished [58]. Each outcome measure is expressed as a score ranging from 100-0, with a higher score representing better functioning.

SIP68:

The SIP68-sa score describes the level at which an individual is autonomous in his or her basic somatic functioning (getting dressed, standing, walking, eating and the fact that help is needed). SIP68-mc describes behaviour related to the level to which an individual has control over his or her body (walking and arm-hand control). SIP68-pa describes behaviour associated with the level to which an individual is able to function without help of others in areas of mental functioning (including communication). SIP68-sb describes a persons´ functioning in relation to other persons (sexual activity, visiting friends and activities in groups of people among others). SIP68-es assesses the effect health status has on the emotional status of a subject

(irritability and acting disagreeably). SIP68-mr describes the influence of health status on a number of usual tasks like shopping, housecleaning and taking care of personal affairs (the range of actions to which a subject has limited disposition). The physical sum score SIP68-phss consists of SIP68-sa, SIP68-mc and SIP68-mr and the psychosocial sum score SIP68-psss consists of SIP68-pa, SIP68-es and SIP68-sb [68]. To calculate the SIP68 score, only those items that a subject was sure to describe the current health situation were added up, with a higher score indicating worst functioning.

Fourteen of the 36 correlations (14/36, 39%) calculated between the ULAM outcome measures and the sum and total scores of the questionnaires (table 7.3) were significant. One correlation coefficient exceeded 0.6 (3%). The body-part specific ULAM outcome measures related to activity of the involved upper limb during sitting were most often (8/12, 67%) significantly related to the questionnaire sum and total scores, whereas the same measures during standing (1/12, 8%) were less often related. Of the questionnaire outcome measures, the DASH-fss was most often significantly related to the generic and specific ULAM outcome measures.

Table 7.3: Significant Spearman rank correlations between ULAM outcome measures and the sum and total scores of the questionnaires. Please note that the absolute values of the significant correlations are shown.

		Generic		Body-part specific			
		ULAM-%dyn	ULAM-body	ULAM-isit	ULAM-%sit	ULAM-istand	ULAM-%stand
Body-part specific total scores	RASQ-tot	-	-	0.48	0.41	-	-
	DASH-fss	0.41	0.36	0.48	0.45	-	-
Generic sum and total scores	RAND36-tot	-	-	0.57	0.53	0.43	-
	SIP68-phss	0.69	0.60	-	-	-	-
	SIP68-psss	-	-	0.39	-	-	-
	SIP68-tot	0.38	-	0.38	-	-	-

Thirteen of the 15 inter-questionnaire correlations (13/15, 87%) were significant (table 7.4); 7 of these 15 (47%) had a correlation coefficient higher than 0.6.The RAND36-tot – RASQ-tot and SIP68-psss – SIP68-phss correlations were not significant (R_s=0.36, p=0.053 and R_s=0.36 p=0.052, respectively). The two ULAM generic outcome measures were significantly inter-related (R_s=0.92, p=0.000), as were the four ULAM body-part specific outcome measures ($0.53<R_s<0.93$). The correlations between the ULAM generic and ULAM body-part specific outcome measures were not significant ($0.03<R_s<0.26$).

Table 7.4: Significant Spearman rank inter-questionnaire correlations between the sum and total scores and respective p-values. Please note that the absolute values of the correlation coefficients are shown.

Spearman R_s x p-value		Body-part specific		Generic			
		RASQ-tot	DASH-fss	RAND36-tot	SIP68-tot	SIP68-phss	SIP68-psss
Sum and total scores	RASQ-tot	x	0.74	-	0.53	0.48	0.52
	DASH-fss	0.000	x	0.43	0.68	0.55	0.68
	RAND36-tot	-	0.018	x	0.64	0.49	0.61
	SIP68-tot	0.003	0.000	0.000	x	0.72	0.87
	SIP68-phss	0.007	0.000	0.006	0.000	x	-
	SIP68-psss	0.003	0.002	0.000	0.000	-	x

Seventeen of the 42 correlations (40%, 5% of these had a R_s>0.6) between ULAM outcome measures and the questionnaire outcome measures at the ICF activity level were significant (table 7.5, Part A). There were more significant correlations between generic ULAM outcome measures and the questionnaire outcome measures at this ICF activity level (9/14, 64%) than between body-part specific ULAM outcome measures and these questionnaire outcome measures (8/28, 29%). Again, the questionnaire outcome measures at this ICF level were more often significantly related to ULAM body-part specific outcome measures during sitting (7/14, 50%) than during standing (1/14, 7%). The RASQ-tot and SIP68-sb scores were not related to the two generic ULAM outcome measures and the RAND36-pf, SIP68-mc and SIP68-mr scores were not related to any of the four body-part specific ULAM outcome measures.

