

# **Determinants of patient reported outcomes in patients with musculoskeletal disorders. A prospective cohort study.**

Master thesis

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“ONDERGETEKENDE

Thymen van Voorst

bevestigt hierbij dat de onderhavige verhandeling mag worden geraadpleegd en vrij mag worden gefotokopieerd. Bij het citeren moet steeds de titel en de auteur van de verhandeling worden vermeld. Deze data is een verkenning op basis van concept data van de Landelijke Database van Fysiotherapie.

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## SAMENVATTING

*Doelstelling:* Patient Reported Outcome Measures (PROMs) kunnen een bijdrage leveren aan betere patiëntgerichte zorg en transparantie in de zorg. Er wordt klinisch weinig gebruik gemaakt van PROMs. In de literatuur is weinig bekend over factoren die uitkomsten van PROMs beïnvloeden. Er zijn verschillende factoren die invloed hebben op de PROMS, zoals patiënt-, therapeut- en praktijk-karakteristieken. Het eerste doel van dit artikel is onderzoeken of een implementatietraject invloed heeft op het inzetten van PROMs in de fysiotherapiepraktijk. Het tweede doel is om te onderzoeken welke karakteristieken van patiënt, fysiotherapeut of praktijk invloed hebben op de uitkomst van PROMs.

*Methode:* Dit artikel heeft een longitudinaal cohort design. Het gebruik van PROMs is onderzocht tijdens het implementatietraject bij fysiotherapeutische intake en bij evaluatie van de behandeling. Vervolgens is het routinematig gebruik van PROMs getest met een multilevel pairwise comparison analyse met Bonferroni correctie. Karakteristieken zijn univariaat geselecteerd en vervolgens gemodelleerd in een hiërarchisch lineaire multilevel regressieanalyse. Deze analyse meet de invloed van de karakteristieken op de uitkomst van de Neck Disability Index, Quebec Back Pain Disability Scale and the Numeric Pain Rating Scale.

*Resultaten:* Het eenmalig gebruik van een PROM tijdens een fysiotherapeutische behandeling nam significant toe met 22,6% ( $p < 0.001$ ), en het herhaald gebruik van een PROM tijdens de behandeling met 18,6% ( $p < 0.001$ ). Voor de Neck Disability Index werd geen variantie verklaard. Verklaarde variantie voor de Quebec Back Pain Disability Scale was 49,1% en voor de Numeric Pain Rating Scale 25,1%. De karakteristieken die een significant invloed hadden zijn: leeftijd van de patiënt en verwacht herstel.

*Conclusie:* Het implementatieprogramma laat een significante toename zien in het gebruik van PROMs. Het is aan te raden een follow-up studie te ontwikkelen om te onderzoeken of dit implementatie programma tot routinematig gebruik van PROMS leidt. De karakteristieken verklaren weinig van de variantie. Verder onderzoek naar andere karakteristieken is nodig om mogelijk meer van de uitkomst te verklaren.

*Klinische relevantie:* Het inzetten van PROMs kan de gezondheidszorg transparanter maken en een betere patiëntgerichte zorg leveren. Wanneer de invloeden van de karakteristieken helder zijn kan er een voorspellingsmodel gecreëerd worden.

## **ABSTRACT**

*Aim:* Patient Reported Outcome Measures (PROMs) can contribute to patient centeredness and can be used to increase transparency of clinical outcomes. Applying PROMs in clinical practices is challenging. Several factors might influence the outcome in physical therapy, such as patient, therapist and organizational characteristics. The evidence regarding which characteristics can influence the outcome of PROMs is scarce. The aim of this study is twofold: firstly, to find out if the use of PROMs in clinical physical therapy practices can be stimulated by using an implementation program; and secondly to investigate which patient, therapist and organizational characteristics can influence the outcome of PROMs in physical therapy.

*Methods:* This study has a longitudinal prospective cohort design. The routine use of PROMs in physical therapist practices is investigated during the implementation program at the intake and evaluation of the treatment. The results of the implementation program were tested with a multilevel pairwise comparison analysis with Bonferroni correction. The characteristics are selected using univariate regression analysis and consequently modelled in a hierarchic linear multilevel regression analysis. This analysis estimates the influences of the characteristics on the outcome of the Neck Disability Scale (NDI), Quebec Back Pain Disability Scale (QBPDS) and the Numeric Pain Rating Scale (NPRS).

