The current use of Patient-Reported Outcome Measures to measure pain and factors associated with pain scores in patients with non-specific neck pain

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ABSTRACT

Background: Patient-Reported Outcome Measures (PROMs) to measure pain are highly recommended and may improve quality of health care physiotherapy. Although, little is known about PROMs use in primary care physiotherapy to measure pain, and if the use leads to differences in number of treatment sessions in non-specific neck pain patients. Besides, understanding what determines the pain score may help physiotherapists to make better management decisions in affecting non-specific neck pain.

Aim: This study assessed 1) the current use of PROMs to measure pain in Dutch primary healthcare physiotherapy, 2) differences in number of treatment sessions between PROM and non-PROM evaluated patients, and 3) patient- and physiotherapist-related variables associated with pain scores in non-specific neck pain patients.

Methods An observational study was conducted, based on electronic health record data in the Nivel Primary Care Database of the year 2018. A total of 1,412 patients aged 18 years or older diagnosed with non-specific neck pain and treated by a primary care physiotherapist were included. Descriptive statistics and Mann-Whitney-U tests were used to explore the current use of PROMs and differences in the number of treatment sessions between PROM evaluated and non-PROM evaluated patients. A backward multiple regression analysis was used to identify associated factors with the change in pain score.

Results: Twenty-seven percent of the included patients were evaluated by using PROMs to measure pain. Three hundred eighty-six PROM evaluated patients (mean age 49±17) and 1,026 non-PROM evaluated patients (mean age 49±17) showed that the number of treatment sessions was significantly higher in PROM evaluated patients (7.1±4.5) than non-PROM evaluated patients (6.3±5.0). Multiple regression showed the age of the patient and the number of treatment sessions as associated variables on the change of pain score. Thirty-eight percent of the proportion in variance is explained by our model.

Conclusion and key findings: This study showed that the minority of non-specific neck pain patients were evaluated by PROMs in Dutch primary care physiotherapy. PROM evaluated patients showed a higher number of treatment sessions. The age of the patient and the number of treatments were found as associated variables on the change of pain score.

Keywords: non-specific neck pain, PROM use, multiple regression

INTRODUCTION

Neck pain is "an unpleasant sensory and emotional experience associated with actual or potential tissue damage" of the region from the superior nuchal line to the spine of the scapula (1,2). With a one-year prevalence ranging from 16.7% to 75.1% neck pain is the fourth leading cause of years lost to disability in the world (3,4). In 2011, the total costs related due to neck pain were 520 million euro in the Netherlands, of which, 377 million euro were related to primary health care costs, including physiotherapy (5).

Considering the high burden for patients, costs, and prevalence, there is a need for high-quality care for patients with neck pain. Quality of care has been defined as 'doing the right thing at the right time, in the right way, for the right person, and having the best possible results (6). To facilitate quality of care among Dutch physiotherapists, the Royal Dutch Society for Physical Therapy (in Dutch: Koninklijk Nederlands Genootschap voor Fysiotherapie) recently implemented an evidence-based clinical neck pain guideline, which gives physiotherapists guidance in the treatment of non-specific neck pain patients(7).

In this guideline, the use of Patient-Reported Outcome Measures (PROMs) during the physiotherapy treatment episode is highly recommended (7) to capture information that is important to patients concerning their health problems (8). For pain inquiry, the evidence-based guideline recommends the Visual Analogue Scale (VAS)(9).

The use of PROMs can contribute to patient-centeredness by improving communication between patients and physiotherapists (8), support shared decision-making, and may improve quality of treatment (10). The use of PROMs that measure pain gives physiotherapists the opportunity to monitor individual patients' pain scores which are an important form of feedback to evaluate the care patients have received (11). This may give physiotherapists opportunities to keep track of treatment impact and to develop, or adjust, management strategies during the treatment process (10).

