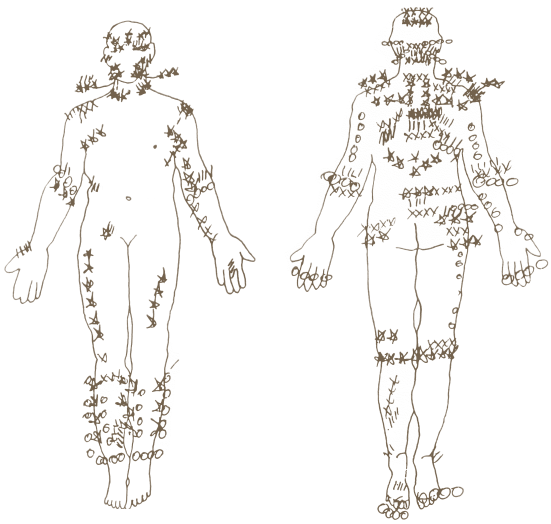
CHAPTER 9

General discussion



The main goal of this thesis was to investigate 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. In order to accomplish this, a large cohort of 917 patients presenting to chiropractors with neck pain and/or LBP was created. We also focused on some measurement issues with great relevance to the cohort study, such as the measurement properties of a patient reported outcome measure for disability, the introduction of a different way to define recovery, and the role of a novel measurement instrument to gather frequent data that were all utilized in the cohort study.

In 1977 Engel highlighted the overall limitations of the traditional biomedical model of disease.[1] Shortly thereafter Waddell et al. made an important translation of Engel's plea to the area of LBP.[2,3] Since the publication of Waddell's paper[3] – introducing the concept of the biopsychosocial model for low back pain – more than 25 years of research on the role of biopsychosocial factors has passed. Nevertheless more research on the topic seems warranted: the position statement of the 12th International LBP Forum clearly indicated that clarity about which predictors of outcome are prognostic factors and which are potential treatment effect modifiers may help guide best practice treatment and prevent disability.[4] In addition, in a recently established research agenda for the chiropractic profession in Europe academics and clinicians working in a chiropractic setting ranked research into biopsychosocial variables as predictors of outcome 5th in order of importance out of 19 research priorities.[5]

All parties involved in spinal health care, including chiropractic, now realize that neck pain and LBP are best understood as biopsychosocial phenomena.[6-8] Chiropractors have long believed that their patients presented with predominantly mechanical, non-specific spinal pain. As a result, until recently, most research within the chiropractic profession has focused on biomedical factors that predict or influence outcome.[9-13] Recent efforts have been directed towards attempting to help the clinician identify the key biopsychosocial factors that can influence outcome. An example of such efforts is the STarT back screening tool (SBT), which was introduced as a tool designed to assist general practitioners' decision-making concerning initial treatment options for patients with LBP in primary care.[14] The SBT has also been examined in a chiropractic setting,[15,16] however, whilst the SBT appears useful in some back pain populations it does not appear to differentiate outcomes in LBP patients seeking chiropractic care.[16]

One of the challenges for researchers lies in giving proper advice for the clinician practicing in a busy clinical environment. We know that the principles of Evidence Based Medicine have full relevance if they are successfully implemented in clinical practice. The average clinician wants to know what questions to ask or which questionnaires to use that will allow him or her to capture as much information as possible with the least amount of effort and time. At the first consultation, chiropractic clinicians, by-and-large, want to identify those factors, including psychological and social factors, that may have clinical relevance and/or may have an impact on decisions regarding

whether or not or how to treat the patient. However, it is equally true that the chiropractor does not want to overburden the patient with multiple and time-consuming questionnaires at a first contact, and that he or she also wants to ensure minimal disturbance of normal office routine. These are probably the main reasons why a large majority of a random sample of 15 chiropractic practices in Belgium and 25 in the Netherlands admitted that they do not routinely or systematically use validated questionnaires to screen for psychosocial status of their patients at baseline.

To meet these concerns we challenged the quality of existing Health-related Patient-reported Outcomes (HR-PRO): if the questionnaires often used by chiropractors would prove to be lacking the measurement properties they purport to have, then we would have to advise to be cautious with the interpretation of the results. If on the other hand the PROs pass the scrutiny of the latest clinimetric and psychometric evaluation, than the systematic use of these questionnaires should be encouraged.

