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Five-Year Follow-Up Study of a Controlled Clinical Trial Using Light Mobilization and an Informative Approach to Low Back Pain

[Clinical Studies: Treatment]

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Outline

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Abstract^

Study Design. A controlled clinical trial.

Objectives. To examine the long-term effect of an informative approach to low back pain.

Summary of Background Data. In management and prevention of low back pain, back school based on an ergonomic approach have played an important role. The effect of such informative interventions is not clear.

Methods. A 5-year follow-up study was done on patients included in a previous study. The outcome was measured by return to work or still on sick leave. The patients were allocated to an intervention group (n = 245) and a control group (n = 244). Only the intervention group was called in for examination and intervention and answered a battery of tests for psychological and health factors. The intervention apart from the clinical examination consisted of education in a "mini back school." The program was based on a new medical model for low back pain.

Results. Forty-seven (19%) of the patients in the intervention group, compared with 84 patients (34%) in the control group, were still on sick leave after 5 years ($P < 0.001$). There were fewer recurrences of sick leave ($P < 0.03$) in the intervention group than in the control group. Based on Internal Health Locus of Control, number of children, and income, 75% were correctly classified as nonreturners in the intervention group.

Conclusions. This study indicates that subchronic low back pain may be managed successfully with an approach that includes clinical examination combined with information for patients about the nature of the problem, provided in a manner designed to reduce fear and give them reason to resume light activity.

Acute low back pain (LBP) has a good prognosis and is regarded as a benign and self-limiting condition.[24,34] However, in some patients, LBP progresses into a chronic disorder, even though no significant physical change may be detected.[34] Hadler [9] suggested that the more seriously the disorder has been managed, the worse it has become. In the management and prevention of back pain, education about avoidance of biomechanical risk factors and lifting techniques has been a major part of most conservative regimes and of the programs in different back schools.[29] The effect of such educational and ergonomic interventions is not clear.[4,8,21]

Waddell [34] stated that LBP by its natural history appears to be a universal, benign, and self-limiting condition. Furthermore, he asserted that the role of conventional medicine in the epidemic of back problems should be reviewed critically. He provided substantial support for a more dynamic approach to the management of LBP. This, and the fact that clinical experience has shown most patients with LBP to have reduced flexibility of the spine and to get even worse by training back and abdominal

muscles, has led to the development of an alternative program of light mobilization for LBP.

A study by Indahl [18] showed that a light mobilization program for patients sick-listed for LBP resulted in a higher rate of return to work (70%) than treatment within a conventional medical system (40%). Haldorsen et al [11] found that after 12 months with this light mobilization program, a model combining medical, psychological, and social variables gave the highest prediction accuracy (77%) for patients not returning to work. Dominant variables were low Internal Health Locus of Control, restricted lateral mobility, reduced work ability, low physical activity, and a greater number of children.

The assessment of reasons for the therapeutic effect is complicated. Is it the attention given to the patients or is it what they learn that matters? It is reasonable to believe that the effect of care-giving will diminish over time, and that any long-lasting effect will be a result of the informative part. The aim of this study was to investigate the long-term effect (5 years) of a light mobilization program for patients with LBP and to define what characterizes patients in the intervention group who have not returned to work at this point as compared with a control group.

Materials and Methods^

Subjects. All patients with subchronic (4-12 weeks) LBP referred to the Spine Clinic at Østfold Central Hospital during the period of November 1, 1991 to August 31, 1992 were included in the study. On November 1, 1991, a large battery of tests for collection of psychological data had been established. The cut-off point was set to 500 patients, based on estimates of statistical power from previous data. The data for this 5-year follow-up study were collected from June to September 1997. Ethical approval for this study was granted by the County Hospital in Østfold, Fredrikstad, and by the Government of Norway.

The National Insurance Act in Norway covers all employed and unemployed persons seeking work. Persons expected to take more than 8 weeks of sick-leave must be issued a special Sickness Certificate II to remain eligible for additional sickness benefits. In cooperation with 25 National Insurance Offices in the county of Østfold, a copy of all new sickness certificates for LBP, with or without radiographs (L84 and L86 according to the International Classification of Primary Care system) and excluding pregnant women, were sent to the Spine Clinic.

