Corticosteroid injections for the treatment of hand and wrist disorders in general practice

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Chapter 7

Psychometric properties of a Dutch version of the Boston Carpal Tunnel Questionnaire

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Abstract

Objectives

To assess indices of reliability, responsiveness and interpretability of a Dutch translation of the Boston Carpal Tunnel Questionnaire (BCTQ).

Methods

The BCTQ is a validated instrument for assessing symptom severity and functional status in carpal tunnel syndrome. We translated the BCTQ into Dutch and investigated the psychometric properties internal consistency, responsiveness and floor and ceiling effects, using data from a randomized controlled trial that assessed effectiveness of local corticosteroid injections for carpal tunnel syndrome in primary care.

Results

Internal consistency was demonstrated by a Cronbach's alpha of 0.86 (95% CI: 0.81-0.91) for the symptom subscale and 0.92 (95% CI: 0.88-0.94) for the functional subscale. Responsiveness was assessed by calculating the standard error of measurement (SEM) and minimal important change (MIC) which were respectively 3.15 and 0.29 for the symptom subscale and respectively 2.34 and 0.29 for the functional subscale of the BCTQ.
The area under the curve of the receiver operating curve was 0.80 (95% CI: 0.67-0.92) for the symptom subscale and 0.70 (95% CI: 0.56-0.83) for the functional subscale using the outcome treatment response as reference standard. Minimal Clinically Important Difference (MCID) was 0.68 for the symptom subscale and 0.31 for the functional subscale using treatment success as an external criterion and respectively 0.50 and 0.05 using patient perceived improvement as an external criterion. No significant floor or ceiling effects were observed.

Conclusions

The Dutch BCTQ has appropriate internal consistency, is responsive and showed no floor or ceiling effects. Minimal Important Clinical Difference (MCID) ranged from 0.50 to 0.68 for the BCTQ-SSS and from 0.05 to 0.31 for the BCTQ-FSS. Therefore it is a valid and reliable tool for assessment of symptom severity and functional status in participants with carpal tunnel syndrome.

Introduction

Carpal tunnel syndrome (CTS) is a condition caused by compression of the median nerve in the wrist. It leads to, mostly nocturnal, numbness and paresthesia of the hand and fingers. Often it is also associated with pain in the hand and wrist, sometimes even radiating to more proximal areas of the arm. The prevalence of CTS in the general population has been estimated to be 3-9%. Symptoms may lead to impaired function of the wrist and hand and thus cause significant costs due to absence from work. CTS can be treated by local corticosteroid injection or splinting or surgical decompression.

There is no reference standard for the diagnosis of CTS and in consensus statements and practice guidelines it is advised to establish the diagnosis using a combination of symptoms, signs and results of electrodiagnostic studies.

In CTS-research outcome measures from a wide range of domains, such as patient reported symptom severity and functional disability scores, results of clinical tests assessing sensibility and motor function, results of electrodiagnostic studies and time taken to return to work are used. This diversity reflects the impact of CTS on various aspects of health, but may also reflect a lack of consensus among clinicians and researchers regarding the outcome measures that are most valid and relevant in the assessment of effectiveness of interventions for CTS. Therefore a standardized set of outcome measures for assessment of CTS would be welcome[1].

Patient Reported Outcomes (PRO) are increasingly regarded as a critical measure in clinical research because they reflect the impact of disease and its treatment from the patient's perspective and therefore have the potential to facilitate patient involvement in treatment decision-making[2]. Criteria that are thought to be important when selecting PRO-measures are appropriateness, reliability (test-retest reliability, internal consistency), validity, responsiveness, interpretability, floor and ceiling effects, acceptability and feasibility[3]. In the past few years an increasing number of systematic reviews of health-related quality of life questionnaires have been published and quality criteria for measurement properties of health status questionnaires using PRO-measures were proposed[4].

