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Can Chronic Disability Be Prevented?

A Randomized Trial of a Cognitive-Behavior Intervention and Two Forms of Information for Patients With Spinal Pain

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Study Design. A randomized controlled design superimposed on treatment as usual was used to compare the effects of a cognitive-behavior intervention aimed at preventing chronicity with two different forms of information.

Objective. To develop a coping-oriented preventive intervention applicable in primary care, and to compare its impact with educational information.

Summary of Background Data. Preventing long-term disability resulting from spinal pain has proved difficult. The information provided by health care professions and early interventions aimed at preventing long-term disability may be important, but little scientific evidence exists concerning their use.

Methods. A protocol for a six-session cognitive-behavior group intervention was developed on the basis of earlier research. The main focus was to prevent long-term disability by changing patients' behaviors and beliefs so they can cope better with their problems. Comparison groups received either a pamphlet shown earlier to have an effect, or a more extensive information package consisting of six installments. All the groups continued to receive treatment as usual in primary care. There were 243 patients with acute or subacute spinal pain who perceived that they were at risk for developing a chronic problem. These patients were randomized to the cognitive-behavioral intervention or one of the two information groups. Because the aim was to prevent long-term disability, the key outcome variables at the 1-year follow-up assessment were sick absenteeism and health care use. Other variables were pain, function, fear-avoidance beliefs, and cognitions.

Results. The comparison groups reported benefits. However, the risk for a long-term sick absence developing was lowered ninefold for the cognitive-behavior intervention group as compared with the risk for the information groups (relative risk, 9.3). Participants in the cognitive-behavior group also reported a significant decrease in perceived risk. In addition, the cognitive-behavior group demonstrated a significant decrease in physician and physical therapy use as compared with two groups receiving information, in which such use increased. All three groups tended to improve on the variables of pain, fear-avoidance, and cognitions.

Conclusions. This study demonstrates that a cognitive-behavior group intervention can lower the risk of a long-term disability developing. These findings underscore the significance of early interventions that specifically aim to prevent chronic problems. This approach might be applied to primary care settings. [Key words: back pain, behavioral, chronic disability, cognitive, early intervention, information, neck pain, prevention, primary care] **Spine 2000;25:2825–2831**

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The devastating extent of chronic low back pain has resulted in calls for early intervention to prevent the development of long-term problems.[1,3,4,9,24,27,35,36] Although this is an attractive proposition, it has been difficult to develop effective early interventions that prevent disability. The primary care level, however, appears to be an appropriate starting point because it is the entry point into the health care system for most patients.[30,34] Early interventions that might empower the patient rather than medicalize the problem have been recommended recently as a research priority in primary health care.[2] Nevertheless, there still is no agreed-on method for early interventions, and care usually focuses on diagnostic evaluations, pharmacologic management, and some brief advice.[29,33]

Despite the difficulties in developing programs, the literature provides some insights on possible methods. The cognitive-behavior conception of how a chronic pain problem develops suggests that early interventions at the primary care level might feature various methods to reduce fear and avoidance and enhance coping.[13,33] In fact, some attempts at very early interventions have sparked hope that prevention may be possible. These attempts range from advice that counteracts the effects of fear and anxiety while underscoring the importance of maintaining daily activities to the formation of lay-led cognitive-behavior groups.[19,23,34]

The purpose of this investigation was to evaluate the effect of a cognitive-behavior group intervention designed to enhance coping behaviors on the prevention of long-term disability. This article reports the results from a large randomized controlled trial with a 1-year follow-up period. This study was unique because it was based on the person's own perception of being "at risk" rather than disability or sick leave.[7,11,14,22,25] The authors hypothesized that a cognitive-behavior intervention would result in a more favorable outcome for the key variables of sick leave and health care than observed in groups receiving information.

Methods

Overview of the Design. A randomized controlled trial with assessments at pretest and at a 1-year follow-up visit compared the effects of a standardized cognitive-behavior therapy (CBT)

