Subgrouping patients with low back pain

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Summary

Chapter 1 provides some background to our research, our research questions and an overview of the studies included in the thesis. In the past decades, more than 1000 randomized controlled trials (RCTs) of conservative treatment methods for low back pain (LBP) have been published, however the evidence regarding many treatments is conflicting. Many physical therapists believe that this conflicting evidence relates to the inclusion of heterogeneous samples of LBP patients, with subgroups of patients that respond differently to the intervention under study. Given the variability inherent in LBP, it has been suggested that the effectiveness of interventions for patients with LBP can be improved by matching interventions to the patient's clinical presentation and predicted clinical course. The importance of identifying meaningful subgroups in patients with LBP was set as a priority as early as 1996 and has remained a research priority ever since.

This thesis focuses on subgrouping patients with LBP. Clinical signs and symptoms are used to subgroup patients in the recognition that in the majority of patients with LBP it is not possible to reliably make a specific patho-anatomical diagnosis. The thesis consists of two parts: (1) the design and results of an observational cohort study in secondary care (Chapter 2-4), and (2) the design and results of a RCT in primary care (Chapters 5-7).

Chapter 2 reports on the development of a screening instrument to identify those patients with chronic LBP in an outpatient rehabilitation setting who need additional psychological assessment. It was decided to develop a screening instrument, because no relatively simple and minimally burdensome screening instrument was available. A total of 229 consecutive patients with chronic LBP who attended an outpatient rehabilitation centre was enrolled in a prospective cohort study. Before treatment started, 17 commonly used signs and symptoms were assessed by physical therapists. The results on these tests were related to the assessments made by the psychologists, which were considered to be the reference standard (relevant psychological disturbances, yes or no). The physical therapists and psychologists were unaware of each other's findings. Ten of the 17 signs and symptoms were significantly associated with the presence of relevant psychological disturbances in the univariable analysis. Multivariable logistic regression resulted in a final model including: presence of Waddell's non-organic signs, high scores for the pain drawing, absence of a directional preference, and daily use of pain medication for chronic LBP (area under the receiver operator characteristic curve 0.81 [95% confidence interval (CI) 0.75 to 0.87]). The results of these multivariate analyses informed the development of a screening instrument that predicts the probability of

needing additional psychological assessment. The results of this study are promising, but further testing of the screening instrument is needed to confirm our preliminary results.

Chapter 3 presents the results of intra-rater and inter-rater reliability testing of the Waddell score, one of the components of the screening instrument presented in Chapter 2. The Waddell score consists of eight standardized physical non-organic signs, divided into five categories. A category is positive if at least one test in that category is positive. The Waddell score is positive if three or more categories are positive. A total of 126 patients with chronic LBP in an outpatient rehabilitation setting volunteered for this study. The intra-rater and inter-rater reliability was established by having two physical therapists administering the non-organic tests directly after each other at the start and at the end of patient's 3-weeks observation period. During the study the examiners were unaware of each other's findings. The degree of reliability was determined by using Cohen's kappa. Cronbach's alpha was calculated for both the original Waddell score (five categories) and a Waddell score consisting of signs only, to assess internal consistency. The prevalence of a positive (original) Waddell score was 36% (n = 45). Analysis of inter-rater reliability with an average time-interval of 14 days showed a kappa value of 0.48 (95% CI 0.30 to 0.65). Analysis of intra-rater reliability with an average time-interval of 14 days showed kappa values of 0.65 (95% CI 0.50 to 0.80) and 0.68 (95% CI 0.53 to 0.84). For both examiners, the internal consistency was lower for the 5 categories (0.65 and 0.72) compared to the 8 non-organic signs (0.71 and 0.78). It was concluded that for trained observers, in a population of patients with chronic LBP in a rehabilitation setting, the inter-rater reliability of the Waddell score was moderate and the intra-rater reliability was good. To optimize the internal consistency and variability of the Waddell score, it may be preferable to sum up the individual signs instead of summing up the categories.