The psychometric properties of several patient-reported generic questionnaires that have been used in patients with CTS (Disability of Arm, Hand and Shoulder Questionnaire, Patient Evaluation Measure and Michigan Hand Outcomes Questionnaire) and disease-specific questionnaires (Historical Objective scale and Boston Carpal Tunnel Questionnaire) have been described[5 6].

The Boston Carpal Tunnel Questionnaire (BCTQ), also known as Brigham and Women's Hospital Carpal Tunnel Questionnaire and Boston Questionnaire was developed by Levine et al. for assessment of severity of symptoms and functional status in patients with carpal tunnel syndrome[7]. De Carvalho Leite et al. performed a systematic review of psychometric properties of the BCTQ and concluded that it is a valid, reliable, responsive and acceptable instrument for assessing outcomes in CTS[8]. The BCTQ has been translated, culturally adapted and evaluated for use in Hong Kong Chinese, Japanese, Portuguese, Spanish, Swedish, Thai and Turkish speaking populations (appendix 1)[9-14]. Recently, results were published on the reproducibility and responsiveness of a Dutch version of the symptom severity subscale of the BCTQ for a primary care population with hand and wrist complaints, and found to be adequate[15].

Since these data were not yet available when we started our study, we also translated the BCTQ into Dutch with the help of a native speaker. The questionnaire was used in a randomized controlled trial investigating the effectiveness of local corticosteroid injections for the treatment of CTS in general practice (HAWITT-trial, trial registration number: ISRCTN 53171398). We subsequently investigated aspects of validity, reliability and responsiveness of this Dutch translation of the Boston Carpal Tunnel Questionnaire.

Methods

Study population
The Groningen Hand and Wrist Injection Therapy (HAWITT) trial investigated efficacy and safety of local corticosteroid injections carpal tunnel syndrome in general practice. In this double-blind, placebo-controlled randomised trial participants were treated with injection of either 1 ml of triamcinolonacetonide 10 mg/ml or 1 ml 0,9% NaCl. Outcomes were assessed at two weeks, one month, three months, six months and twelve months after injection. Patients presenting to participating general practitioners in the northern part of the Netherlands with symptoms and signs suggestive of carpal tunnel syndrome were eligible for inclusion. Exclusion criteria were thenar atrophy, being less than 18 years of age, presence of contraindications for corticosteroid injection, prior treatment for CTS in the last six months with steroid injection or surgery, traumatic or neoplastic origin of symptoms, inability to fill in follow-up questionnaires, or absence of self-determination in the participant. The symptom severity and functional status scales of the Boston Carpal Tunnel Questionnaire, short-term treatment response to injection and improvement in symptoms as perceived by participants were used as primary outcome measures. We used baseline and post-intervention (2 weeks after injection) data of all 69 participants with carpal tunnel syndrome enrolled in the trial during the recruitment period of 33 months (February 2003 to October 2005) to validate our Dutch translation of the Boston Carpal Tunnel Questionnaire.

Outcome measures

Boston Carpal Tunnel Questionnaire
The BCTQ is a disease-specific questionnaire of self-reported symptom severity and functional status and has been developed specifically for patients with CTS. The six domains that are covered are pain, paresthesia, numbness, weakness, nocturnal symptoms and overall functional status of the hand and wrist.
The questionnaire is divided into two parts: the symptom severity scale and the functional status scale. The symptom severity scale has 11 items, the functional status scale 8 items and both use a 5-point rating scale. The sum of individual item scores is divided by the number of items for each of the two scales and higher scores indicate more severe symptoms and greater disability. The final score of each of the two subscales may range from 1 to 5.

Treatment response
The outcome treatment response was measured using a 4-point numeric rating scale, based on consensus between treating general practitioner and participant: 0 = no

response, warranting further treatment; 1 = partial not satisfactory response, warranting further treatment; 2 = partial satisfactory response, not warranting further treatment; 3 = complete resolution of symptoms, not warranting further treatment.

Patient perceived improvement

Improvement after treatment as perceived by participants was recorded by using a 5-point transition scale: -2 = much worse; -1 = worse; 0 = not better, not worse; 1 = better; 2 = much better.