The sick-leave certificates were mailed to the clinic from the insurance offices. Without evaluating the context of these forms, the Spine Clinic's secretary systematically allocated every second certificate to either the control group or the intervention group. The allocation was done by opening the envelopes and placing the certificates upside down and drawing every other certificate into each group. The certificates were given a number, even numbers for the intervention group and odd numbers for the control group. The certificates then were given to the nurse who gave the appointment for the patients in the intervention group. The sick-leave certificates, which were one-page forms, contained only information on the name, address, International Classification of Primary Care diagnosis, and a brief anamnestic report from the primary physician advising further sick-leave for the patient. None of this

information was used by the secretary in her systematic allocation to the groups. All patients on her original assignment list were included, which was in strict accordance with the intention-to-treat principle.

The patients in the control group were unaware of their status and were not called in for examination. They were treated within the conventional medical system, where the treatment can be assumed to be representative of the practices in Norway and in other industrialized countries.

Data Collection and Clinical Examination. During the first consultation, a standardized form of data collection was used. In addition, a battery of tests for psychological and health factors was used. The patients underwent a routine clinical examination by a physician, which included a physical capacity test, according to that proposed by Åstrand,[36] and a test for isokinetic muscle strength. Plain side and front radiographs of the lumbar region and computed tomographic scans of the three lower discs were obtained.

Intervention. When all results were available, the patients were given a new appointment. They were informed about the clinical findings and given advice. The intervention apart from the clinical examination consisted of education in a "mini back school," which lasted 2 hours the first day and 1 hour on an individual basis after 2 weeks. The clinical findings were recorded, and copies of the report were sent to the patient, the primary physician, and the insurance office. Recommendation for return to work was never given either in the written report or when communicating with the patient; only advice for light activity was given.

The "Mini Back School". The patients were told how a possible "crack" in a disc or ligament could cause an inflammation, which in turn could cause a reflex activation in the paraspinal muscles.[10,19,20,30] It was explained to them how such activation could lead to stiffness and pain.[2] They also were told how pain, or anticipation of pain, could add to the binding and guarding of the back and lead to increased muscular activation and, subsequently, increased pain.[7] They also were given the assurance that light activity would not further injure the disc or any other structures that could be involved in the process, and that it was a general medical observation that light activity would even enhance the repair process. The link between emotions and LBP was explained, as was the fact that increased tension in muscles, for whatever reason, would increase the pain and add to the problem. Time was also taken to explain how long-standing pain could create a vicious chronic pain circle. It was strongly underlined that being too careful was the worst form of self-treatment, and all patients were told to mobilize the lumbar spine by light activity. No fixed exercise goals were set by the therapist; rather, the patients were encouraged to set their goals.[23] Great emphasis was put on the effort to remove fear about LBP and avoid sickness behavior.[27,32] Major misunderstandings about the causes of LBP were dealt with.

The main recommendation was to normalize the gait and to try to walk with as much flexibility as possible. Activities involving static work for the back muscles were discouraged. If a patient experienced acute stabbing pain in the back, he was told to treat it as an acute muscle spasm and

perform stretching and light activity. For lifting activities, the following guidelines were given:

1. Avoid twisting and bending when lifting.
2. When lifting very heavy objects, lift correctly with the back as vertical as possible, and make use of the thighs.
3. For the rest of the time, use the back and flex it.
4. Carrying involves static work for the back muscles; therefore, any excess carrying should be avoided.
5. In short, there is generally no reason to be afraid of using the back; therefore, do not be overcautious and try to be as flexible as possible.

Information was reinforced when the patients were called back for another appointment after 3 months and 1 year, and all patients had permission to call or contact the outpatient clinic if they felt any need to do so.

Measures. At the consultation before the clinical examination, each patient in the intervention group was asked to complete a self-administered battery of questionnaires. The staff stressed that there were no right or wrong answers, and that responses would be completely confidential. Demographic data included age, gender, marital status, years of education, work conditions, income, time for onset of pain, smoking, leisure time physical activity, and social network. The work conditions factors were the following: work/unemployed, secure/insecure job, the physical/psychological demand of the work, overtime, and the experience of any problems concerning the workplace. The psychological battery of tests measured anxiety, personality, subjective health, and health locus of control.