For the purpose of this thesis, we used the Dutch version of the Neck Disability Index (NDI-DV). Our research team decided to critically assess the NDI, as it is the most frequently used and evaluated disease-specific patient reported outcome questionnaire in patients with neck pain.[17]

How well does the Dutch Version of the Neck Disability Index (NDI-DV), as an example of the measurement instruments (HR-PRO) used in the cohort study, meet the current clinimetric and psychometric properties, as defined by the COnsensus-based Standards for the development of Measurement INstruments (COSMIN)?

Our research showed that the test-retest reliability, applied to a subgroup of patients presenting to a chiropractor with neck pain, and the responsiveness of the NDI-DV is good.[18] The Smallest Detectable Change (SDC) and Minimal Important Change (MIC) scores can well be defined.[18] It is important to note that not every change on a measurement instrument can be considered to be a real or true change. Small changes may be due to measurement error, i.e. these small changes might be comparable in size or even smaller than the differences found when repeated measurements are performed in a stable population. Therefore, the SDC is defined as a change beyond measurement error. The MIC is the smallest change in score that patients consider important.[19] This means that clinicians can actually use this HR-PRO, when used at baseline and at a later stage in treatment, to see whether or not the patient has made the progress that patients in general consider to be important.

However, our research also showed that the NDI-DV does not measure what most clinicians believe it to measure. Most clinicians and many researchers interpret the questionnaire as a measure of physical functioning,[20,21] but our study suggests it measures other constructs as well, such as pain or pain intensity, mental/cognitive functioning,

dysfunction/symptoms, personal care. When on the other hand we considered the original construct 'self-reported disability' proposed by the developer of the NDI, we found that important items such as sports and computer use were missing.[22] In methodological terms, we can state that the NDI-DV is not a unidimensional questionnaire and that its content validity is poor.[22]

Be aware however, that the advice we give regarding the NDI-DV may well apply to many if not all the questionnaires developed in the '80s and '90s of the past century, most often by clinicians for clinicians, in an attempt to come up with a way to quantitatively measure the impact of a condition on a patient's life.

Given current quality standards for patient-reported outcome (PRO) instruments, questions could be raised whether the NDI-DV should still be considered the first instrument of choice as a PRO in studies on patients with neck pain. We therefore advocate the development of a new neck-specific instrument, starting from a clear definition of the construct to be measured and using more advanced psychometric techniques. The Patient Reported Outcomes Measurement Information System (PROMIS), a recent initiative funded by the National Institutes of Health (NIH), is a system of highly reliable, valid, flexible, precise, and responsive assessment tools that measure patient–reported health status. As a result, for the measurement in neck pain patients, pure and unidimensional questionnaires can be developed from the PROMIS Physical Function item bank and the PROMIS Pain Interference item bank. One-factor or unidimensional questionnaires allow to look for mutual relationships between different constructs. It also allows for comparison of the same constructs that are measured in different studies. PROMIS measures have been standardized so there are common domains and metrics across conditions, allowing for comparisons across domains and diseases.

Does that mean we should disregard all evidence that came from studies using the NDI? Of course not. Nor does it mean that the change score of 5 points can no longer be considered important for the patients and the clinicians. Chiropractors in Belgium and the Netherlands should continue to use the NDI-DV until a new and better neck-specific instrument has been developed, but they should be made aware that it does not exactly measure what they have always believed it measured.

What is the relative impact of biopsychosocial factors on outcome in patients with neck pain and low back pain presenting to chiropractors in Belgium and the Netherlands?

Gordon Waddell's VOLVO award winning paper entitled 'A new clinical model for the treatment of low-back pain' introduced the biopsychosocial model of low back pain, emphasizing the distinction between pain and disability and the need to address the biological, psychological and social aspects of the condition.[3] Waddell has really challenged the traditional approach to evaluating and treating LBP. At that time, in 1987,

health care workers in general focused on nothing but the biological side of spinal pain: most diagnoses at that time were nominal and of doubtful validity.[3] It is a good evolution that clinicians nowadays pay attention to the different aspects of neck pain and LBP. All clinicians will tell us that they are well aware of the relation between stress and physical complaints, especially in those patients presenting with neck pain. This can be different in any patient, and many times neck pain or LBP start when the load bearing capacity of a structure is surpassed by the load that has been put on that structure. That load bearing capacity and the load are both comprised of physical, mental and biochemical components. Advice coming from research is often aimed at a heterogenic group of patients, for instance males and females aged 18 to 65, complaining of neck pain of varying duration. One of the difficulties for the clinician, in the understanding that a complaint has many facets to it, is to distill just that specific advice that could be applicable to the patient sitting in front of him or her.