Knowledge and prediction of the course of neck pain helps guiding the expectations of the patient and their physiotherapist (12). In addition, understanding what determines the pain score may help physiotherapists to provide better advice and make better management decisions in affecting pain (13). Patient-related factors such as female gender, older age, history of neck symptoms, and a longer duration of complaints have been associated with a longer duration of symptoms in non-specific neck pain (12,14,15). Also, the frequency of treatment sessions and the duration of the treatment episode are patient-related factors that can contribute to modify the outcome of the physiotherapeutic treatment (18).

Physiotherapist-related factors have been associated with the clinical outcome. The specialization (i.e. manual therapy) of the physiotherapist is an associated factor at the physiotherapist-level (18). It is hypothesized that the number of times PROMs were used during the treatment episode plays a role in the course of pain scores. If the given treatment does not seem to influence the pain, physiotherapists may adjust their management

strategies in time. This could lead to more effective treatment and a greater decrease in pain symptoms. Besides, at the physiotherapist level, we hypothesize the physiotherapists' gender to be related to the pain score. Previous research reported differences in treatments given by female and male physicians(19), which could lead to a different outcome in pain scores. It is also hypothesized that the physical therapists' professional experience could play a role in the choice of treatment. Experienced physiotherapists may have a broader knowledge of musculoskeletal disorders and may recognize physical complaints in a more adequate way which could lead to a greater decrease in neck pain.

In short, the usefulness to enhance quality of care by using PROMs is already proven (10). Although, little is known knowledge of how many Dutch physiotherapists are routinely using PROMs to measure pain and if the use leads to a different number of treatment sessions in neck pain patients is desirable. Moreover, identification of pain associated factors may help Dutch physiotherapists to improve clinical decision-making and is relevant for targeting and optimizing management of neck pain. To our knowledge, this has never been investigated in a large research study.

The first aim of this study is to obtain insight in the current use of PROMs by Dutch primary care physiotherapists to measure pain. Secondly, this study will compare possible differences in the number of physiotherapy treatment sessions in patients with non-specific neck pain, among Dutch primary care physiotherapists who are using PROMs and who are not using PROMS. Thirdly, we will explore which patient- and physiotherapist-related factors are associated with the pain score in non-specific neck pain patients, with the use of routinely collected data of the Nivel-PCD in Dutch primary healthcare physiotherapy.

METHODS

Study design

The current study is an observational study, based on data of physiotherapists in the Nivel Primary Care Database (Nivel-PCD). This longitudinal database contains pseudonymized routinely recorded electronic data from several health care professions in the Netherlands, including physiotherapy. For this study, data of participating physiotherapists were used, within January 2018 and December 2018.

Ethical considerations

This study has been conducted according to the principles of the Declaration of Helsinki (version 64, October 2013); Nivel handles the data in accordance with the Dutch Data Protection Act. According to Dutch legislation, and under certain conditions, neither obtaining informed consent nor approval by a medical ethics committee is obligatory for this type of observational studies (Dutch Civil Law, Article 7:458) (20).

Study population

Patients of at least 18 years, diagnosed with non-specific neck pain, and treated by a primary care physiotherapist between January 2018 and December 2018, were selected from the Nivel-PCD (N= 3486). Non-specific neck pain is operationalized by a selection of two numbers belonging to the Dutch diagnosis code system for allied healthcare DCSPH (i.e. diagnosecodesyteem): (1) 3026, or (2) 3126, referring to degenerative diseases and muscle, tendon, or fascia diseases of the cervical or cervico-thoracal vertebral column.

Data collection

Data of this study were derived from health records of primary care physiotherapists participating in the Nivel-PCD. These health records consist of patient demographics and treatment characteristics. Physiotherapist characteristics are linked to submitted health records.

Patient- and therapeutic-related variables of the current study were selected based on previous research and based on our hypotheses. These variables were: (1) age of the patient in years, (2) gender of the patient, (3) duration treatment episode in days, (4) number of treatment sessions belonging to one treatment episode, (5) number of times PROMs were used during one treatment episode, (6) result of the treatment filled in by the physiotherapist after closing the treatment episode subdivided into goals not achieved; goal partly achieved; goals achieved, (7) age of the physiotherapist in years, and (8) gender of the physiotherapist.