Subjective work ability was measured by a Graded Reduced Work Ability scale constructed for the Norwegian Ministry of Health and Social Affairs. The scale consists of six items grading the perceived working capacity of the patient in relation to the symptoms for which they are sick-listed. The internal consistency for the scale was 0.75 (Chronbach's alpha).[3]

Subjective health was measured by Ursin's Health Inventory, which consists of 29 questions regarding common somatic and psychological symptoms.[33] The scoring format of Ursin's Health Inventory relates the intensity and duration of symptoms over the last 30 days. The intensity scale has four levels: 0 = no pain, 1 = mild pain, 2 = moderate pain, 3 = severe pain. The internal consistency of the scale in this material was 0.83 (Chronbach's alpha). Based on factor analysis, five indices were included in the analysis (Chronbach's alpha value in parentheses): musculoskeletal pain (0.82), psychological problems (0.70), immunologic problems (0.63), headache (0.58), and stomach problems (0.63). Cold was excluded because of a low Chronbach's alpha value (0.42).

Anxiety was measured by the Spielberger State-Trait Anxiety scale.[16,17,31] The State-Anxiety scale consists of 20 statements that ask the subject how he/she feels at a particular moment in time. The Trait-Anxiety scale consists of 20 statements that ask the person to describe how he/she generally feels. Subjects respond to items by rating themselves on a four-point scale from "not at all" to very much" for the State-Anxiety test and from "almost never" to "almost always" for the Trait-Anxiety

test. Alpha reliability for the State-Anxiety and Trait-Anxiety tests were 0.90 in this study.

Personality was measured by the Eysenck Personality Inventory.[5,15] This test, which consists of 57 items with "yes" or "no" answers, is designed to measure two dimensions of personality, neuroticism-stability (Chronbach's alpha = 0.84) and extroversion-introversion (Chronbach's alpha = 0.74). The Lie scale, which supposedly can signify "good faking," was excluded from this study because of a low Chronbach's alpha (0.40).

Health locus of control was measured by the Multidimensional Health Locus of Control questionnaire (form A).[1,35] This contains a series of statements designed to elicit beliefs about responsibility for health. The Multidimensional Health Locus of Control contains 18 items (Chronbach's alpha = 0.75) answered on a six-point Likert scale from "strongly disagree" to "strongly agree." Three dimensions of the health locus of control are measured: "internality" (Chronbach's alpha = 0.76), which is the extent to which the respondent believes that power to affect his state of health lies within his own control; "powerful others" (Chronbach's alpha = 0.66), which measures how much the respondent believes that the medical profession, in particular, has a determining influence on one's state of health; and "chance, externality" (Chronbach's alpha = 0.75), which is concerned with fatalistic beliefs about health and illness.

Follow-Up Data Collection. The 5-year follow-up study was done by submission of data from the insurance offices, which included information on length of sick-leave, return to work, number of recurrent sick-leaves, and length of each sick-leave. The insurance officer retrieving the data was blinded to the group assignment of the patients, and the data processing and statistical analyses were done by an independent observer. No patients were lost to follow-up.

Statistics. Statistical analyses were conducted using the Statistical Package for Social Sciences (SPSS/Windows 6.0).[26] Differences between groups were evaluated by one-way analysis of variance with Bonferroni correction for overall error rate and the Chi-square test.

Separate discriminant analyses were carried out to classify subjects into one of two groups with regard to return to work, based on variables that showed statistically significant differences between returners (patients that returned back to work) and nonreturners (patients that remained on sick-leave), when age and gender were controlled for.

Test for multivariate normality and for equal variance-covariance matrices were performed before the discriminant analyses. In addition, the correlation matrices of the predictor variables were examined. Most of the variables were not distributed normally. A logarithmic transformation was performed to approximate a normal distribution, reduce the impact of extreme values, and create equal variances in returners and nonreturners. However, the results for the discriminant analyses were almost identical both with and without a logarithmic transformation.