Patients presenting to the chiropractor consult with musculoskeletal complaints of moderate intensity on average that moderately affect their activities of daily living (ADL).[23] The majority of patients visiting a chiropractor in Belgium consult with spine related complaints.[23] Our research confirmed the assumption made by practicing chiropractors that their patients in general do not present with complicated psychological profiles. Indeed, less than 1% scored the highest score on all 4 subdomains (distress, depression, anxiety and somatization) of the 4 Dimensional Symptom Questionnaire (4DSQ).[24] These patients on average also score higher on the NDI and the Oswestry Disability Index (ODI), 6 out of 50 and 23 out of 50 points respectively. As a consequence, for those patients with the highest scores, it would appear plausible to first address the underlying psychological or psychosocial problem(s) rather than choosing a mechanical approach like chiropractic. In the separate subdomains of the 4DSQ we found interestingly enough that up to 29.3% (22.6% score slightly elevated, 6.7% score strongly elevated) of LBP patients and 37.3% (27.5% score slightly elevated, 9.8% score strongly elevated) of neck pain patients have slightly or strongly elevated scores for distress. For somatization 1 in 4 (25.5%, with 21.8% scoring slightly elevated, and 3.7% scoring strongly elevated) LBP patients and even 1 in 2 (50.6%, with 42.4% scoring slightly elevated, and 8.2% scoring strongly elevated) neck pain patients have slightly or strongly elevated scores. This implies that, even though patients consulting with chiropractors do not exhibit complex or complicated psychological profiles, certain subdomains warrant at least some attention.

Somatization was the only variable consistently found to be associated with diminished perceived recovery, diminished functional status and increased neck pain or LBP. In addition, we demonstrated an association between depression at baseline and reported functional status for patients with LBP and a very small, 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. However, knowing that there's only a very small minority of the patients presenting with complicated psychological profiles and considering that Chapter 6 of this thesis clearly showed that psychosocial variables measured at baseline barely improved chiropractors' ability to predict outcome in patients presenting with neck pain or LBP,[25] we advise chiropractors not to spend a lot of time and effort on collecting baseline information on the psychosocial status of their patients. This advice meets the clinicians' concern that too many questionnaires at baseline might not be perceived well by the patient new to his/her practice, and it ensures minimal disturbance of normal office routine.

Novelties in data gathering and outcome definition. Are novel ways of data gathering always better?

In order to understand more about the clinical course of neck pain and LBP, it is necessary to collect data frequently over a long period. In most studies, the effects of interventions for relieving neck pain or LBP have been examined by using questionnaires for assessment of outcomes at specific points in time. Typically, pain or functional status is measured at specific intervals throughout the course of a year, for example at 1, 3, 6 or 12 months.

In the absence of frequent data, in Chapter 6 we had proposed to take 'lasting recovery' as outcome measure.[25] 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.[25] As far as we know, it is the first time that lasting recovery is considered as outcome measure in longitudinal cohort studies on neck pain and LBP. We used this novel outcome measure based upon discussions with practitioners in the field and within the research team. Since spine pain fluctuates, considering outcome at a single moment in time is nothing more than a snapshot and might therefore not reflect real change. In this case, the data gathering is not novel, but the way the traditional data gathering is interpreted most certainly is.

Chapter 6 illustrated the discrepancies between a single measurement and outcome measured over time (lasting recovery). This has implications for chiropractors and patients: for patients presenting with neck pain, 73.8% reported to be much improved or completely recovered at 3 months but 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 only 51.2% of the patients with LBP had lasting recovery.[25] This significant difference in proportion of improved patients can lead to interesting discussions, for instance on the need for regular follow-up at the chiropractor, or on the need for specific exercise therapy to improve the load bearing capacity of the soft tissues of the cervicothoracic and/or lumbosacral spine. This information about potential relapses might thus be used by the chiropractors to inform their

patients on the natural course of neck pain or LBP, and patients might find motivation to be more consistent in doing their home exercises, stretching, adhere to postural advice and other measures that might have been advised in an attempt to prevent recurrence of their problem.[26]

More information on the course of spine pain has become available in the last couple of years; a couple of studies have examined the course of LBP and therefore used frequent text messaging (SMS) via patients' cell phones to collect longitudinal data.[27-30] Data collection through the use of text messaging is a novel technique that has the potential of profoundly changing the methods of data collection in spine research in the future. Frequent data gathering, for instance weekly over a period of 26 to 52 weeks allows for much better charting of the course of spinal pain.[27-30] We are the first research group that documented the course of neck pain over a period of 26 weeks, based on weekly information on pain and limitations in activities of daily living obtained through SMS on patients' cell phones.