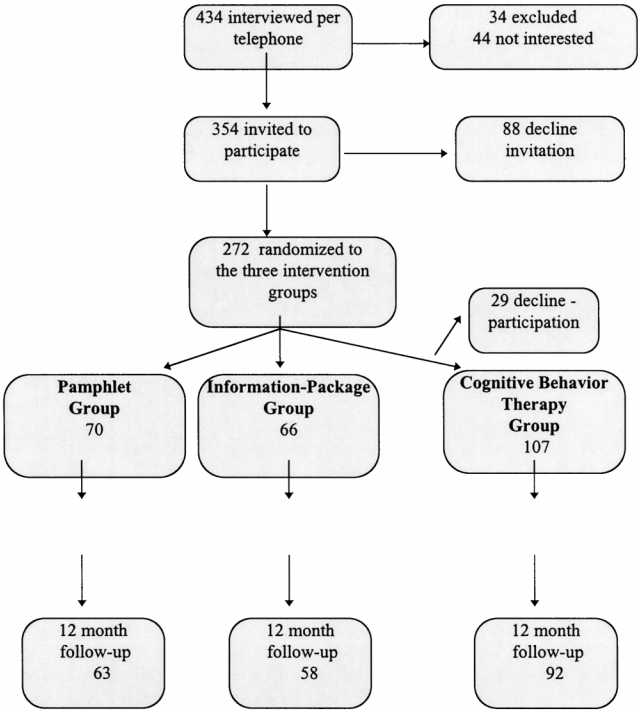

Figure 1. Overview of the recruitment.

group intervention to either a pamphlet or a series of information packets. All the participants were free to pursue treatment as usual in the health care system.

Recruitment of Participants. An overview of the recruitment and design is presented in Figure 1. The inclusion criteria required that the participants be 18 to 60 years of age, report less than 3 months of cumulative sick leave during the past year, and have a self-perceived risk of a chronic problem developing. Candidates were excluded if they were retired or had other medical problems or handicaps that contraindicated participation.

Participants were recruited from local primary care facilities and *via* an advertisement in a local newspaper. A total of 434 people expressed interest, and 354 people who fulfilled the criteria were subsequently mailed the pretest assessment questionnaire. A block randomization, executed by an independent researcher and a table of random numbers, was used for the 272 people who completed the questionnaire. Because it was anticipated that several people would not be able to attend the CBT sessions because of scheduling problems, a block randomization procedure was chosen, in which half of the applicants (n = 136) were assigned to the CBT intervention group and one fourth (n = 68) to each of the information groups. However, because the last six applicants did not make up a full block, they were randomized individually, which resulted in a slightly uneven number of participants in the groups.

As anticipated, 29 people assigned to the CBT group declined before attending any sessions because of scheduling. Of these people who declined, 20 were never assigned a time slot for a group, whereas 9 withdrew before attending any session. The 29 who declined participation were similar to the participants in the three groups with regard to education, Swedish origin, pain intensity, and sick leave. However, they were slightly younger (38 years old), comprised fewer women (59%), and had somewhat fewer health care visits (*i.e.,* 3.2). Thus there were 107 participants in the CBT group, 70 in the pamphlet group, and 66 in the information package group.

Table 1. Overview of the Participants

Variable	CBT	Pamphlet	Infopack
n	107	70	66
Mean age (yrs)	44	45	44
Gender (% female)	70	71	74
Education (%)			
Compulsory	19	19	17
Technical high school	31	35	32
High school	13	16	16
University	37	30	35
Employment status (%)			
Employed	79	69	73
Student	08	10	08
Unemployed	07	13	10
Other	06	08	09
Born in Sweden (% yes)	91	97	89
Neck pain (% yes)	78	80	70
Multiple pain sites (% yes)	22	6	19
Back pain (% yes)	87	95	90
Pain during past week (mean, 0–10)	4.85	4.78	4.98
Sick leave (mean no. of days in past 6 mos)	3.15	3.94	5.14
Activities of Daily Living (0–60; 60 = maximum function)	45	42	43
Health care visits (mean no. during past year)	5.78	7.00	5.17

CBT = cognitive-behavior therapy.

Table 1 presents an overview of the groups at pretest, illustrating that their characteristics were quite similar. This study was approved by the Hospital's Board on Research Ethics.

Outcome Evaluation. Assessment questionnaires were administered at the pretest and 12 months after the intervention. Participants completed the questionnaires at home and returned them in a prepaid envelop. If a response had not been received within 2 weeks, a reminder was sent. If the questionnaire was not received within an additional 2 weeks, a second reminder was mailed.

Key Outcome Variables. Because the interventions being evaluated were preventive in nature, outcome focused on the key variables of long-term sick leave, health care use, and the patient's own perception of risk for developing long-term pain. The participant's experienced risk level was measured with a question from a screening questionnaire that has been found to have good psychometric characteristics.[16] Health care use was assessed by the self-reported number of visits to a physician, physical therapist, specialist or hospital, and alternative care provider during the preceding year.[20] Sick absenteeism was assessed with self-report items concerning sick leave previously shown to be valid.[6,18] Specifically, participants were asked how many days of sick leave they had taken during each clearly labeled month during the past 6 months.