*Results:* The use of one single PROM in a therapy period increased significantly with 22,6% ( $p < 0.001$ ) and repeated use of PROMs increased with 18,6% ( $p < 0.001$ ). Two significant characteristics were identified: age of the patient and expected recovery. The characteristics explain none of the variance of the NDI, 49.1% of the QBPDS and 25.1% for the NPRS.

*Conclusion:* The implementation program showed significant improvements in the routine use of PROMs. The patient characteristics give little explanation of the outcomes. Further investigation is necessary to find out if the implementation program can ensure the routine use of PROMs and if different characteristics can explain more of the outcome.

*Clinical Relevance:* Applying PROMs can make healthcare transparent and contribute to patient centeredness. Knowing the influence of patient characteristics can result in a predictive outcome model in the future.

*Keywords:* PROMs, implementation, characteristics

## INTRODUCTION

Evidence-based medicine can be identified as integration of best available evidence, professional expertise and patient values, with the aim of improving the quality of healthcare (1,2). This evidence-based medicine is stimulated, among others, by clinical practice guidelines (CPGs). Besides describing the most suitable diagnosis and treatment according to the latest evidence, CPGs recommend the use of different outcome measures to make the preferred outcome of the treatment objective. A specific example of these outcome measures are Patient Reported Outcome Measures (PROMs). These are “standardized and validated questionnaires that are completed by patients to measure their perception of their functional status and wellbeing” (3).

Research has shown that PROMs can contribute to patient centeredness by improving patient-provider communication (4,5) and shared decision-making (5-7). PROMs can be integrated as a clinical tool or for use at aggregate level (8). In a clinical setting PROMs can be used for evaluating the outcome of patients in healthcare. Aggregated PROMs can be used for assessing clinician performance or compare the effectiveness of research (9,10). The challenge with the use of PROMs is to routinely apply them in clinical practice (13).

Aggregated PROMS-data can be used to increase transparency of clinical outcomes (11,12), which provide information for quality improvement and can be used by patients to choose healthcare providers (13). This aggregated data can be used for the development of quality indicators, which can increase the healthcare quality (14-16). Quality indicators include structure, process and outcome indicators (14,15). The use of quality indicators in physical therapy, and especially the use of PROMs as outcome indicators, has increased (10). Outcome indicators give an indication about the quality of the provided healthcare (13). The more PROMs that are collected, the better the development of an outcome indicator in healthcare will be (13). In literature the evidence about what influences the outcome of PROMs is scarce. Several factors can influence this outcome: patient characteristics, therapist characteristics and organizational characteristics. Various characteristics have been explored regarding their influence on the treatment outcome in patients with musculoskeletal disorders in the lower back and neck (17,39,40). The patient characteristics include: age (39,40), social environment (29), gender (44), additional pathology (43), duration of problems in functioning prior to consultation (39,40), course of experienced problems prior to consultation (39,40), expected recovery (42), and recurrent injury (41). The physical therapist characteristics include: age (46), gender (48) average hours work a week in physical therapy (46), and the manual therapist (45). The organizational characteristic is: plus/top clinic (47). If these characteristics are explored further, this could provide new insights into developing PROMs as outcome measures for healthcare. When the influence of the characteristics on the outcome of the PROMs is made clear, a predictive model can be developed. This can contribute to a transparent and more patient-centered healthcare system in physical therapy.

In 2012 the Royal Dutch Society of Physical Therapy launched a five-year program in the Netherlands called ‘Quality in Motion’. This program is meant to develop a transparent quality system for physical therapy and increase the use of PROMs in clinical physical therapy practices. Three different pilot groups were used, consisting of three physical therapy networks. The implementation program was conducted in a total of five course meetings. The aim of the implementation program was threefold in the application of the PROMs: 1) Support physical therapists and patients in setting goals and

monitoring the patient's health throughout the care process, thus enhancing patient-centered care; 2) Support physical therapists in quality improvement activities with continuous feedback of process and outcome data; 3) Allow physical therapists to provide transparency of their care to stakeholders, such as health insurance companies and patients, with aggregated data.

