# The Nordic Back Pain Subpopulation Program: A 1-Year Prospective Multicenter Study of Outcomes of Persistent Low-Back Pain in Chiropractic Patients

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## Abstract

**Objectives:** The aims of the study are to describe the low-back pain and disability status at baseline, the fourth visit, and at 3 and 12 months in Norwegian patients treated by chiropractors for persistent low back pain (LBP) and to describe movements between various subgroups over time.

**Design:** Prospective uncontrolled multicenter study.

**Methods:** Self-reported pain was measured with a 0-10 box scale and disability with the revised Oswestry LBP questionnaire. The main outcome measures were mean pain or disability values and numbers of LBP-free patients. LBP status was assessed through patient questionnaires at baseline, the fourth visit, and after 3 and 12 months.

**Study Subjects and Setting:** Of 205 invited chiropractors, 115 Norwegian chiropractors were each willing to recruit 10 consecutive patients who had LBP for at least 2 weeks at the time of consultation and a minimum of 30 days altogether within the preceding year. The numbers of participants were 875 (baseline), 799 (fourth visit), 598 (3 months), and 512 (12 months).

**Results:** Considerable improvement was noted between baseline and the fourth visit both for mean values and in numbers of LBP-free patients. There was virtually no further mean improvement up to the third month, whereas the number of LBP-free individuals doubled. At 12 months, no additional improvement was noted, and 80% reported that they had experienced recurrent problems. Less than 1% reported considerable worsening. Severity of symptoms at baseline determined the subsequent outcome, mild symptoms tending to worsen, and severe symptoms tending to improve.

**Conclusion:** The outcome pattern is similar to that found in other clinical studies. Treatment outcome should be measured early with follow-up at 3 rather than at 12 months, because patients will improve or recover quickly but may experience recurring problems. Numbers "cured" appear to be a feasible outcome variable in this type of study population. (J Manipulative Physiol Ther 2005;28:90-96)

**Key Indexing Terms:** *Low Back Pain; Chiropractic; Treatment Outcome; Prognosis; Subacute; Chronic*

In recent years, it has become evident that episodes of nonspecific low back pain (LBP) do not necessarily have the self-limiting course as previously thought. Instead, a high percentage of patients seen in general practice continue to complain of LBP.[1,2] The profiles of patients who improve and do not improve need to be elucidated. In particular, it is important to prevent the persistence of LBP, which is costly and generally agreed to be largely therapy-resistant.

The optimal clinical management of this type of LBP is not known. The choice of treatment is largely based on patients' own choice of therapist, as there are no clear indicative criteria that can direct patients to specific therapies. The clinician's decisions are partially evidence-based but to a large degree governed by his/her professional and subcultural background. Practice patterns are rarely challenged, as it is usually not possible to determine whether treatment was necessary or indeed successful because neither the natural course of LBP nor the prognostic picture is well understood.

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Because it is reasonable to assume that nonspecific LBP is made up of specific subgroups, there is a need to conduct trials for specific subgroups of patients to determine which of the different therapeutic methods (if any) is best suited to particular subgroups.[3] Absence of generally accepted specific classic pathoanatomic diagnostic subgroups, however, makes such studies difficult.

For these reasons, a research program is underway in Scandinavia, where several research teams work in collaboration toward a better understanding of this area. As part of this program, a prospective uncontrolled multicenter study was conducted to describe the LBP and disability status at baseline, the fourth visit, 3 months, and 12 months in patients treated by chiropractors for persistent LBP. Another aim was to describe movements over time between various subgroups in relation to pain and disability.

## Methods

The materials and methods have been described in detail elsewhere,[4] and a summary is provided below. A research group consisting of 7 chiropractors practicing in Norway designed the study, invited all their colleagues to participate in the study, provided written and verbal instruction, and maintained contact with the participants throughout the study. One team member (A.G.) was responsible for the logistics of the data collection. The first author supervised the entire process.

In the year 2000, 115 (56%) chiropractors of all 205 eligible Norwegian chiropractors collected data on 10 consecutive patients each, which fulfilled the following inclusion criteria: pain between T12 and the lower gluteal folds, present problem having lasted at least 14 days, pain in that area for at least 30 days in total during the preceding 12 months, not treated by a chiropractor during the past 6 months, able to read and write in Norwegian, and willing to participate in the study. Treatment consisted of chiropractic treatment, including spinal manipulative therapy and other supportive modalities, such as exercise and individual advice, based on the chiropractor's own choice. Patients were excluded from the study if the treating chiropractor at baseline detected any contraindications to treatment or if the patient did not attend further consultations.

Data were collected by the treating chiropractors at baseline in relation to the medical history. Clinical findings were noted at baseline and at the fourth visit. Clinical events over the coming year were recorded by the chiropractors 12 months later.

Demographic and clinical information was collected from patients at baseline. Follow-up status was determined at the fourth visit (questionnaires given to the patient in the clinic) and at 3 and 12 months (postal questionnaires). It was not possible to identify patients who were eligible for the study but not recruited. LBP status was defined on the basis of pain and disability. The level of pain was obtained with a 0-10 box pain scale, with 0 described as "no pain" and 10 as "unbearable pain." The level of disability was graded with the revised Oswestry LBP questionnaire that had been translated into Norwegian and successfully retranslated into English. It ranges from 0 to 100 points, covering all 10 questions on pain intensity, pain pattern, and activities of daily living, each with 6 alternatives. The revised Oswestry LBP questionnaire is extensively used and previously validated and found to be both valid and responsive,[5] as is the 11-point box scale.[6]

All participants signed an informed consent form and were informed that they could withdraw at any time, without this affecting their treatment. Participation in the study did not affect the usual clinic procedure in any other way. Rules for safe data storage and appropriate analysis were followed, and permission to perform the study was obtained from the regional ethics committee.

The questionnaires were optically read using a Canon DR 3020, transferred to a database, cleaned, and validated. The general strategy for data analysis was made by the first author, in cooperation with all of the authors. Data were analyzed by a new member of the team, K.L., using STATA 7.0 (StataCorp, LP, College Station, Tex) in accordance with the pre hoc data analysis strategy, together with the first author, who was also responsible for the final report. All members of the team provided feedback in relation to data interpretation and report preparation.

Descriptive data were obtained for all baseline variables. To investigate whether the dwindling number of responders throughout the study was caused by bias, the baseline values were compared for those who participated at the different points in time. As reported elsewhere,[4] there were virtually no differences between these profiles, indicating that the reasons for the relatively large dropout rates throughout the study were unrelated to bias of the initial demographic and clinical factors.

The mean scores of the pain scale and the Oswestry questionnaire scores were identified at baseline, at the fourth visit, 3 months later, and 12 months after commencement of treatment. All patients were classified in relation to severity of pain and disability, based on the statistical spread and clinical judgment. Thus, pain was divided into "mild" (pain scale 0-2), "moderate" (3-7), and "severe" (8-10). Disability was classified as "mild" (Oswestry score 0-25), "moderate" (26-45), and "severe" (46-100).

Our definitions of outcome at the time of each follow-up were made with the purpose of reflecting changes obvious to both clinician and patient and outside any statistical uncertainty. Therefore, "improvement" in relation to pain was defined as a reduction of 2 increments or more on the pain scale or as a 30% reduction in the pain score. "Improvement" in relation to disability was defined as a reduction of 20 points or more on the Oswestry question-