Analysis

Internal consistency of the two subscales of the BCTQ was determined by using the baseline data of all participants of the HAWITT trial and calculating Cronbach's alpha for the symptom and functional subscale. A Cronbach's alpha between 0.70 and 0.95 is regarded as appropriate.

Floor and ceiling effects of the symptom and functional subscale were investigated by calculating the percentages of respondents who achieved the lowest or highest possible scores on both scales at baseline. If more than 15% of participants achieved the lowest or highest possible scores, floor and ceiling effects were considered to be present.

Effect-size and effect size for difference for both subscales were derived from mean change scores of the outcome treatment response.

To determine indices of responsiveness of the symptom and functional subscale of the BCTQ the pre-intervention and post-intervention (two weeks after the last injection) outcomes for treatment response of participants of the HAWITT-trial were used. We first calculated the Standard Error of Measurement (SEM), which is a measure of responsiveness, when defined as the ability to detect change in general. The SEM was calculated using the formula: $SD_{scale}*\sqrt{(1-Crohnbach's\ alpha)}$. Thereafter, the Minimally Important Change (MIC) was calculated by dividing the SEM by the number of scale items. The MIC is another measure of responsiveness, when defined as the ability to detect change in general.

The area under the Receiver Operating characteristics Curve (ROC) was generated for changes scores of the symptom and functional subscale using treatment response and patient perceived improvement as external criteria. The Area Under the receiver operating characteristics Curve (AUC) is considered to be a measure of responsiveness, when defined as the ability to discriminate between patients with and without treatment response (or with and without perceived improvement)[16]. An AUC of 0.70 is considered to be an adequate outcome for responsiveness.

Finally, cut-off points for changes on both scales of the BCTQ showing optimal combinations of sensitivity and specificity were determined, which can be considered as estimates of Minimal Clinically Important Difference (MCID, a measure of responsiveness, defined as the ability to detect clinically important change) using the Youden-method[17]. Jaeschke et al. have defined MCID as the smallest difference in a score in a domain of interest that patients perceive as beneficial and that would mandate, in the absence of side-effects and a change in the patient's management[18]. To calculate values for MCID the outcomes treatment response and patient perceived improvement were used as two different external anchors.

Missing values were imputed based on the available follow-up scores using the EM algorithm, assuming that missing data occurred completely at random (MCAR)[19].

Results

Cronbach's alpha was 0.86 (95% CI: 0.81-0.91) for the symptom subscale and 0.92 (95% CI: 0.88-0.94) for the functional subscale and did not improve by deletion of single items on any of the two scales.

No significant floor or ceiling effects were observed, since for the symptom subscale only 1,5 % of participants had the highest score and 1,5 % the lowest score and for the functional subscale 9.1 % had the highest score and 3.0 % the lowest score.

Mean change score for the symptom subscale between baseline and short-term assessment was 0.92 (95% CI: 0.68-1.17), the effect size 1.18 and the effect size for difference 0.81. Mean change score between baseline and short-term assessment for the functional subscale was 0.58 (95% CI: 0.28-0.87), the effect size 0.65 and the effect size for difference 0.57.

The SEM was 3.15 and the MIC 0.29 for the symptom subscale. For the functional subscale the SEM was 2.34 and the MIC was found to be 0.29.

When treatment success was used as an external criterion the area under the curve of the ROC-curve was 0.80 (95% CI: 0.67-0.92) for the symptom subscale and 0.70 (95% CI: 0.56-0.83) for the functional subscale (figure 1a). When patient perceived improvement was used as an external criterion the area under the curve of the ROC-curve was 0.76 (95% CI: 0.67-0.92) for the symptom subscale and 0.70 (95% CI: 0.56-0.83) for the functional subscale (figure 1b). When treatment success was used as an external anchor the MCID was found to be 0.68 for the symptom subscale and when perceived improvement was used as an external anchor the MCID was 0.50. For the functional subscale the MCID was 0.31 when treatment success was used as an external anchor and 0.05 when perceived improvement was used as an external anchor.