The aim of this study is twofold: firstly, to assess whether the implementation program used by 'Quality in Motion' can improve the use of PROMs in clinical physical therapy practices; secondly to investigate if any of the patient, therapist and organizational characteristics significantly influence the PROMs of patients with musculoskeletal disorders in the lower back and neck in physical therapy and if so, which ones.

## METHODS

### Research setting and participants

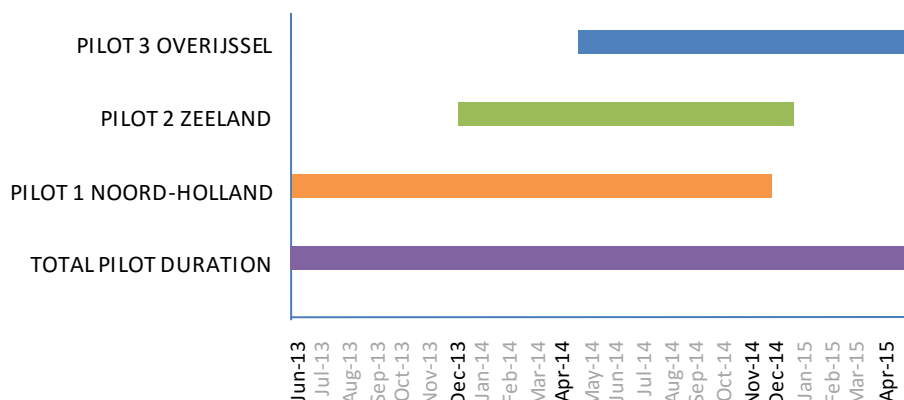
This study has a longitudinal prospective cohort design and used data from the survey of the implementation program ‘Quality in Motion’ from the Royal Dutch Society of Physical Therapy, and the database from the national registry. The data of the national registry includes all patient characteristics and outcome variables. The data from the survey includes the physical therapist characteristics and organizational characteristics. The data for this study was collected from June 2013 to April 2015. To investigate if the implementation program can influence the use of PROMs, the national registry was used. For the investigation of the influence of the characteristics on health outcomes measured with PROMs, both datasets were used. During the implementation program, three pilot groups were trained to apply PROMs in physical therapy. We conducted a baseline measurement and follow-up measurement of the number of PROMs that were used, to investigate if the implementation program influenced the PROM use. The three pilot groups consist of three physical therapy network groups in the Dutch provinces Noord-Holland, Zeeland and Overijssel. These network groups are pro-active members of the KNGF and volunteered to be a part of this implementation program. Each participating clinic formally provided written consent to participate and all patients were informed about the study and gave permission to use their data anonymously. The database of the national registry is compiled by MediQuest.

### Measures and statistical analysis of PROM use

To measure the number of PROMs at baseline and follow-up of the implementation program, the data from the pilot groups was extracted from the national registry to a separate database, including the timeframes of the pilots only (Figure 1). The first five months and the last five months of the timeframe are chosen to measure the number of PROMS at baseline and follow-up. We chose five months because – in the start-up of the pilots – several electronic-health-record (EHR) systems were not completely compatible for data delivery to the national registry. In measuring the use of PROMs, single and repeated measurements were distinguished. Single measurements were defined as the use of one PROM at the therapy episode. Repeated measurements were defined as the use of multiple PROMs during the therapy session.

To assess the differences of PROM use at the baseline and at the follow-up measurement of the implementation program, a multilevel pairwise comparison with Bonferroni correction was performed.

Figure 1. Timeframe of the pilots





### Measures and statistical analysis of the characteristic influences on the PROMs

To investigate the influences of the patient, therapist and organizational characteristics on patients with musculoskeletal disorders in the lower back and neck we used three PROMs. The Quebec Back Pain Disability Scale was used for patients with musculoskeletal disorders in the lower back. For the patients with musculoskeletal disorders in the neck we used the Neck Pain Disability Index. To measure the characteristic influence on generic pain, we used the Numeric Pain Rating Scale. We combined the datasets of the national registry and survey with the unique personal code of the physical therapist (AGB-code). The datasets were selected from June 2013 to April 2015 (Figure 1). The NPRS, QBPDS and NDI have a high reliability, construct validity and their minimal clinically important differences have been estimated (19-24). The use of these PROMs are also recommended in the guidelines of the Royal Dutch Society of Physical Therapy (30,31). The NDI measures limitations in activities and participation for neck patients with a 50-point scale. The QBPDS does the same for lower back patients with a 100-point scale. The NPRS measures the pain on a 11-point scale. The data of the national registry included every patient with musculoskeletal disorders in the lower back and neck. The patient, therapist and organizational characteristics were chosen because these influenced the outcome of treatment in patients with musculoskeletal disorders of the lower back and neck (Table 1). The dichotomized and categorized characteristics are explained in Appendix 1.