Outcome variable

Primary outcomes of the first two aims in this study were: (1) percentage of patients evaluated by PROMs to measure pain and, (2) the possible differences in the number of treatment sessions between physiotherapists who are using PROMs and those who are not using PROMs. The use of PROMs was operationalized by the use of clinimetric properties

(VAS) to measure pain, at least two times during one treatment episode. The VAS is the most uniform en complete registration PROM of the Nivel-PDC participants. Therefore, the VAS was included as the operationalization of the outcome variable.
The primary outcome of the third aim in this current study was the change in pain intensity. This value was defined as the patients' pain scored during the last treatment session, minus the pain score given during the first treatment.

Independent variables
All available variables at the patient level and physiotherapeutic level, that might affect the course of neck pain, were selected from Nivel-PCD. The selected variables included patients' age, gender, number of treatment sessions, duration of treatment episode, number of times used PROMs, and physiotherapists' age and gender. Treatment result was included as an extra variable for descriptive statistics.

Statistical analysis

Descriptive statistics
All characteristics, mentioned in table 1, were described for the total group of patients. Furthermore, all characteristics were described separately for groups' use of PROMs 'yes' and 'no'. Since data showed abnormally distributions, Mann-Whitney-U test was used to test between-group differences the groups.
Continues variables were tested for normality and equal variances by using QQ-plots, the Kolmogorov-Smirnov test, and Levene's tests; categorical variables were tested by using Pearson Chi-Square test. P-values of <0.05 were considered significant.

Identification of pain associated factors
Due to the nested structure of the used data of patients within physiotherapists, backward multiple regression analysis with clustering was used to identify associated factors with the pain score during the last treatment session. A backward regression was performed to preclude possible suppressor effects and to retaining only the strongest predictors (21). As the pain score during the first treatment is a possible confounder, this variable was included in the regression analysis. Besides, the proportion of explained variance (adjusted R^2) on the outcome measure was presented to indicate the predictive power of the final model.
Assumptions belonging to a multiple regression analysis were tested before using the final analysis. Explanatory variables were checked for linearity by using scatterplots, normally distributed residuals by using QQ-plots, multicollinearity by calculating and analyzing the variation inflation factor (VIF) and homoscedasticity by using scatterplot of residuals versus predicted values.
Missing data in the explanatory and response variables were assumed to be missing at random (MAR). Due to a high number of available cases and skewed data, complete case analysis was used; variables exceeding a missing amount of 50% were excluded from the final

analyses. These variables were 1) history of neck symptoms; 2) longer duration of complaints prior to treatment; 3) specialization (i.e. manual therapy), and 4) professional experience of the physiotherapist.

The number of missing values per explanatory variables are presented in table 1.
All statistical analyses were conducted using Stata version 14.2 (StataCorp LP, College Station, Texas).

RESULTS

Population characteristics

In total, 1,412 patients were included in the study. Table 1 shows the characteristics of the study population. The mean age of the patients was 49 years (SD±17) and the majority of the patients were female (N= 1,006, 71%). The mean duration of a treatment episode was 62 days (SD±72), and the mean number of received treatment sessions was 6.5 (SD±4.9). During treatment episodes, the average number of times that PROMs were used during one episode was 1.0 (SD±1.5). Treatment goals were fully achieved in 878 (80%) patients and partly achieved in 24 patients (2%).
A total number of 149 physiotherapists were included in the study population. The mean age of the physiotherapists was 39 years (SD±11) and 59% of them were female.