Discussion

Our results indicate good internal consistency and adequate responsiveness for our Dutch translation of the Boston Carpal Tunnel Questionnaire in participants with a clinical diagnosis of CTS who were treated with injections in the setting of general practice. We did not observe any floor and ceiling effects for both subscales of the BCTQ. Responsiveness was studied by us using both distribution-based and anchor-based methods and sensitivity to change was found to be adequate. Interpretability was investigated by us by determining the MCID, which ranged from 0.50 to 0.68 for the symptom subscale and from 0.05 to 0.31 for the functional subscale of the BCTQ, depending on the external anchor that was used.

None of the previous studies assessing measurement properties of the BCTQ investigated all aspects of validity but it was done to varying degree and all seem to confirm validity regarding critical measurement properties such as reliability, construct validity and responsiveness of the BCTQ in different settings (1 primary care, 15 secondary care), for different interventions (7 surgery, 1 corticosteroid injection) and for translations in different languages and cultural settings (Hong Kong Chinese, Japanese, Portuguese, Spanish, Swedish, Thai and Turkish) (see appendix 1). We found in our study a MCID for the symptom subscale of 0.50-0.68 which was higher than the MCID (0.23) reported Spies-Dorgelo et al. who analyzed a cohort of participants with wrist complaints in primary care (the score of 7-point rating scale for change in ability to perform daily activities was used as external criterion) and lower than in the study by Ozyurekoglu et al. (1.04), who included participants with CTS in

secondary care who where treated with corticosteroid injections in secondary care (treatment response to steroid injection was used as an external criterion)[15 20]. These differences in MCID may have been caused by the different anchors that were used in the three studies or the different populations and healthcare settings which were used to calculate the MCID.

With the outcomes we found for different aspects of validity it can be concluded that our Dutch translation is a valid, reliable and responsive tool for measuring symptom severity and functional status for evaluative purposes in participants with CTS in Dutch speaking populations.

Funding

Competing interests

Acknowledgements

Tables

Table 1. Clinical and demographic characteristics of study population

		NaCl (n=33)	TCA(n=36)	Total (n=69)
mean age (SD)		57.6	56,2	56.92 (30.21)
Sex (female/male)		26/7	27/9	53/16
mean duration of symptoms (weeks; P25,P75)		29	76	25.5 (7.8,52)
repetitive movements of hands		10/22	15/18	25/40
affected hand/ arm (right/ left)		21/9	18/14	39/23
dexterity (right/ left)		32/0	31/3	63/3
quality of symptoms:	a. dull aching discomfort arm/hand	25	28	53
	b. weakness/ clumsiness hand	22	23	45
	c. paresthesia hand	30	35	65
	d. nocturnal complaints	28	32	60
	e. presence of relieving factors	25	25	50
	f. presence of provocative factors	30	31	61
score Katz hand diagram				
	classic	12	11	23
	probable	19	22	41
	unlikely	1	2	3
mean BCTQ symptom score (SD)		2.8	3.0	2.86 (0.78)
mean BCTQ functional score (SD)		2.3	2.5	2.42 (1.03)
comorbidity				
	diabetes	0	1	1
	hypothyroidism	2	2	4
	rheumatoid arthritis	1	1	2
	pregnancy	0	1	1