*Table 1. Chosen characteristics*

<b>Therapist characteristics</b>
1. Age
2. Gender
3. Average hours work a week in physical therapy
4. Manual therapist or other physical therapist

<b>Organizational characteristics</b>
5. Plus/top clinic

<b>Patient characteristics</b>
6. Duration of problems in functioning prior to consultation
7. Social environment (based on postal codes)
8. Age
9. Gender
10. Additional pathology
11. Expected recovery
12. Recurrent Injury
13. Course of experienced problems prior to consultation

To analyse the characteristic influences on the outcome of the PROMs, first the normality of the PROMs were tested. Normal distribution of the data was analysed with the skewness, kurtosis, Kolmogorov-Smirnov test and QQ-plots.

When the characteristics had >20% missing values, the determinants were excluded (Appendix 2). For the remaining missing values <20%, the cases of the patients were excluded. This resulted in no missing values in the characteristics of the PROMs. Finally, univariate analyses were performed to select the characteristics with  $p < 0.20$  for the models in multilevel analyses.

The sample size for the patients in this study is calculated using the rule of thumb in multilevel analysis (25,26). It is based on the 100/10 rule. That means for this study, every clinic needed at least ten participants. We made a selection of the weighted mean differences of the NDI, QBPDS and NPRS with at least ten measurements per clinic to achieve the desired power. With this sample size, a two-level model of the hierarchical linear multilevel regression analysis was performed to investigate the influence of the characteristics on the weighted mean differences of the NDI, QBPDS and NPRS. The data of the characteristics were clustered between the level of the patient and clinic of the pilots. To aggregate the influence of the characteristics on the outcome of the PROMs, we took account for the variance of the outcome on clinical level. First a random intercept model needed to be made to get the estimated variance of the clinic. To determine the variance of the clinic in the multilevel model, we needed to calculate the Inter Cluster Correlation coefficient (ICC). The ICC can be determined with the formula:  $ICC = \text{variance clinic} / (\text{variance clinic} + \text{variance patients})$ . This model did not explain the variance, but divided the total variance of the lowest level (patient-level) with the highest level (clinic-level). Secondly, a model was made to measure the influence of the characteristics of the weighted mean differences of the PROMs, with the clinics as intercept and the chosen characteristic as fixed factor. The influence of the characteristics was determined with the formula:  $ICC = (\text{variance clinic of the zero-model} - \text{variance clinic of the second model}) / \text{variance clinic of the zero-model}$ . Based on the results of the univariate analysis, the characteristics with  $p < 0.20$  were entered in the multilevel analysis. The non-significant characteristics were removed one by one in the multilevel analysis. This resulted in a model with only significant characteristics.

All statistical analyses were performed using IBM SPSS Statistics for Windows, version 20.0 (IBM Corp, Armonk, New York).

## RESULTS

### Responses and patient characteristics

Table 2 represents the characteristics of the databases that were used for this study and the included number of patients with musculoskeletal disorders in the neck and lower back. The genders of the participants with musculoskeletal complaints in the lower back were almost equally divided (49,2%), while for the participants with neck complaints there were more female patients (67,4%). The mean age of musculoskeletal disorders in the lower back and neck in this study was middle-age. These results were representative for the general population in the Netherlands (37,38). It is commonly known that the female gender is more often encountered in the physical therapy clinic (36), a factor also represented in this study.

Table 2. Database characteristics

Characteristics:	Databases:			
	National registry	Pilot	Neck patients	Lower back patients
Patients (N)	261.584	32.533	291	366
Gender female %	60.2%	58,8%	67,4%	49,2%
Mean age (SD)	50,0 (20,3)	50,3 (20,0)	52,8 (20,0)	51,4 (16,4)

### Outcome of PROM use

The results of the baseline and follow-up measurements are shown in Table 3. These measurements showed a significant increase in the application of PROMs in 22,6% of the single measurements ( $p < 0.001$ ) and 18,3% of the repeated measurements ( $p < 0.001$ ) during the implementation program of 'Quality in Motion'.

