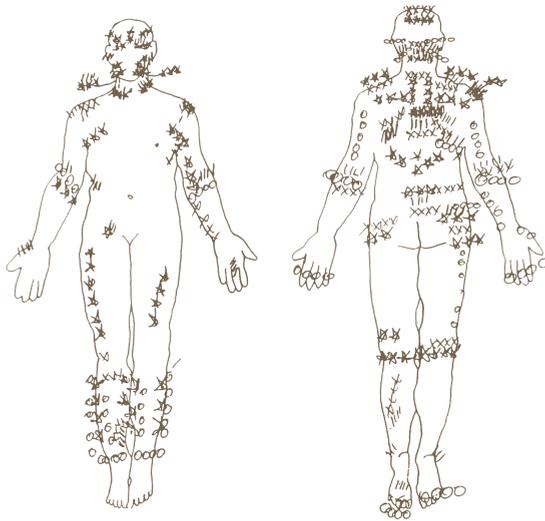


# CHAPTER 10

## Summary / Samenvatting



This thesis focused on two themes: The main focus was on the investigation of the relative impact of biopsychosocial factors on outcome in patients with neck pain and low back pain (LBP) presenting to chiropractors in Belgium and the Netherlands. Secondly, in two clinimetric studies we evaluated the psychometric characteristics of a measurement instrument, the Dutch version of the Neck Disability Index (NDI-DV), and in two other studies we evaluated the use of frequent data collection by means of text messaging. In order to do so, a large cohort of 917 patients presenting with neck pain and/or LBP to chiropractors in Belgium and the Netherlands was created.

## CHAPTER 1

### **Introduction**

In Chapter 1, a brief rationale for and an overview of the studies included in this thesis is provided. We formulate the principal research questions addressed and present the outline of this thesis.

## CHAPTER 2

### **Characteristics of chiropractors and their patients in Belgium**

In Chapter 2, we present the results of a descriptive study of the characteristics, the practice characteristics, and opinions of chiropractors and the sociodemographic characteristics and the type of complaint of patients presenting to chiropractors in Belgium. 80 Dutch speaking chiropractors provided information on 517 of their patients. The sociodemographic characteristics of both the chiropractors and their patients are in line with previous published data from the United States and Europe. Patients present with neuromusculoskeletal complaints of moderate intensity and moderate effect on their activities of daily living. 28.5% of the patients present with neck pain and neck-pain related complaints, 63.0% with LBP and LBP-related complaints like herniated discs and radicular pain. Patients have high expectations regarding the effectiveness of the chiropractic treatments for their musculoskeletal problem. A very small percentage (<1%) of the patients present with non-musculoskeletal complaints, which suggests that chiropractors in Belgium, much like in other European countries, by and large concentrate on neuromusculoskeletal complaints.

### **CONCLUSION**

*This was the first study describing doctors of chiropractic and their patients in Belgium. Chiropractors in Belgium primarily focus on the diagnosis and treatment of neuromusculo-*

*skeletal complaints in adults, with emphasis on the spine. Patients presenting to the chiropractor consult with neuromusculoskeletal complaints of moderate intensity that moderately affect their activities of daily living.*

## CHAPTER 3

### **Definition of the construct to be measured is a prerequisite for the assessment of validity. The Neck Disability Index as an example.**

In Chapter 3 we provide the results of a clinimetric study on the validity of the Dutch version of the Neck Disability Index (NDI-DV). To assess content validity, 11 neck pain experts and 10 patients commented on the construct, comprehensiveness, and relevance of the NDI. The developers poorly defined what the NDI aimed to measure. The Dutch translation of some items proved to be suboptimal and the content validity is poor. Structural validity was assessed by item factor analysis (FA) and item response theory modeling. Unidimensionality of the NDI could not be confirmed. The goodness-of-fit statistics for FA with one factor were satisfactory when the item “concentration” was omitted. Differential Item Functioning (DIF) analysis for gender showed DIF for the headache item. DIF occurs when people from different groups with the same latent trait (ability/skill) have a different probability of giving a certain response on a questionnaire. The NDI-DV measures more than physical function, but for the measurement of the broader construct that disability is important items are missing. Good correlation was found with the DASH, supporting construct validity.