One of the research questions of this thesis was to find out if the course of LBP in patients treated by chiropractors followed those trajectories seen in primary medical care as described by Dunn et al.[31] The frequent data gathered by our study in Chapter 7 allowed us to demonstrate that the trajectories that we found for LBP differed from the models proposed by Dunn and colleagues and also from those proposed by Tamcan and colleagues.[32] Only the 'recovering from mild baseline pain' trajectory in our data set, albeit the largest group, was similar to the 'recovering' trajectory from Dunn and the 'fluctuating' trajectory from Tamcan. We had 3 trajectories that displayed a 30% improvement on the VAS pain scores within 6 weeks, whereas the trajectories by Dunn and Tamcan showed a rather horizontal pattern, fluctuating around the baseline values or showing a small decline in the trajectory curves. This discrepancy can possibly be explained by the differences in patient population. The study by Tamcan et al used data from 305 individuals who were taking part in a population-based cross-sectional study of musculoskeletal health in Switzerland. The study by Dunn et al comprised of 342 primary care low back pain consulters in the UK. It is fair to assume that Dunn's patient population resembled the patient population of Croft et al, who did a study in 2 large general practitioner practices in Manchester.[33] Although not specified in the methods section of the studies, one can assume that those patients received 'usual care' and were not routinely referred for a specific form of therapy as Croft concluded that 'since most consulters continue to have long term low back pain and disability, effective early treatment could reduce the burden of these symptoms and their social, economic, and medical impact'.[33] Our study included 448 patients who consulted a chiropractor and were actually treated for their neck pain or LBP. It is tempting to assume that the therapeutic chiropractic intervention was responsible for the more favorable trajectories in our study. However, high quality evidence suggests that there is no clinically relevant difference between spinal manipulative therapy and other interventions

(including usual care) for reducing pain and improving function in patients with acute and chronic low-back pain.[34,35] For neck pain on the other hand, a recent Cohrane review showed that support can be found for use of thoracic manipulation versus control for neck pain, function and quality of life.[36]

So yes, this novel way of data collection is certainly better and provides much more profound insight in a patient's complaint than when data are only collected on the traditional intervals, for example at 1, 3, 6 or 12 months. In our study in Chapter 8 'how well do measurements of pain measured by monthly questionnaires correlate with data collected weekly?' we demonstrated that there is poor agreement on the individual level between reported number of days with pain when collected by text messages and by monthly questionnaires.

However, not all that glitters is gold. Our study in Chapter 7 showed that researchers should strictly follow-up on the weekly answers by all the participants: about 20% of those people agreeing to participate in the weekly follow-up by SMS failed to reply to the first set of 4 questions and never entered the study. Also, technical problems from the provider or the participant can occur, leading to missing data. In our study, due to technical problems the sending of text messages was interrupted for a period of 6 to 9 weeks. This was not immediately detected by the research group, but it also took several weeks for the national phone companies to come up with a lasting solution. To maximize the effectiveness of collecting data via SMS, it appears that the system might need a research assistant to closely monitor the entire process, thereby compromising or even undoing the monetary advantages of the follow-up via text messaging.

What are the potential implications of this thesis for clinical practice?

1. ***Psychosocial factors***: In general, patients present to chiropractors with neck pain and LBP of moderate intensity, that moderately affect their activities of daily living, and without complex psychosocial profiles. Since standard questionnaires to screen for psychosocial factors are long and exhaustive, and thus have an impact on normal office routine, and since psychosocial variables measured at baseline barely improve the chiropractors' ability to predict outcome in patients presenting with neck pain or LBP, we cannot advice chiropractors to routinely and extensively screen the psychosocial status of their patients at the initial consultation.
   1.1. Our recommendation to not routinely screen for psychosocial status of new patients at baseline can be viewed as an approval and confirmation of existing practice procedures and office routine, where chiropractors in Belgium and the Netherlands use questionnaires that screen only for sociodemographic and biomedical characteristics of the patients and their complaints.
   1.2. Although patients in general do not present with complicated psychological profiles (less than 1% scored the highest score on all 4 subdomains of the 4DSQ),

up to 1 in 6 (15.6%) neck pain patients and 1 in 11 (9.1%) LBP patients have strongly elevated scores for one of the four subdomains (distress, depression, anxiety and somatization) of the 4DSQ. If patients fail to respond to treatment within a reasonable time, chiropractors might want to consider to screen for somatization before continuing care, since somatization was the only psychosocial variable that was associated with worse outcome in patients presenting to chiropractors with neck pain or LBP.