Table 3. PROM measurements

	baseline of the implementation	follow-up of the implementation	increase	Significant
Single measurements	1200 (49,5%)	1747 (71,2%)	547 (22,6%)	$p < 0.001$
Repeated measurements	510 (21,1%)	968 (39,4%)	458 (18,3%)	$p < 0.001$
Total patients	2416	2453		

### Outcome of the characteristic influences on the PROMs

To investigate the influences of the characteristics on the weighted mean differences of the NDI, QBPDS and NPRS, this study included 291 patients for the NDI, 366 patients for the QBPDS and 3299 patients for the NPRS (Appendix 4). The data of the PROMs were normally distributed. The exclusion of the characteristics with the missing values of more than 20% are presented in Appendix 2. This resulted in the inclusion of seven characteristics in the data analysis (Table 4).

Table 4. Characteristics for multilevel analyses

<b>Therapist characteristics</b>	
1.	Age
2.	Gender
3.	Average hours work a week in physical therapy
<b>Organizational characteristics</b>	
4.	Plus/top clinic
<b>Patient characteristics</b>	
5.	Age
6.	Gender
7.	Expected recovery

The characteristics that were selected in a univariate analysis for the hierarchic linear multilevel regression model are shown in Appendix 3. The multilevel model of the NDI explains none of the variance of the weighted mean differences and had no significant characteristics. The model of the QBPDS explains 49.1% of the weighted mean differences (Table 6). The characteristic expected recovery was significant ( $p < 0.001$ ) with a negative influence on the outcome (Table 5). The multilevel model of the NPRS explains 25.1% of the weighted mean differences (Table 6). The characteristics are significant for age of the patient ( $p < 0.001$ ) and expected recovery ( $p < 0.001$ ), both had a negative influence on the outcome of the PROM (Table 5).

Table 5. Two-level hierarchic linear multilevel regression analysis

Multilevel analyses	Coefficient	SE	Confidence Interval (95%)	
			Lower	Upper
<b>QBPDS</b>				
Intercept	-29.830	1.630	-33.540	-26.120
<u>Fixed Factors:</u>				
Expected recovery: reduction of complaints	10.346*	1.899	6.608	14.084
<b>NPRS</b>				
Intercept	-4.781	0.195	-5.175	-4.397
<u>Fixed Factors:</u>				
Expected recovery: not to determine	1.110*	0.314	0.492	1.727
Expected recovery: reduction of complaints	0.490*	0.107	0.279	0.702
Expected recovery: hold stabilisation	2.320*	0.432	1.480	3.178
Age of the patient	0.009*	0.002	0.004	0.013

\* $p < 0.001$

*Table 6. Explanation of the variance of the PROMs*

<b>PROM models</b>	<b>Variance patient</b>	<b>Variance clinic</b>	<b>ICC</b>
Zero-model QBPDS	258.434	31.609	0.108
QBPDS model	243.032	16.060	0.491
Zero-model NPRS	5.597	0.397	0.066
NPRS model	5.464	0.297	0.251

## DISCUSSION

The study showed significant improvement in the single and repeated measurements of the PROMs after the implementation program. The multilevel model of the NDI, QBPDS and NPRS explained some part of the weighted mean differences. The relevant characteristics were: age of the patient and expected recovery.

Aggregated PROMs can be used for assessing clinician performance or to compare the effectiveness of research (9,10). The outcome of this study is improvement of PROM use. It is one of the first studies that shows implementation can influence PROM use in a clinical setting and for quality improvement in aggregated PROMs. To apply PROMs routinely, it is recommended to perform a follow-up study, to find out if the physical therapists will reach the routine stage after the implementation program (28).