A significant Pearson Chi-squared statistic is necessary, but not sufficient to concluded that a rule

yields better than chance classification.[12,13] This is because only the diagonal entries are of interest as far as the significance question is concerned. Because of this and because the group sizes are unequal, the statistical significance of the improvement in accuracy of classification over chance for each sample was tested using a *z* test for the significance of a proportion.

Results^

Comparisons Between the Intervention and Control Groups^

The intervention group consisted of 245 persons: 156 men and 89 women, with a mean age 41.2 ± 11.3 years (range, 18-65 years). The control group consisted of 244 persons: 150 men and 94 women with a mean age at entry of 42.2 ± 10.0 years (range, 18-65). Mean duration of sick-leave at the time of entry was 68.6 ± 15.0 days (range, 42-109 days) in the intervention group and 68.8 ± 13.3 days (range, 43-112) in the control group. At the time of entry, 14 (6%) patients in the intervention group and 12 (5%) patients in the control group had gone back to work. There was no significant difference between the groups regarding age, gender, mean length of sick-leave, and return to work at time of entry.

In the intervention group, 198 (81%) patients had returned to work 5 years after entry into the study, compared with 160 (65%) in the control group. Forty-seven (19%) patients were on long-term or permanent disability in the intervention group *versus* 84 (34%) patients in the control group ($P < 0.001$). There were no differences in the intervention group regarding gender and return to work, whereas in the control group, more women than men did not return to work ($P < 0.04$). In the intervention group, there was a significant difference between the returners and nonreturners and the age group "60 years or more" (n = 15). Those who had not returned to work (n = 3) in this group were all 60 years of age, whereas the median age for those who had returned to work was 63 years ($P < 0.01$).

One-hundred and forty-two (58%) patients in the intervention group, compared with 118 (48%) patients in the control group, had been sick-listed for back pain during the 5-year follow-up study. When adjusting for the patients that went on permanent disability and therefore were not available for sick-listing (245 - 47 = 198 in the intervention group and 244 - 84 = 160 in the control group), there remained 72% in the intervention group and 74% in the control group who were sick-listed for back pain during the follow-up period. Information regarding sick-listing resulting from causes other than LBP were not available. However, as seen in Table 1, a greater percentage of patients in the control group (69%) had been sick-listed two or more times than had been in the intervention group (49%) ($P < 0.03$).

Table 1. Sick-Leave Recurrence due to Low Back Pain During Follow-up

Intervention Group^

Different factors were analyzed for their possible relation with back to work (returners, n = 198) or still on sick-leave (nonreturners, n = 47).

Medical Factors. Compared with the returners, the nonreturners had a longer history of back pain ($P < 0.02$), greater finger-to-floor distance ($P < 0.05$), and less aerobic capacity ($P < 0.05$). However, these differences diminished when controlling for age and gender. In the patient group, 57% were smokers, but no significant difference was found between the returners and nonreturners.

Demographic Factors. Compared with the returners, the nonreturners were older ($P < 0.001$), more likely to be married ($P < 0.05$), less educated ($P < 0.03$), had more children ($P < 0.01$), and were less physically active ($P < 0.04$). When controlling for gender, the "age" significantly differed between the groups ($P < 0.04$). When controlling for age and gender, only "number of children" showed a significant difference between returners and nonreturners ($P < 0.04$).

Work-Related Factors. The nonreturners had the same type of employment for a longer period of time ($P < 0.04$), had less income ($P < 0.03$), reported shorter total working time during a week ($P < 0.04$), and spent less time traveling to work ($P < 0.04$), as compared with the returners. When controlling for age and gender, "income" and "working time during a week" showed significant differences between returners and nonreturners ($P < 0.02$).

Psychological Factors. Compared with the returners, the nonreturners showed low Internal Health Locus Control ($P < 0.02$), high Chance Health Locus of Control ($P < 0.01$), and were more extroverted ($P < 0.04$). Both Internal and Chance Health Locus of Control showed significant differences between the returners and nonreturners, when controlling for age and gender ($P < 0.03$ and $P < 0.01$, respectively).