2. ***Pragmatic use of measurement instruments***:
   2.1. Chiropractors in Belgium and the Netherlands should continue to use the NDI-DV until a new and better neck-specific instrument has been developed, but they should be aware that it measures more than physical function alone. Vernon had initially developed the NDI to measure "self-reported disability" which he saw as "the perceived effect of pain and impairment on the patient's performance and enjoyment of daily living".[37] Our analyses demonstrate that the NDI does not measure this broader construct, since important items which make up the daily activities of most people, such as sports and computer use, are missing.[20]
   2.2. A change score of 5 points (out of 50) on the NDI-DV is considered important for the patients (with a <7% chance of being due to measurement error). Research findings have to find implementation into clinical practice: We advise clinicians to discontinue chiropractic care if their patients' score on the NDI-DV has not improved by ≥ 5 points after 3 months of chiropractic treatment.
3. ***Scope of practice***: Chiropractors in Belgium and the Netherlands assess, diagnose, and treat musculoskeletal problems: 97% of their patients present with musculoskeletal complaints and 92% have spinal complaints with or without radiation to an extremity. Chiropractors should convey this message to potential patients and potential referral sources that chiropractors indeed have developed strong expertise and experience in the treatment of a broad range of musculoskeletal problems, with a strong emphasis on the spine.
4. ***On the course of neck pain and LBP***: Our data demonstrate that the majority of patients treated by chiropractors for non-specific neck pain or LBP improve, regardless of their pain at baseline. More than 90% of neck pain patients and 88% of patients with LBP will demonstrate a reduction of more than 30% in pain within 6 weeks. If patients do not show this improvement at 6 weeks, chiropractors should either screen for the psychosocial status of these patients and/or refer those patients for further diagnostic work-up and/or additional therapeutic approach. Our data can help primary care physicians and other health care clinicians including chiropractors to inform patients on the course of neck pain or LBP when treated by chiropractic.

What are the potential implications of this thesis, translated in recommendations for future research?

1. ***Psychosocial factors***: As a result of the introduction of the biopsychosocial model of LBP by Waddell, researchers and clinicians have a better idea about what factors contribute to LBP. However, a number of issues remain unknown or uncertain. We advise chiropractors to not routinely screen for psychosocial factors in patients presenting with neck pain and/or LBP. Still, a minority of patients score high on psychological variables. For those with neck pain with strongly elevated scores on one of the four subdomains of the 4DSQ, 68.4% are recovered at 3 months, but only 27.5% show lasting recovery at 12 months. For those with LBP with strongly elevated scores on one of the four subdomains of the 4DSQ, 53.7% are recovered at 3 months, but only 25.9% are lasting recovered. These percentages are significantly lower than for the entire study population. We believe that, in order to establish a more appropriate therapeutic approach, further research in chiropractic and other manual therapy disciplines should try to describe this small subgroup with psychosocial problems and a high risk for chronicity in terms of, among other things, co-morbidities, previous treatments and mode of referral (general practitioner or self-referred).
2. ***Measurement instruments***: In Chapter 3 we described that the NDI-DV measures more than physical functioning, but also that for the measurement of a broader construct, important items are missing. We therefore advocate the development of a new neck pain-specific measurement instrument, starting from a clear definition of the construct to be measured and using more advanced psychometric techniques such as Item Response Theory (IRT).
3. ***On the course of neck pain and LBP***: Future research efforts in chiropractic and other disciplines on the course of neck pain and LBP should use SMS methodology for data collection, whenever possible and relevant (that is, frequently posing few questions allowing for short answers). However, as with any data collection methodology, closely monitoring data collection is necessary, although monitoring large cohorts presents particular challenges. As a result of the practical problems we encountered, we suggest to start with a trial period of 2 weeks: at that time, participating patients have experienced the process and thus could better and more informed answer whether or not they would be interested to participate in a study with weekly text messages on their cell phones over the period of one year.
4. Since we advocate the use of "lasting recovery" as novel outcome measure in clinical practice, particularly in patients presenting with acute neck pain or LBP (<6 weeks duration), more studies using this outcome measure are warranted. Chronic patients might have different expectations towards treatment outcome(s); research shows that previous experiences are a major influencing factor for LBP patients' expectations.[38] Since chronic patients, based on previous experiences, might not expect "lasting recovery" but only "improvement", "lasting recovery" might not be an appropriate outcome measure in chronic LBP patients.

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