Self-Report Inventories. Items from several self-report inventories were used to provide a comprehensive assessment of outcome. Pain perception was captured by using items about intensity, frequency, and medication consumption from the Outcome Evaluation Questionnaire because these variables have been shown to have good reliability and validity.[8,17,21]

Anxiety and depression were measured with the Hospital Anxiety and Depression (HAD) scale, which has been shown to have acceptable psychometric characteristics,[39] whereas the Pain Catastrophizing Scale was used to assess the cognitive evaluation of the pain.[26] Fear-avoidance beliefs were measured with 12 items from the Tampa Scale of Kinesophobia[10,32] and 4 items from the Fear-Avoidance Behavior Questionnaire (FABQ).[15,38] To assess self-perceived risk, one item from a validated screening questionnaire was used: "In your view, how large is the risk that your current pain may become persistent?"[16]

Six items reflecting activities of daily living were used: work, walking, household chores, weekly shopping, sleep, and sitting.[12] Finally, participants were asked to make an overall rating of the treatment by responding to the following question: "To what extent did you find this intervention to be of help?" The response choices were "no help," " a little help," "a fair amount of help," "considerable help," or "a great deal of help."

Interventions. The participants in all the groups were informed that they were free to pursue any ordinary treatment they deemed to be warranted from a general practitioner to physical therapist.

Pamphlet. Participants randomized to the pamphlet group received a previously evaluated pamphlet to read concerning back pain.[28] The pamphlet provided straightforward advice about the best way to cope with back pain by remaining active and thinking positively. It was aimed at preventing fear-avoidance and promoting coping. The reader was encouraged to confront rather than avoid activities that could be associated with pain.

Information Package. The information package group received a packet of information once a week for 6 weeks. The number and timing of the packages was meant to match the number of sessions the CBT group received. This material, using more traditional sources of information, was based on a back school approach. Each package contained advice and illustrations showing how the patient might cope with spinal pain or prevent it by such methods as lifting properly and maintaining good posture. The information also encouraged participants to maintain their usual activities to speed recovery. However, the information was broad and relatively general.

Cognitive-Behavior Therapy Intervention. A six-session structured program was offered, in which participants met in groups of 6 to 10 people for 2 hours once a week for 6 weeks. The therapy followed a written manual, and the therapists were certified behavior therapists who had received special training and guidance in administering this group treatment.

Sessions were organized to activate participants and promote coping. Each session began with a short review, in which homework was covered. Subsequently, the therapist introduced the topic for the session and provided information for a maximum of 15 minutes. In structured exercises, participants solved typical problems facing people with pain. Subsequently, new skills were introduced and modeled by the therapist, with the participants then practicing them. Homework assignments were given, and these were tailored to each participant's needs, although all of the participants were asked to apply each of the skills learned. Finally, the session was reviewed with an emphasis on what the participants had learned and the homework assignment to be done. Table 2 summarizes the focus of each group meeting.

Table 2. Overview of the Cognitive-Behavior Therapy Intervention Content

Session	Focus	Skills
1	Causes of pain and prevention of chronic problems	Problem solving Applied relaxation Learning about pain
2	Managing your pain	Activities, maintaining daily routines Activity scheduling Relaxation training
3	Promoting good health; controlling stress at home and at work	Warning signals Cognitive appraisal Beliefs
4	Adapting for leisure and work	Communication skills Assertiveness Risk situations Applying relaxation
5	Controlling flare-ups	Plan for coping with flare-ups Coping skills review Applied relaxation
6	Maintaining and improving results	Risk analysis Plan for adherence

Statistical Analyses. The data were first summarized and examined using descriptive statistics. Change scores were calculated for each variable to allow direct statistical comparisons between the groups. An overall analysis based on ranks was first conducted. Because all three groups received an active intervention, within-group analyses were calculated to determine whether changes over time were significant for each of the three groups, and between-group comparisons were made to assess whether the differences in improvement were significant. The data were analyzed by Student's t test, X^2 tests, Kruskal-Wallis analysis of variance (ANOVA), and the Mann-Whitney test to determine statistical significance at a P value less than 0.05 (two-tailed).

■ Results

Participation Rate

Of the 243 people that began the study, 213 (88%) completed both the pretest and the 12-month follow-up assessments, and these data were used in the data analyses. An analysis of the dropouts indicated that they were similar to those completing the study with regard to pretest background (age and gender) and pain variables (pain intensity and sick leave), and no statistically significant differences were found.