#### **CONCLUSION**

*It is questionable whether in research the NDI should be the instrument of first choice for use as a primary outcome measure. Definition of the construct to be measured is a prerequisite for the assessment of validity.*

## CHAPTER 4

### **Reliability, responsiveness and interpretability of the Neck Disability Index-Dutch version in primary care.**

In Chapter 4, we report an evidence-based recommendation for the pragmatic use of the NDI-DV in primary care based on an assessment of the reliability, the responsiveness and the interpretability of the NDI-DV. The reliability of the NDI-DV was assessed in 155 patients at the 6 months measurement point (and 10 days later). Test-retest reliability and measurement error were good with a  $ICC_{\text{agreement}}$  of 0.88 and SEM of 1.95. Responsiveness is the ability of an instrument to detect change over time in the construct to be measured. For responsiveness, assessed in a sample of 265 patients, the ROC analysis showed an area under the curve of 0.85; this implies good responsiveness. The interpretability of the NDI for use in individual patients was tested by relating

the smallest detectable change (SDC) to the minimal important change (MIC). The MIC (4.50) was slightly smaller than the SDC (5.40), but when a 90% confidence level instead of 95% level for a standard error of measurement (SEM) was used, the SDC became 4.50, thus equivalent to the MIC. The anchor-based MIC distribution determining the MIC for the NDI-DV in patients with neck pain used “perceived recovery” as anchor. Although the correlation between the anchor and the change in scores on the NDI was only 0.54 – which is moderate – the change scores on the NDI were well able to distinguish patients who indicated to be importantly improved on the anchor, with an AUC of 0.85.

#### **CONCLUSION**

*The reliability and responsiveness of the NDI-DV, applied to patients with non-specific neck pain in a chiropractic setting in Belgium and the Netherlands are good. Considering a MIC value of 4.50 and SDC of 5.40, the NDI-DV could be used in clinical practice. When a change score of 5 is considered important for patients, it has a 7% chance to be due to measurement error.*

## **CHAPTER 5**

### **Somatization is associated with worse outcome in patients with neck pain and low back pain**

In Chapter 5 we report on a prospective, multi-center chiropractic practice-based cohort study in Belgium and the Netherlands. We use the cohort of 917 patients, of which 326 with neck pain and 591 with LBP to examine the association between psychosocial factors measured at baseline and outcome in patients with neck pain or LBP. Patients completed self-administered questionnaires at baseline, following the second visit, and at 1, 3, 6 and 12 months. Psychosocial factors assessed at baseline were: distress, depression, anxiety and somatization via the 4 Dimensional Symptom Questionnaire, patient's beliefs regarding the effect of physical activity and work on their complaint via the Fear Avoidance Beliefs Questionnaire, and social support via the Feij social support scale. Primary outcome measures were perceived recovery, pain intensity, and functional status; the latter was measured with the NDI-DV for neck pain and Oswestry Disability Index (ODI) for LBP. A univariable regression analysis to estimate the relation between each psychological variable and outcome was followed by a multivariable multilevel regression analysis. We showed an association of somatization with perceived recovery, function and pain. In addition, we demonstrated an association between depression at baseline and reported functional status for patients with LBP and a very weak, albeit statistically significant association between fear and reported functional status and pain, both for patients with neck pain and patients with LBP. We did not find any association between distress, anxiety or social support with any of the 3 outcome measures.

## CONCLUSION

*Patients consulting Belgian and Dutch chiropractors do not often present with strongly compromised psychosocial profiles. Of all the psychosocial variables examined in this study, somatization was the only variable consistently found to be associated with diminished perceived recovery, diminished functional status, and increased neck pain or LBP. Other psychosocial variables such as depression and fear showed an association with selected outcomes, thereby demonstrating an inconsistent pattern. As a result, these variables would appear less clinically relevant.*

## CHAPTER 6

### **Adding psychosocial factors does not improve predictive models in patients with spinal pain enough to warrant extensive screening for them at baseline**

In chapter 6 we report on a prospective, multi-center chiropractic practice-based cohort study in Belgium and the Netherlands to determine whether certain psychosocial factors provide added value to predict recovery in patients presenting with neck pain or LBP. Data of the same 917 patients were used, of which 326 with neck pain and 591 with LBP. They completed self-administered questionnaires at baseline, following the second visit, and at 1, 3, 6 and 12 months. We used lasting perceived recovery as outcome. Patients were considered to have a lasting recovery if they reported to be completely recovered or much improved at the 3 months follow-up, and remained recovered at 6 and 12 months follow-up. We used stepwise, backward GEE regression models to take into account the clustering of patients within practices. To assess the added value of the psychosocial variables, we compared two model fit indices. The backward GEE regression analysis resulted in a prediction model which included patients' expectations for patients with NP and the degree of somatization for patients with LBP. The addition of these specific psychosocial variables did not substantially improve the model's fit indices.

The data also illustrated the impact of the definition of lasting recovery: for patients presenting with neck pain, 73.8% reported to be much improved or completely recovered at 3 months. However, only 50.6% of the patients with neck pain had lasting recovery. For patients presenting with LBP, 66.7% reported to be much improved or completely recovered at 3 months, whereas that percentage went down to 51.2% of the patients with LBP when considering lasting recovery as outcome measure.