Fourteen of the 42 correlations (33%) between ULAM outcome measures and the questionnaire outcome measures at the ICF participation level were significant (table 7.5, Part B). There were far less significant correlations between generic ULAM outcome measures and the questionnaire outcome measures at this ICF participation level (1/14, 7%) than between body-part specific ULAM outcome measures and these questionnaire outcome measures (13/28, 46%). The RAND36-prl and SIP68-es scores were not related to any of the ULAM outcome measures, whereas the RAND36-sf and RAND36-vit scores were significantly related to each of the four body-part specific ULAM outcome measures. In contrast with the results of table 7.3 and table 7.5A, no relevant differences between sitting and standing were found with respect to the number of significant correlations between the questionnaire outcome measures and the ULAM body-part specific outcome measures.

Table 7.5: Significant Spearman rank correlations between ULAM outcome measures and the questionnaire outcome measures that measure at the ICF activity level (Part A) and between ULAM outcome measures and the questionnaire outcome measures that measure at the ICF participation level (Part B). Outcome measures that mainly contained items beyond activity and participation levels were not classified. Please note that the absolute values of the significant correlations are shown.

		Generic		Body-part specific			
		ULAM-%dyn	ULAM-body	ULAM-isit	ULAM-%sit	ULAM-istand	ULAM-%stand
ICF activity level *Part A*	RASQ-tot	-	-	0.48	0.41	-	-
	DASH-fss	0.41	0.36	0.48	0.45	-	-
	RAND36-pf	0.41	-	-	-	-	-
	SIP68-sa	0.48	0.46	0.38	0.41	-	-
	SIP68-mc	0.68	0.59	-	-	-	-
	SIP68-sb	-	-	0.45	-	0.40	-
	SIP68-mr	0.61	0.55	-	-	-	-
ICF participation level *Part B*	RAND36-sf	-	-	0.60	0.64	0.57	0.45
	RAND36-prl	-	-	-	-	-	-
	RAND36-erl	-	-	-	-	0.53	-
	RAND36-mh	0.40	-	0.43	0.39	-	-
	RAND36-vit	-	-	0.69	0.68	0.48	0.41
	SIP68-sb	-	-	0.45	-	0.40	-
	SIP68-es	-	-	-	-	-	-

7.5 Discussion

Although the body-part specific questionnaires indicated worse problems with functioning than the generic questionnaires, these 30 chronic upper limb CRPSI subjects did not generally perceive their functioning as very limited or restricted. Descriptive statistics were in accordance with other studies [21, 22, 40]; most SIP68 outcome measures had little value in upper limb CRPSI and only a few RAND36 outcome measures were worse than the Dutch norm population [53].

The structure of this study was based on two main assumptions; first, ULAM measures will be related to scores from questionnaires, but this relationship will be weak, and weaker than the mutual relationships between questionnaires. Second, relationships will be stronger between outcome measures that are aimed at the same aspects of functioning. Because the ULAM aims at measuring roughly the same concept as the questionnaires (i.e. functioning), but is at the same time different in many aspects, we expected no ($p > 0.05$) or weak ($R_s < 0.5$) relationships. Because the difference between questionnaires is smaller than the difference between ULAM

and questionnaires, we expected stronger and more significant relationships between questionnaires. We realise that especially our “correlation threshold” of 0.5 is arbitrary, but regarded from the percentage of the variability that is ‘explained’ by the relationship between two outcome measures ($100r^2$) we consider this choice to be reasonable. For example, the significant correlation between ULAM-isit and RASQ-tot (R_s=0.48, p=0.008) implies that only about 23% of the variability may be explained by this relationship. Furthermore, the level of the threshold does not influence the conclusions drawn from this study. The data clearly support the first assumption: generally the relationships between ULAM measures and questionnaire scores were non-significant or weak, whereas significant and stronger relationships were more often found between questionnaire scores. This supports our hypothesis that the ULAM significantly differs from questionnaires, with the difference between actual behaviour and perceived functioning probably being the most important. The difference or discrepancy between these two aspects of functioning is described in literature: e.g. health care professionals do not always agree with patients when it concerns their self-perceived functioning [54, 55].

