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Introduction

It has been estimated that about 80% of people in western society will suffer from low back pain (LBP) at some point over their lifetime.[1] A Dutch study found in a population of 25 years of age and older, a prevalence of current and chronic (> 3 months) LBP of 27% and 21%, respectively.[2] LBP is responsible for enormous costs for health care and society. In 2007 the total costs were estimated to be €3.5 billion and 0.6% of the gross national product (GNP) in the Netherlands.[3] To reduce the impact of LBP in society and to lessen the suffering of patients, it is essential to offer optimal therapeutic interventions.

There are promising advances in many aspects of LBP management. For example, in the Netherlands, the total societal costs of back pain have decreased between 1991 and 2007.[3] At the same time the average quality of the guidelines dealing with LBP in primary care has improved.[4] The content of these guidelines, irrespective of country, is broadly similar regarding the use of the diagnostic triage (1. serious spinal pathology such as cancer, 2. nerve root problems such as spinal stenosis and 3. ordinary 'non-specific LBP)[5] and regarding the use of diagnostic and therapeutic interventions.[4,6] For patients with 'non-specific' acute LBP treatment guidelines generally recommend; patient education and encouraging activity and participation and for 'non-specific' chronic LBP patients; exercise therapy as single treatment or as the key component of multimodal treatments (back school, behavioral programs and multidisciplinary programs). Manual therapy interventions, including specific types of passive mobilization and/or manipulation procedures, can be applied if indicated.[7]

The majority of LBP patients are labeled 'non-specific'. In less than 15% of all people suffering from LBP an accurate patho-anatomical diagnosis can be made, and hence, most LBP is a symptom only.[5] The term 'non-specific', although applied to an estimated 85% of patients with LBP, is thought by many to be a meaningless and unproductive label.[8,9] Waddell stated in 2005; 'It is intellectually and scientifically inadequate and fails to provide any biological basis for real understanding.'[8] Guidelines provide little specific guidance about distinguishing characteristics of different treatment needs in patients with 'non-specific' LBP. It has been suggested that, especially in a heterogeneous condition as 'non-specific' LBP, outcomes can be improved by moving away from the one-size-fits-all approach, towards matching subgroups of patients to interventions that they are likely to benefit from.[10,11]

Subgrouping patients with LBP

There are several arguments for subgrouping patients with LBP; clinicians and researchers have strong opinions about potential causes for LBP,[5,12,13] the heterogeneity

of patient samples is regarded as a potential explanation of the small effect sizes in LBP research,[14] and there is promising early evidence for subgrouping.[9,15-17] There are also arguments against subgrouping. One of these arguments is that clinical homogeneity of people within a subgroup does not imply prognostic homogeneity or treatment responsiveness.[18] For example, although research showed that patients who were positive on the clinical prediction rule (CPR) for manipulation responded better on manipulation compared to exercise intervention,[19] recently, researchers found for patients positive on the manipulation CPR no significant differences between patient that were treated with manipulation or mechanical diagnosis and therapy (MDT), indicating that this CPR may not be exclusive for lumbar manipulation.[20] Another argument is that most subgrouping approaches have been based on unproven theories and are not or poorly validated.[21]

Since 1996, the identification of homogenous subgroups of patients with LBP has been specified as one of the main challenges in LBP research and recently has been identified as a consistent research priority.[22] Although research is making progress in subgrouping LBP,[14,15,23] recent reviews about targeting physical therapy interventions to subgroups concluded that there is, at present, little evidence that this approach improves outcomes.[21,24-28] The review authors concluded, that further studies utilizing appropriate research designs and rigorous methodology are warranted.[18,24,29]

Potential research directions
There are at least two avenues that may provide additional contributions to the clinical feasibility of the subgrouping approach in patients with LBP. One of these directions relates to the diagnostic issue of LBP. A potential way forward is via a clearer focus on individuals' clinical presentations to screen LBP patients or categorize them for targeted treatment. Although several factors as centralization, fear avoidance and depression appear to be important clinical characteristics for subgrouping patients with LBP, to date there is limited or contradictory evidence about their clinical usefulness.[23,30-33] A second direction is to test or validate available classification systems that have undergone a rigorous derivation process. There is an urgent need for this kind of research, because '..it appears researchers are creating new rules but not validating the existing ones.'[21] The validation process is an important step in the evaluation of classification systems for possible clinical use and may require several studies. McGinn et al.[34] has described three steps that have to be taken before a classification system can be confidently incorporated into clinical practice; (1) creation of the classification system, (2) testing or validating the system i.e. to test the accuracy

of a classification system at a different setting, and (3) assessing the impact of the system on clinical behavior and/or resource consumption.

The first aim of this thesis

The first aim of this thesis was the development of a screening instrument to identify those patients with chronic LBP in an outpatient rehabilitation setting who need additional psychological assessment.

Background

Twelve years ago, the outpatient rehabilitation department of the Medical Centre Alkmaar (a general hospital in the North-Western part of the Netherlands) started a three-week observation period for patients with chronic LBP. The main goal of this observation period was to establish the patient's suitability for rehabilitation treatment and to customize interventions based on patient profiles. Patients were screened by a physical therapist, an occupational therapist, a social worker and a psychologist using a standardized assessment program. The patient's biomedical, psychosocial and behavioural characteristics were discussed in a rehabilitation team meeting and a treatment strategy tailored to the needs of the person was formulated.

Soon after the introduction of this process, it became clear that no psychological issues requiring direct attention by a psychologist were present in a substantial proportion of patients. It was concluded, that only patients who might benefit from additional psychological assessment should be referred to a psychologist in order to limit resource use and to improve patient care. However, the question was, how to best identify patients who need referral to a psychologist. A literature review for available screening instruments to direct the need for psychological assessment was conducted, but little information was found. Therefore, we decided to develop a screening instrument ourselves. Chapter 2 describes the development of a screening instrument aimed at alerting clinicians in secondary care to the need for additional psychological assessment in patients with chronic LBP. Chapter 3 and 4 deals with the intra and inter-rater reliability and the cross-sectional construct validity of one part of this screening instrument; the Waddell score.

The second aim of this thesis

The second aim of this thesis was to determine whether a classification-based treatment approach that has shown effectiveness in the U.S. is clinically effective and cost-effective in the Dutch health care system.

Background

Over the years, many attempts have been made to classify patients with LBP into homogeneous subgroups, usually underpinned by theories regarding the likely response to specific interventions. In 2007, Billis et al.[28] identified 39 diagnostic and classification-based treatment systems. Most of these systems have not been tested, but some are promising enough to move forward to the validation phase. One of these systems is Delitto's classification-based treatment approach.[35] This approach is developed to help physical therapists to identify the treatment most likely to benefit the patient. In our research, we aimed to validate this classification approach in the Dutch health care system. In Chapter 5 the design of the Classification Algorithm Low Back Pain Study is described, i.e. the cost-effectiveness of a classification-based system for sub-acute and chronic LBP in primary care. Chapter 6 and 7 report the results of this study.

Chapter 8 addresses the main findings of our research and discusses its implications. Recommendations for future research are presented.

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