PROM evaluated vs non-PROM evaluated

Of the included patients, 386 were evaluated by using the VAS at least two times in a treatment episode. The non-PROM evaluated group consisted of 1,026 patients. No statistically significant differences in age were found between the PROM evaluated and the non-PROM evaluated patients (49 years, SD±17; P>.05). PROM-evaluated patients showed significantly higher duration of treatment episodes in days than non-PROM evaluated patients (70±73 and 60±72, respectively; P<.05). Besides, the number of performed treatments was statistically significant higher in the PROM-evaluated group compared to the non-PROM evaluated group (7.1±4.5 and 6.3±5.0; P<.05). Nine percent (N=97) of the non-PROM evaluated group, received one treatment for their complaints. In the PROM-evaluated group, none of the patients received any treatment. Treatment results were significantly more achieved in the PROM evaluated group (90% vs 75%; P<.05).
The minority of the physiotherapists evaluated their non-specific neck pain patients with the use of PROMs (28%; N= 41). The age and gender of the physiotherapists did not differ significantly between the two groups (P>.05).

Factors associated with pain score

Patients were excluded from the analysis of the third research question if no change in pain score was available (N=1,177) and if missing values existed on variables (N=36). A total number of 199 complete cases were included for the final model (appendix 1). The characteristics of the excluded patients compared well to the characteristics of the included patients (appendixes 2 and 3).
The final backward regression was performed with hierarchical clustering. Patients were clustered into the 'highest level' physiotherapists. The final model revealed three variables that were significantly associated with a change in pain intensity: pain score during the first treatment, age of the patient, and the number of treatment sessions. The given pain score during the first treatment, which is included as a covariate, showed a negative ß of -.834 (-1.016-.670). This means that for every 1-unit of change in the variable 'pain score during the

first treatment' the degree of change in the outcome variable is -.834. Since the outcome change of pain intensity is a negative value, a negative association will result in a higher number in change of pain intensity.
The number of treatment sessions showed also a negative association (ß -.055[-.21 to -.0004]. The only positive associated variable was the age of the patient (ß .015 [.011-.021]), which means that a higher age of the patient will decrease the change of pain intensity. The final multiple regression showed an explained variance (R^2) of 38% (table 2).

Table 1: Characteristics of the study population

Patient characteristics	**Total study population (N=1,412)**	**Use of PROMs Yes (N=386)**	**Use of PROMs No (N=1,026)**	**P-value**	**Missing values**
Age, mean (SD) (min-max)	49(17)(18-96)	49(17)(18-91)	49(17)(18-96)	.957	-
Gender, n(%) Female	1,006(71%)	274(71%)	732(71%)	.000*	-
Duration treatment episode (days), mean (SD)(min-max)	62(72)(1-359)	70(73)(4-359)	60(72)(1-353)	.000*	-
Number of treatment sessions, mean (SD)(min-max)	6.5(4.9)(1-47)	7.1(4.5)(2-30)	6.3(5.0)(1-47)	.000*	-
Number of times PROMs used, mean (SD)(min-max)	1.0(1.5)(0-13)	2.8(1.7)(2-13)	-	-	-
Treatment result				.000*	307
Goals not achieved Partly achieved Goals achieved	203 (18%) 24 (2%) 878 (80%)	19 (6%) 14 (4%) 312 (90%)	184 (24%) 10 (1%) 566 (75%)		

Therapist characteristics	**Total number (N= 149)**	**Use of PROMs Yes (N= 41)**	**Use of PROMs No (N= 108)**	**P-Value**	**Missing values**
Age, mean (SD)(min-max)	39 (11)(27-66)	39 (11)(27-60)	37 (9)(27-66)	.445	58
Gender, n(%) Female	55 (59%)	11(52%)	44(60%)	.528	55

% = percentage n= number of subjects, SD= standard deviation, min-max= minimum maximum, PROMs = Patient Reported Outcome Measures, * P ≤ 0.05 for Mann-Whitney-U test and Pearson's chi square test

Table 2: Multiple regression analysis

Change of pain intensity	***ß***	***Std. Err.***	***t***	***P> I t I***	***95% CI Interval***	
Pain score start	-.834	.082	-10.18	.000	-1.016	-.670
Age patient	.015	.032	-1.73	.099	.011	.021
Number of treatment sessions	-.055	.007	2.15	.044	-.21	-.0004
Adjusted R^2 (%)	38					