Figures

Figure 1a. ROC-curve, when treatment response was used as an external criterion

ROC Curve

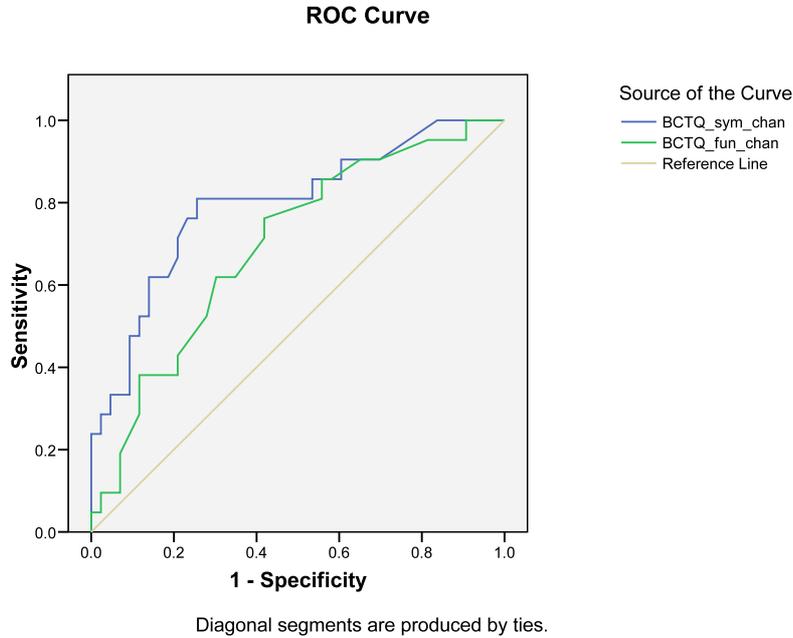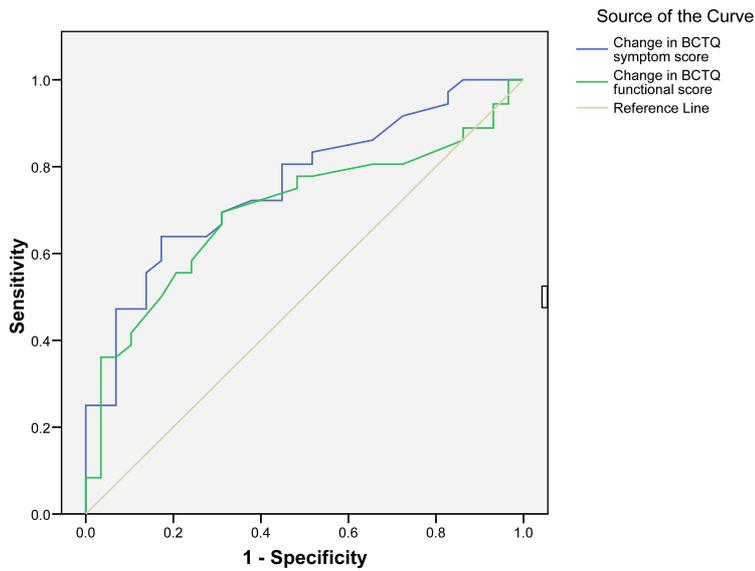Diagonal segments are produced by ties.

Figure 1b. ROC-curve, when patient perceived improvement was used as an external criterion

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Appendix 1: Studies that assessed psychometric properties of the BCTQ

(adapted from Leite et al.[8])

study (year)	number of participants/ setting/ language/ intervention	psychometric property assessed						floor or ceiling effects
		content validity	internal consistency	construct validity	agreement	reliability (reproducibility)	responsiveness	
Amadio (1996)	n=22, secondary care US English surgery	?	?	?	?	?	SSS: SRM=1.26 FSS: SRM=1.75 (n=22)	?
Atroshi (1998)	n=102 secondary care swedish, surgery	?	+(n=102)	+(n=48)	?	+ (n=22)	SSS: ES=2.1 SSS: SRM=1.7 FSS: ES 0.94 SSS: SRM= 0.94 (n=102)	?
Bessette (1998) {Bessette, 1998 #15}	n=196 secondary care US english	?	?	?	?	?	SSS+FSS: ES=1.67 SSS+FSS: SRM=1.39 (n=196)	?
de Campos (2003)	n=50 secondary care portuguese surgery	?	+(n=50)	+(n=23)	?	+ (n=50)	?	?
Fok (2007)	n=50 secondary care Hong Kong Chinese	?	+	?	?	+	?	?
Gay (2003)	n=34 secondary care US English	?	?	+	?	?	SSS: ES_{6wk}=1.74 SSS: ES_{12wk}=1.96 SSS: SRM_{6wk}=1.67 SSS: SRM_{12wk}=2.01 FSS: ES_{6wk} =0.48 FSS: ES_{12wk} =1.05 FSS: SRM_{6wk} =0.46 FSS: SRM_{12wk} =1.05 (n=34)	?
Greenslade (2004)	n=88 secondary care UK English surgery	?	?	?	?	+ (n=31)	SSS: SRM=1.07 FSS: SRM=0.62 (n=57)	?
Imaeda (2006)	n=87 secondary care Japanese surgery	?	+	+	?	+	SSS: ES=0.99 SSS: SRM=0.85 FSS: ES=0.61 FSS: SRM=0.70 (n=42)	+