For this study, we investigated the patient, therapist and organizational characteristics that influenced the treatment outcome in patients with musculoskeletal disorders in the lower back and neck. No significant characteristics were presented for the NDI. Most of the characteristics that were chosen had more influence on the outcome of musculoskeletal disorders in the lower back, and this can explain why there was less influence measured on the NDI. The significant characteristics for expected recovery were the same for the QBPDS and NPRS. It is recommended to investigate if these characteristics also influence other PROMs. Expected recovery had a negative influence on the outcome of the PROM. If the physical therapist does not believe the patient will fully recover, it could affect the compliance and adherence of the physical therapist or patient to the treatment (49). It is recommended to explore the compliance and adherence further in physical therapy treatment sessions and to investigate if this can influence the outcome of the treatment. The models of the QBPDS explains 49.1% and NPRS 25.1%. This variation in percentage can be explained by the number of patients. The NPRS had almost ten times more patients than the QBPDS. The outcome of the NPRS had, because of the high number of patients, more regression towards the mean and could have resulted in a lower explanation of the variance.

This study included seven characteristics in the multilevel analysis. It is recommended to perform more research on other characteristics that can explain the outcome of the PROMs. This could result in a predictive outcome model in the future for patients with musculoskeletal disorders in the neck and lower back. Several characteristics can contribute to a predictive outcome model. The number of treatments can be used to investigate if long treatment episodes or short treatment episodes will lead to different outcomes (34). The characteristic social environment of the patient is interesting, because it is well known in the Netherlands that some neighbourhoods need more healthcare than others (29). Duration of the complaint can be explored, because chronic complaints can have different outcomes in healthcare than acute complaints (35).

In summary, the results of the implementation program are promising for improving the use of PROMs in clinical physical therapy practices. It is recommended to perform a follow-up study to investigate if the pilot groups ended up in the routine stage. The patient, therapeutic and organizational characteristics explain some part of the weighted mean differences of the PROMs. It is also recommended to perform further research on other characteristics, which can result in a predictive outcome model for patients with musculoskeletal disorders in the lower back and neck.

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## APPENDIX

<i>Appendix 1. Categorized variables</i>		
<b>Variables</b>	<b>Categories</b>	
Gender	Male	Female
Reason of consultation registered	Yes	No
Expected recovery	Not to determine	Reduction of complaints
	Hold stabilisation	Complete recovery
Additional pathology	Yes	No
Relapse of injury	Yes	No
Course of experienced problems prior to treatment	Nothing registered about change in complaint	Complaints are declined in time
	Complaints are not changed in time	Complaints increased in time
	Complaints varying in time	
Manual therapist or other physical therapist	Manual therapist	Other physical therapist
Plus/top clinic	Yes	No

<i>Appendix 2. General analysis</i>		
<b>Characteristics therapist</b>	<b>Missing values (%)</b>	<b>Included characteristics</b>
1. Age	13.2%	x
2. Gender	13.2%	x
3. Average hours work a week in physical therapy	14.0%	x
4. Manual therapist or other physical therapist	51.1%	
<b>Characteristics clinic</b>		
5. Plus/top clinic	19.6%	x
<b>Characteristics patient</b>		
6. Duration of problems in functioning	42.5%	
7. Postal code	55%	
8. Age	0.0%	x
9. Gender	0.0%	x
10. Additional pathology	79.4%	
11. Expected recovery	0.0%	x
12. Relapse injury	61.5%	
13. Course of experienced problems prior to treatment	82.5%	

<i>Appendix 3. Univariate analysis</i>			
<b>Characteristics therapist</b>	<b>Univariate NPRS</b>	<b>Univariate NDI</b>	<b>Univariate QBPDS</b>
1. Age	0.000	0.001	0.000
2. Gender	0.467	0.011	0.510
3. Average hours work a week in physical therapy	0.000	0.067	0.002
<b>Characteristics clinic</b>			
4. Plus/top clinic	0.507	0.124	0.228
<b>Characteristics patient</b>			
5. Age	0.004	0.406	0.259
6. Gender	0.077	0.189	0.315
7. Expected recovery prior to consultation	0.000	0.029	0.000

<i>Appendix 4. Characteristics weighted mean differences of the PROMs</i>				
<b>PROMS</b>	<b>Scale</b>	<b>Mean score</b>	<b>SD</b>	<b>N</b>
NDI	50 points	-4.034	2.409	291
QBPDS	100 points	-25.106	16.740	366
NPRS	11 points	-8.680	6.808	3.299