ß= standardized regression coefficient, Std. Err.= Standard Error, t= coefficient divided by its standard error, P> I t I= P-value, 95% CI Interval= 95% confidence interval

DISCUSSION

By evaluating real-life practice data from primary healthcare physiotherapists during the year 2018, this study showed a PROM use rate of 27% to measure pain in non-specific neck pain patients. Additionally, this study showed a significantly higher mean of treatment sessions of the PROM evaluated patients versus non-PROM evaluated non-specific neck pain patients. As third, this study identified three variables that were associated with the change in pain score. As could be expected, the pain score measured at baseline is highly associated with the change in pain score. Besides, the current study showed the number of treatments and the age of the patients as predictive variables, even though the coefficients were small.

The observed PROM rate of our study (27%) showed consistency with a previous study (22). However, previous research (23) showed a higher PROM use rate (72%) by Dutch physiotherapists in non-specific low back pain patients. The current study assessed the use of PROMS if physiotherapists used them at least twice to measure the actual pain score during a treatment period, while Brinkman et al. (23) have set the criterium for PROM use on at least once. A higher average number of treatments was found, which was in accordance with other research (23). An explanation for the higher average number in treatment sessions of the PROM-evaluated group in the current study could be that a considerable number of the non-PROM evaluated patients received only one treatment for their complaints. All of the PROM-evaluated patients received at least two treatment sessions. Also, treatment goals were much more achieved in PROM evaluated patients (90% vs 75%). Apparently, PROM using physiotherapists treated their patients until treatment goals were achieved, which could have led to a higher mean of treatment sessions.

Not surprisingly, the baseline pain score as included covariate was associated with the change in pain score in the current study. Patients with higher baseline pain scores showed higher change pain scores, compared to patients who scored a low baseline pain score. The multiple regression showed a positive association between the age of the patient and the change in pain intensity. This means that older people show less improvement in pain intensity. In accordance with the current study, several studies previously showed that older age was associated with poor outcomes on pain intensity (12,24,25). This finding can be explained by the fact that elderly persons are more likely to have disorders associated with pain, like arthritis bone and joint disorders, and other chronic disorders (26).

The number of treatments showed a significant association in our performed regression analysis. However, the beta coefficient showed a very small effect size on the outcome variable of this study. Nevertheless, more treatments may seem to have beneficial effects on the change of pain intensity in non-specific neck pain complaints. Adjustment for interventions and stratification on clinical or human-related characteristics has not been executed. Therefore, it is unknown for which 'type of patient' more treatment sessions would be beneficial. Besides, a ceiling value of the number of treatments that will be effective in decreasing pain intensity was not evaluated in this study. Therefore, it is still unclear after how many performed treatments physiotherapists should consider treatment discontinuation

due to no effect on the change of pain intensity. To our knowledge, identification of ceiling values for the number of treatments is lacking.

This study has some strengths. The Nivel-PCD, contains a great amount of data from physiotherapists, recorded under real-world conditions. This type of data contains a broad spectrum of patients in physiotherapy practices captured over long periods of time, which leads to representativeness and generalizability for clinical practice (27). Therefore, the results of this study can be considered as real-world evidence and are usable for physiotherapists in the Netherlands. Another strength of this study is the used analysis method which involved patient – and physiotherapist-related factors. The individual observations of the Nivel-PCD are not independent but clustered within physiotherapists. To minimize the risk of inefficient parameter estimates and negatively biased standard errors, due to the dependency of patients within physiotherapists, multiple regression analysis with clustering was used.

Some weaknesses need to be highlighted as well. High quality of patient documentation is a prerequisite in an observational study using routinely collected databases (27). Due to the high amount of missing values (>50%), four variables were excluded from the analysis. Therefore, evaluation of the influence of the duration of complaints prior to the treatment, history of neck symptoms, the years of experience of the physiotherapist, and the specialization of the physiotherapist was impossible. Besides the high number of missing values, a limited number of variables were included in this already existing database. This does not mean that more variables related to neck pain do not exist. For example, previous studies showed already psychological factors and coping patterns as strongly related factors to experienced pain in neck patients (28,29). Including more variables or covariates would enhance the results of this study and would probably increase the predictive power of the model, which was only 38% (R^2 adjusted) in the current study.