Separate Correlation Analyses. Separate correlation analyses between those variables that discriminated significantly between the returners and nonreturners showed that no two variables were highly correlated, when controlling for other factors.

Discriminant Model. As seen in Table 2, a discriminant model consisting of Internal Health Locus of Control, number of children, and income resulted in a classification accuracy of 75% for the nonreturners and 68% for the returners ($P < 0.01$). These three variables discriminated between the returners and nonreturners, independent of gender and age. Number of children and Internal Health Locus of Control were most closely related to the discriminant function with a structure coefficient of 0.68 and 0.66, respectively. Patients who had not returned to work after 5 years had more children and showed low Internal Health Locus of Control and less income, compared with those who had returned to work. The improvement over chance was significant for the nonreturners ($P < 0.001$), but not for the returners. Including the variables "age," "working time during a week," or Chance Locus of Control in the discriminant function did not increase the classification accuracy.

Table 2. Number of Patients Correctly Classified at 5-Year Follow-up Based on Set of Variables

Discussion^

The results of this 5-year follow-up study indicate that subchronic LBP may be managed successfully with a "mini back school" approach. Eighty-one percent of the patients in the intervention group, compared with 66% in the control group, had returned to work after 5 years. Five years after the light mobilization program, prediction of nonreturners at the follow-up assessment was best achieved by a combination of variables (75% correct classification accuracy). This is in accordance with the results of follow-up assessment of these patients performed after 1 year [11] and with other studies in this field.[6,24] Internal Health Locus of Control and number of children were important variables in both discriminant models. Unlike the returners, the nonreturners expressed that their health status was under the control of chance or powerful others, rather than under their own control. In addition, they had more children and reported less income than the returners.

Harkäpää et al [14] found that Internal Health Locus of Control was associated with less pain, better functioning, and a positive treatment outcome. In a study by Lundberg et al,[22] where the total workload for men and women was investigated, women reported higher levels of work overload, stress, and conflict than the men, which increased significantly with the number of children. However, in the current study, the number of children was a good predictor for the men as well. The material in the current study does not permit further analysis of whether the predictive effect of "number of children" for men signals that they participate significantly in child care in Norway, or if other social factors are involved.

The intention of a selection model is to create comparable groups. It is commonly agreed that this is best done by a strict randomized model. For the systematic assignment method, the most common flaw [28] is that it is known which group the next patient will be assigned to, which allows room for manipulation. In the current study, this was not believed to be a risk factor that could influence the results in any significant way. The Spine Clinic was newly established with no patient records, and systematic assignment was done on certificates of unknown patients. When comparing the information recorded equally from the two groups, they seemed to be almost identical. It therefore is believed that the procedures executed in this study provided comparable groups, and that there is no reason to suspect any systematic error that would favor the outcome in one group *versus* the other. Even when all psychological, medical, social, and employment information was combined, it was not possible to arrive at a prediction rate of success with this or other treatment methods that was higher than 77%.[11]

The program consisted of a clinical examination and information. The information part focused on explaining the findings from the extensive examination, the implications of these findings for treatment and prognosis, and general information on low back physiology and pathophysiology. Attention was paid to explaining the proprioceptive recruitment system for the paraspinal muscles,

and that perturbation of this system could cause hyperactivation of these muscles. The program focused on creating an awareness and understanding for the patients, rather than giving them instructions on what to do. In many aspects, this information differed from that which they had received previously. Many expressed relief about not having to live according to ergonomic guidelines that were hard to follow and that gave them a bad conscience and little relief. The care-giving in the current study was hardly different from that which the patients normally experienced in the health care system. The thorough examination coupled with the assurance that the patient's situation was not serious, gave the patient the confidence needed to follow the advice and resume light normal activity. Lasting behavioral modification is achieved only through experience. It is believed that it was the patient's positive experience that resulted in the favorable long-term effect. The outcome supports the view that a substantial part of LBP may be a functional disturbance, and that light normal activity may help restore normal function.

Conclusion^

Informing patients with subchronic LBP about the nature of their problem, in a manner designed to reduce fear and give them reason to resume light normal activity as a form of treatment, may reduce long-term disability.

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