## CONCLUSION

*Psychological and social variables have little added value in predicting outcome in patients presenting to the chiropractor with NP or LBP. We therefore advise chiropractors not to focus on collecting baseline information on the psychosocial status of their patients. However, a minority of patients score high on psychological variables. New stratified care models in primary care have used simple screening tools for identifying this high risk group. Identification of the small*

*subgroup with psychosocial problems and a high risk for chronicity needs further investigation in a chiropractic setting.*

## CHAPTER 7

### **Trajectories of neck pain and low back pain. A latent class growth analysis.**

In chapter 7 we report on a sample of 448 patients (153 neck pain, 295 LBP) from the prospective, multi-center practice-based cohort study who agreed to provide answers to four consecutive text messages (SMS) that were sent on a weekly basis to their mobile phones. There is very little information on the trajectories of neck pain and LBP. In the past, researchers relied primarily on data collected on a small number of time points during the follow-up period of 3 months to one year. We wanted to chart the course of neck pain and LBP, based on data collected by SMS. The outcome measure was “pain intensity”. Distinct patterns of pain were analyzed with quadratic latent class growth analysis. The final model was chosen based on a stepwise procedure, starting with a one-class solution, then adding one class at the time. To determine the final model, two statistical fit indices were used (the Bayesian Information Criterion and the posterior probabilities).

To our knowledge, it is the first time that the course of neck pain has been depicted and described based on frequent and detailed longitudinal data over a period of 26 weeks. Neck pain and LBP have similar but not the same pain trajectories over a period of 26 weeks. Two trajectories, the “recovering from mild baseline pain” and the “recovering from high baseline pain” show similar patterns, with the main difference being the pain intensity at baseline. These 2 trajectories are also the most common. The other 2 trajectories show a specific course for neck pain and LBP. The trajectories that we found for LBP however, differed from the models proposed by Dunn and colleagues.

#### **CONCLUSION**

*We classified neck pain and LBP patients into distinct groups by using LCGA of detailed longitudinal data on the course of their pain over time. Both neck pain patients and patients presenting with LBP each demonstrated 4 distinct groups with different trajectories of pain in the six months following the first consultation with the chiropractor.*

## CHAPTER 8

### **How well do measurements of pain measured by monthly questionnaires correlate with data collected weekly?**

In chapter 8 we compared data collected from monthly questionnaires to data collected by weekly SMS tracking. As a secondary objective, we examined whether the number of days with pain and the number of days that patients reported to be limited in their activities of daily living (ADL) as measured by questionnaires for the previous month

strongly correlated with the SMS data for the number of days in the most recent week. Data were obtained from 169 patients with neck pain and 326 patients with LBP. The weekly SMS data were compared with the questionnaires' responses using paired T-tests, where the standard deviation of the differences represents the agreement on individual level. Data were analyzed separately for patients with stable and those with fluctuating pain. We identified substantial differences on the individual level in days with pain as reported by a monthly questionnaire as compared to data collected by SMS tracking. The agreement was better for number of days limited in ADL than for number of days with pain. Moreover, patients with a rather stable pain pattern throughout the month did not show better agreement between both methods compared to patients with fluctuating pain patterns. Finally, recall of total number of days with pain and days limited in ADL over the previous month were not more influenced by the reported SMS data in the most recent week of that month.

#### **CONCLUSION**

*This study demonstrated poor agreement on the individual level between reported number of days with pain when collected by text messages and by questionnaire; for number of days limited in ADL, the agreement was better but on the individual level we found substantial differences. Patients with a stable course of LBP did not show a better agreement than those with a fluctuating course. We did not find convincing evidence that the most recent week was disproportionately weighted when estimating the number of days in the previous month.*

## **CHAPTER 9**

### **General discussion**

In this chapter the principal findings of this thesis are presented and discussed. We discussed how well the Dutch Version of the Neck Disability Index (NDI-DV), as an example of the measurement instruments (HR-PRO) used in the cohort study, meets current clinimetric standards and psychometric properties, as defined by the COnsensus-based Standards for the development of Measurement INstruments (COSMIN). We also discussed what the relative impact of biopsychosocial factors is on outcome in patients with neck pain and low back pain presenting to chiropractors in Belgium and the Netherlands. Finally, we discussed the pro's and con's of novelties in data gathering.

The chapter concludes with a summary of the implications of this research for the chiropractors and their patients in Belgium and the Netherlands. We describe four implications for clinical practice and four recommendations for further research.