Descriptive statistics of this study showed highly significant results on several included variables despite means and standard deviations showed small differences between the two groups. In this study, great sample sizes were captured which more easily could have led to significant differences. Despite statistically significant differences, it is doubtful if the observed small differences in means are clinically relevant in daily practice. Besides, in our final regression model small beta coefficient was shown for age of the patient. In previous research minimal clinically important difference (MCID) for VAS is considered as 2.5(30). Patients should be unrealistic high aged to reach this MCID and clinically relevance of this association is questionable. Additionally, in our model some variables showed significant differences between excluded and included participants, which could have biased the results of the regression model. For these three reasons, significant results of this study should be interpreted with caution.

The present study shows that only 27% of the non-specific neck pain patients were evaluated by using PROMs. Even though some studies investigated barriers and facilitators regarding the use of PROMs (31–33) more research on associated factors in non-specific neck pain patients is needed to increase the use of PROMs among physiotherapists. In addition, it is recommended to perform a statistical analysis including more associated variables to

explain a higher percentage of the variation in the outcome change of pain intensity. For example, psychological factors of the patient, the experience level and the specialization of the physiotherapist might influence the pain score in non-specific neck pain patients. It would be interesting to gain more insight into 'new' variables that might influence the change in pain intensity and finally to develop a prognostic model to support clinicians in the daily clinical practice.

CONCLUSION

This study showed that 27% of the non-specific neck pain patients were evaluated by using PROMs in Dutch primary care physiotherapy. The use of PROMs showed a significantly higher number of treatments for treated patients.
Furthermore, this study revealed that a higher age of the patient was associated with a lower change of pain intensity and that a higher number of treatment sessions was associated with a higher change of pain intensity, although both variables showed small beta coefficients. In future, it is recommended to perform a statistical analysis including more associated variables to explain a higher percentage of the variation in the outcome change of pain intensity.