Chapter 4 describes the study that assesses the construct validity of the Waddell score. In this cross-sectional study, a total of 20 hypotheses regarding the associations between the Waddell score and measures from five different domains (demographic, pain, physical, illness behaviour and psychological) were formulated *a priori*, based on a detailed examination of the literature (Medline database search 1980-2010). A total of 229 consecutive patients with chronic LBP at an outpatient rehabilitation centre underwent psychological and physical assessments, by psychologists and physical therapists respectively. Assessments included a comprehensive set of psychological

questionnaires, questionnaires regarding demographics, physical status, illness behaviour and pain intensity and a physical examination including the Waddell score. The psychologists and the physical therapists were blinded to each other's findings. The results showed that 75% of the *a priori* hypotheses were accepted, and the Waddell score was found to have satisfactory cross-sectional construct validity. However, most of the observed correlations between the Waddell score and the different domains were weak. It was concluded that the presence of Waddell signs does not indicate exactly what the specific problems are and the Waddell score cannot be regarded as a straightforward 'psychological screener'.

Chapter 5 describes the design of a RCT and economic evaluation from a societal perspective that assesses a classification-based treatment system originally proposed by Delitto et al. Two previous studies have investigated the validity of this system. Both showed outcomes slightly in favor of the classification-based approach as compared with other physical therapy management strategies in patients with acute and sub-acute LBP with mild to severe disability. This raised the question whether this approach would be effective in another health care system and patients with more chronic LBP. Therefore, we compared the classification-based treatment approach with usual physical therapy care according to the Dutch LBP guidelines in patients with sub-acute (6-12 weeks) and chronic (> 12 weeks) LBP in primary care. The classification algorithm was updated based on new evidence and adapted to the Dutch health care situation. Four research physical therapists, not involved in delivering the intervention, classified patients into one of the following subgroups: direction-specific exercises, manipulation, or stabilization exercises. Randomization was computer-generated, with centralized allocation concealment. The participating patients and the assistants who collected follow-up questionnaires were blinded. The statistician and the physical therapists who provided treatment were not blinded. Patients assigned to the classification-based group were treated according to their primary classification category for a minimum of 4 weeks. Patients assigned to usual physical therapy care received individually tailored treatment according to the current Dutch physical therapy guidelines. Patients completed questionnaires at baseline, and 8, 26, and 52 weeks after the start of the treatment. The primary outcomes were global perceived effect (GPE), disability (Oswestry Disability Index [ODI], 0-100) and pain intensity (Numerical Rating Scale [NRS], 0-10). Secondary outcomes were general health status, quality of life, fear-avoidance beliefs and psychosocial status. Direct and indirect costs were measured by means of self-completed cost diaries and the Productivity and Disease Questionnaire (PRODISQ).

Chapter 6 reports on the above described RCT. A total of 156 patients were included (classification-based group n = 74; usual physical therapy group n = 82). The primary analysis was performed according to the intention-to-treat principle, using multilevel analysis. There were no statistically significant differences between the treatment groups for any of the clinical outcomes at any of the follow-up time points. There were no statistically significant differences between the treatment groups for any of the outcomes at any of the follow-up time points. After 8 weeks, patients in the classification-based group had greater GPE scores; adjusted odds ratio of 1.01 (95% CI 0.31 to 3.28), and higher adjusted ODI and NRS scores; mean adjusted differences of 0.48 points (95% CI -4.59 to 3.63) and 0.49 points (95% CI -1.34 to 0.37) respectively, but all differences were statistically non-significant. Our outcomes differed from previously reported RCTs and probably reflect differences in patient selection criteria, the comparison treatment and the classification algorithm. It was concluded that the classification-based treatment approach as used in this study was not effective for improving physical therapy care outcomes in a population of patients with sub-acute and chronic LBP.

Chapter 7 reports on the cost-effect and cost-utility results of the RCT. The outcome analyses using t-tests showed a significantly better outcome on global perceived effect favoring the classification-based approach, and no differences between the groups on pain, disability and quality-adjusted life-years (QALYs) after one year. Mean total societal costs for the classification-based group were €2287, and for usual physical therapy care €2020. The difference was €266 (95% CI -€720 to €1612) and not statistically significant. Cost-effectiveness analyses showed that the classification-based approach was not cost-effective in comparison with usual physical therapy care for any clinical outcome measure. At present, national implementation of the classification-based treatment approach is not recommended. Nevertheless, subgrouping has been identified as a consistent research priority. Therefore, further high-quality research exploring the effectiveness and cost-effectiveness of this classification and comparable approaches is required before firm conclusions can be drawn.

Chapter 8 presents an overview of this thesis and discusses the strengths and limitations of the studies and possible implications of the results and recommendations for future research.