From the second assumption it was expected that ULAM measures and scores from questionnaires focused on the same aspect(s) of functioning would have stronger relationships than measures and scores focused on different aspects. Therefore, it was expected that mutual correlations between generic outcome measures would be relatively strong. This was indeed true for ULAM correlations with SIP68-phss, but not for ULAM correlations with SIP68-psss and RAND36-tot. One of the factors that may explain this finding is that the ULAM differs considerably from the SIP68-psss and RAND36-tot in other aspects. For example, there is more similarity with respect to HRQoL domains between SIP68-phss and ULAM than between ULAM and SIP68-psss or RAND36-tot. Furthermore, the RAND36-tot and SIP68-psss are generally aimed more at measuring ICF participation level (and beyond) than activity level. Finally, both ULAM and SIP68 score the subject’s performance rather than their capacity, whereas the RAND-36 clearly stresses capacity. Apparently, the more characteristics generic questionnaires have in common with the ULAM, the stronger the correlations, which supported the second assumption. This conclusion is additionally supported by significant correlations between the generic items containing DASH-fss and the two generic ULAM outcome measures versus the lack of significant correlations between the plain body-part specific RASQ-tot and these ULAM outcome measures.

With the same type of reasoning it was expected that the DASH-fss would be more strongly correlated with body-part specific ULAM outcome measures than with generic ULAM outcome measures. This was true, but only for the ULAM body-part specific outcome measures during sitting. Since subjects with upper limb CRPSI were investigated, the correlations between mutual body-part specific outcome measures were of primary importance and expected to be significant. Hence, it was striking that the correlations between body-part specific questionnaire outcome

measures were all significant with the ULAM outcome measures during sitting, whereas none was significant during standing. This unexpected finding was reinforced by the proportion of questionnaire items; far more items describe upper limb activity during standing than during sitting, which would lead one to expect opposite results. Although it has been shown that the impact of upper limb CRPSI on ULAM outcome measures was somewhat greater during sitting than during standing [11], unfortunately this cannot adequately explain the present findings.

An important factor still to be discussed is the ICF level. Classification of questionnaire outcome measures according to the ICF resulted in a remarkable pattern of correlations between the ULAM and questionnaires. The lack of significant correlations between generic ULAM outcome measures and questionnaire outcome measures at the participation level is most probably due to differences in ICF level; the ULAM mainly measures activity, whereas these generic questionnaire outcome measures mainly measure participation. The strikingly large number of significant correlations between questionnaire participation outcome measures and ULAM outcome measures *during standing* was difficult to explain because both groups of outcome measures have major differences with regard to type of instrument, ICF level, and problems with functioning (ULAM is body-part specific, at activity level and shown to be limited in CRPSI [11], whereas questionnaires were generic, at participation level, and not perceived as limited). It may be that when subjects are questioned about their functioning, aspects of activity and of participation and even beyond (i.e. HRQoL) are taken into account, whether subjects realise this or not. Such latter aspects can of course not be measured with the ULAM, but may perhaps to some degree be reflected in its outcome measures. The concept activity is generally less broadly defined than the concept participation [56, 57], which was also confirmed by the present inter-questionnaire correlations. Questionnaire outcome measures at the activity level were more often significantly inter-related than the questionnaire outcome measures at the participation level.

It should be noted that the ULAM also has some limitations that may affect methodological quality [6, 11, 52, 58]. For example, the current ULAM does not validly measure fine motor skills and holding of objects and is therefore a rather rough outcome measure. Another possible limitation related to (test-retest-)reliability is the 'between-day variance of upper limb activity'. Unfortunately, this measure for biological variability of upper limb usage has not yet been fully studied because only 24-hour measurements have so far been performed. However, previous 48-hour measurements with the ULAM´s `older brother` the AM [59, 60] have shown that between-day variance for (ULAM-)%dyn and (ULAM-)body was small and not significantly different between the first and second 24 hours, both in patients and in healthy subjects. But this is of course no guarantee for biological variability of upper limb usage. Although there certainly are some differences in methodological quality (reliability and validity aspects) between the presently used questionnaires, it is clear that their methodological strengths and weaknesses can be compared. In contrast,

the aspects of methodological quality of the ULAM are less easily applicable to questionnaires and the ULAM can therefore only in part be compared with the questionnaires, which may also explain the ambiguous relationships between ULAM and questionnaire outcome measures.

Finally, it is important to realise that the present findings should not be confused with the idea that the ULAM is a new reference method and that measurement of what a person really does during everyday life is most important. The ULAM should be regarded as a relevant and valuable addition to other techniques; however, we agree with others [61-63] that the choice for an instrument should always depend on a complexity of factors, including clinical problem, research question and study design, activity aspects of interest, and cost and availability of instruments [4].

7.6 Conclusion

Generally the relationships between ULAM measures and questionnaire scores were non-significant or weak, whereas more often significant and stronger relationships were found between questionnaire scores. This supports our hypothesis that the ULAM measures similar aspects of functioning only to a certain extent. It also appeared that the more characteristics the instruments and outcome measures had in common, the stronger and more often significant the correlations were. From the findings it may be concluded that the ULAM has a distinct place in the field of outcome assessment; it offers an alternative but important insight into the impact a disorder may have on a subject's functioning.

7.7 References

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