Appendix 1 (cont.):

study (year)	number of participants/ setting/ language/ intervention	psychometric property assessed						
		content validity	internal consistency	construct validity	agreement	reliability (reproducibility)	responsiveness	floor or ceiling effects
Katz (1994)	n=43 secondary care US English surgery	?	?	?	?	?	SSS: ES=2.03 SSS: SRM=2.02 FSS: ES=0.86 FSS: SRM=0.96 (n=43)	?
Katz (1996)	n=268 secondary care US English surgery	?	+	+	?	?	x	?
Levine (1993)	n=67	+	+ (n=67)	+ (n=43)	?	+ (n=39)	(n=26)	?
Özyürekoğlu (2006)	n=28 secondary care US English steroid -injection	?	?	?	?	?	SSS: AUC=0.846 MCID=1.04 (external criterion: satisfactory response)	?
Rosales (2002)	n=50	?	+ (n=42)	?	?	?	?	?
Sezgn (2006)	n=67 secondary care Turkish	?	+	+	?	+	?	?
Spies-Dorgelo (2006)	n=84 Dutch primary care "wrist complaints"	?	?	?	?	+	AUC=0.90 SDCgroup=0.11 MIC=0.23 (external criterion: change in ability to perform daily activities)	?
Upatham (2008)	n=31 secondary care Thai	?	+	?	?	?	?	?

rating: + = positive, 0 = intermediate, - = poor, ? = no information available

Appendix 2. Dutch version of the Boston Carpal Tunnel Questionnaire

A. Schaal voor de ernst van de symptomen:

De volgende vragen hebben betrekking om de ernst van uw klachten gedurende een kenmerkende dag in de afgelopen 2 weken. Graag het antwoord dat op u van toepassing is omcirkelen:

a. Hoe ernstig is de pijn in de arm, pols of vingers 's-nachts?
1. ik heb 's-nachts geen pijn in de hand, pols of vingers
2. geringe pijn
3. matig ernstige pijn
4. ernstige pijn
5. zeer ernstige pijn

b. hoe vaak werd u 's-nachts wakker ten gevolge van een pijnlijke hand, pols of vingers gedurende een kenmerkende nacht in de afgelopen twee weken?
1. nooit
2. eenmaal
3. twee of drie keer
4. vier of vijf keer
5. meer als vijf keer

c. hebt u wel eens een pijnlijke pols, hand of vingers overdag?
1. ik heb nooit pijn overdag
2. ik heb geringe pijn overdag
3. ik heb een matig ernstige pijn overdag
4. ik heb ernstige pijn overdag
5. ik heb zeer ernstige pijn overdag

d. hoe vaak hebt u een pijnlijke hand, pols of vingers overdag
1. nooit
2. een of tweemal per dag
3. drie tot vijfmaal
4. meer als vijfmaal
5. de pijn is constant aanwezig

e. hoe lang duurt, gemiddeld, een periode met pijn overdag
1. ik heb overdag nooit pijn
2. minder dan tien minuten
3. tien tot zestig minuten
4. meer als zestig minuten
5. de pijn is constant overdag aanwezig

f. voelt u doofheid (verminderd gevoel) in uw hand of vingers
1. neen
2. geringe doofheid