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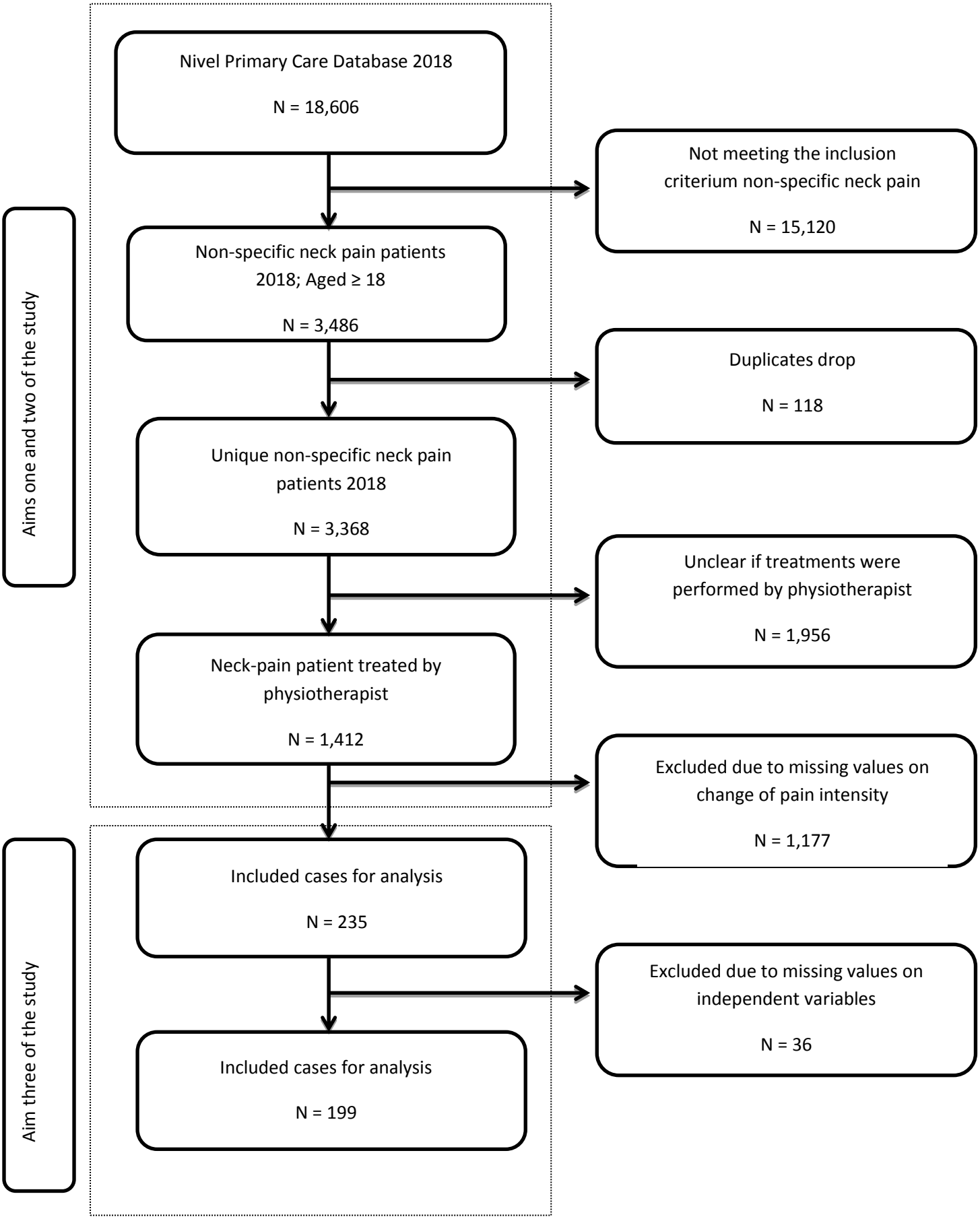
APPENDIX

Appendix 1: Study population selection process



Appendix 2: Comparison of characteristics after the first exclusion

Patient characteristics	**Excluded study population (N=1,177)**	**Included study population (N=199)**	**P-value**
Age, mean (SD)	49(17)	49(17)	0.828
Gender, n(%) Female	842 (72%)	136 (68%)	0.358
Duration treatment episode (days)	63(73)	60 (68)	0.584
Number of treatment sessions, mean (SD)	6.6(5.1)	6.3 (4.2)	0.397
Number of times PROMs used, mean (SD)	0.7(1.2)	2.9 (1.7)	0.000*
Therapist characteristics	**Total number (N= 70)**	**Total number (N= 43)**	
Age	39 (11)	42 (10)	0.041*
Gender, n(%) Female	43 (59%)	32 (16%)	0.000*

% = percentage n= number of subjects, SD= standard deviation, * P ≤ 0.05 for Mann-Whitney-U-test and Pearson's chi square test

Appendix 3: Comparison of characteristics after the second exclusion

Patient characteristics	**Total study population (N=36)**	**Included study population (N=199)**	**P-value**
Age, mean (SD)	45(15)	49(17)	0.170
Gender, n(%) Female	28 (78%)	136 (68%)	0.257
Duration treatment episode (days) (SD)	53(52)	60 (68)	0.535
Number of treatment sessions, mean (SD)	5.9(3.0)	6.3 (4.2)	0.590
Number of times PROMs used, mean (SD)	2.47(0.81)	2.9 (1.7)	0.000*
Therapist characteristics	**Total number (N= 36)**	**Total number (N= 43)**	
Age	-	42 (10)	-
Gender, n(%) Female	-	32 (16%)	-

% = percentage n= number of subjects, SD= standard deviation, * P ≤ 0.05 for Mann-Whitney-U-test and Pearson's chi square test