3. matig ernstige doofheid
4. ernstige doofheid
5. zeer ernstige doofheid

g. is er sprake van een verminderde kracht in uw hand, pols of vingers
1. geen krachtsvermindering
2. geringe krachtsvermindering
3. matig ernstige krachtsvermindering
4. ernstige krachtsvermindering
5. zeer ernstige krachtsvermindering

h. voelt u wel eens tintelingen in uw hand/vingers ?
1. geen tintelingen
2. tintelingen in geringe mate
3. tintelingen in matig ernstige mate
4. tintelingen in ernstige mate
5. tintelingen in zeer ernstige mate

i. hoe ernstige is de doofheid (het verminderde gevoel) of zijn de tintelingen 's-nachts?
1. ik heb geen last van doofheid of tintelingen 's-nachts
2. in geringe mate
3. in matig ernstige mate
4. in ernstige mate
5. in zeer ernstige mate

j. hoe vaak werd u 's-nachts wakker gedurende een kenmerkende nacht in de afgelopen twee weken?
1. nooit
2. eenmaal
3. twee of drie keer
4. vier of vijf keer
5. meer als vijf keer

k. ondervindt u moeilijkheden om kleine voorwerpen (zoals sleutels of een pen) op te pakken en te gebruiken?
1. geen moeilijkheden
2. geringe moeilijkheden
3. matige moeilijkheden
4. ernstige moeilijkheden
5. zeer ernstige moeilijkheden

B. Schaal voor de functionele status:

De volgende vragen hebben betrekking op een kenmerkende dag gedurende de afgelopen twee weken. Hebt u gedurende zo een kenmerkende dag wel eens moeite gehad om een van de volgende bezigheden uit te voeren? Graag het antwoord dat op u van toepassing is omcirkelen.

a. schrijven:
1. geen moeite
2. geringe moeite
3. matige moeite
4. veel moeite
5. ik kon deze bezigheid niet uitvoeren t.g.v. de klachten die ik in mijn pols en/of hand en/of vingers ondervond

b. kleding dichtknopen:
1. geen moeite
2. geringe moeite
3. matige moeite
4. veel moeite
5. ik kon deze bezigheid niet uitvoeren t.g.v. de klachten die ik in mijn pols en/of hand en/of vingers ondervond

c. een boek vasthouden tijdens het lezen:
1. geen moeite
2. geringe moeite
3. matige moeite
4. veel moeite
5. ik kon deze bezigheid niet uitvoeren t.g.v. de klachten die ik in mijn pols en/of hand en/of vingers ondervond

d. de hoorn van de telefoon vasthouden:
1. geen moeite
2. geringe moeite
3. matige moeite
4. veel moeite
5. ik kon deze bezigheid niet uitvoeren t.g.v. de klachten die ik in mijn pols en/of hand en/of vingers ondervond

e. (draai)deksels van conserven openen:
1. geen moeite
2. geringe moeite
3. matige moeite
4. veel moeite
5. ik kon deze bezigheid niet uitvoeren t.g.v. de klachten die ik in mijn pols en/of hand en/of vingers ondervond

f. huishoudelijke activiteiten:
1. geen moeite
2. geringe moeite

3. matige moeite
4. veel moeite
5. ik kon deze bezigheid niet uitvoeren t.g.v. de klachten die ik in mijn pols en/of hand en/of vingers ondervond

g. boodschappentassen dragen:
1. geen moeite
2. geringe moeite
3. matige moeite
4. veel moeite
5. ik kon deze bezigheid niet uitvoeren t.g.v. de klachten die ik in mijn pols en/of hand en/of vingers ondervond

h. wassen en aankleden:
1. geen moeite
2. geringe moeite
3. matige moeite
4. veel moeite
5. ik kon deze bezigheid niet uitvoeren t.g.v. de klachten die ik in mijn pols en/of hand ondervond