Adherence was assessed by examining attendance for the CBT group and the reading of the material for the two groups receiving information. Findings showed that 13% attended one session, that 72% attended four or more sessions, and that 53% attended five or more of the six sessions. Self-reports of the extent to which participants read the written material showed that 83% of the pamphlet group and 72% of information package group

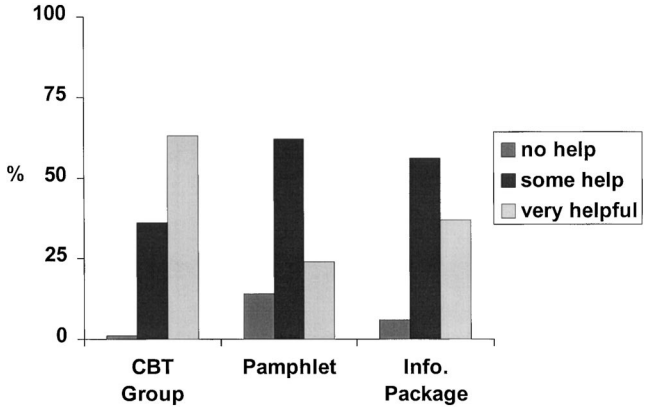

Figure 2. Average degree of self-reported help for each of the three groups.

said they had read the material word for word one or more times. However, a behavior test, in which a message was randomly placed in the text asking readers to call the authors' clinic for free cinema tickets, indicated a much lower adherence rate of 36% for both the pamphlet and the information package groups. An "intent to treat" approach was used, which included all the participants in the data analysis who completed the questionnaires, regardless of attendance or reading adherence.

Self-Reported Degree of Help

Figure 2 shows that whereas all three groups found the respective interventions to be helpful, the CBT group had the most positive response ($P < 0.001$, Kruskal-Wallis). *Post hoc* analyses showed that the CBT group had a significantly better rating than either the pamphlet ($P < 0.05$) or the information package group ($P < 0.05$).

Group Analyses

An overview of the results is presented in Table 3 as point estimates and 95% confidence intervals. A review of Table 3 shows that participants had relatively mild problems at pretest, which is consistent with the selection procedure and the aim to prevent the development of chronic problems.

Pain Experience

Although the within-group improvement was significant for both the CBT ($P < 0.05$) and pamphlet groups ($P < 0.05$), the between-group comparison showed no significant difference. For ratings of pain at its worst, all three groups demonstrated significant within-group improvements ($P < 0.05$), but the difference between groups was not significant. Similar results were rendered for the number of pain-free days, with all three groups showing significant within-group improvements ($P < 0.05$), but no significant between-group difference.

Activity Level

Scores on the activities of daily living scale were relatively high on the pretest, and there were no significant within- or between-group differences.

Catastrophizing and Fear Avoidance

Scores on the Pain Catastrophizing Scale improved somewhat from pretest to follow-up assessment for all three groups, but only the pamphlet and information package groups demonstrated a significant within-group improvement ($P < 0.05$). The between-group comparison was not significant. Concerning fear-avoidance, scores on the Fear-Avoidance Behavior Questionnaire showed significant decreases for all three groups ($P < 0.05$), although the between-group difference was not significant. On the other hand, scores on the Tampa Scale of Kinesophobia were stable between pretest and follow-up assessment, and there were no significant changes within or between groups.

Health Care Use

Visits to the physician and physical therapist during the preceding year for the three groups at pretest and follow-up assessment are shown, respectively in Figures 3 and 4. Whereas the two information groups reported an increase in their number of visits to a physician or a

Table 3. Summary of the Point Estimate and 95% Confidence Intervals for the Three Groups

	Pamphlet Group		Information Package		CBT Group	
	Before	Follow-Up	Before	Follow-Up	Before	Follow-Up
Variable	x CI	x CI	x CI	x CI	x CI	x CI
Average pain (0–10)	4.8 (4.4–5.3)	4.0 (3.5–4.6)	5.0 (4.3–5.6)	4.2 (3.4–5.0)	4.8 (4.3–5.3)	3.9 (3.3–4.4)
Worst pain (0–10)	7.1 (6.6–7.6)	6.1 (5.6–6.7)	7.3 (6.8–7.8)	6.5 (5.9–7.1)	7.0 (6.5–7.4)	5.7 (5.3–6.3)
Pain-free days (0–7)	0.9 (0.5–1.3)	1.8 (1.3–2.4)	1.2 (0.61–1.8)	2.1 (1.4–2.8)	1.4 (0.96–1.85)	2.1 (1.5–2.6)
Days of medicine consumption (0–7)	1.7 (1.0–2.3)	1.6 (0.95–2.2)	1.2 (0.65–1.8)	1.2 (0.6–1.8)	1.1 (0.7–1.4)	0.8 (0.4–1.1)
Days of sick leave (0–184)	3.0 (−0.5–6.4)	13.0 (1.2–24.8)	5.0 (0–10.0)	19.4 (3.4–35.3)	3.0 (0.5–5.5)	2.6 (−1.6–6.7)
Doctor visits (0–11)	1.2 (0.8–1.6)	1.7 (0.9–2.0)	1.1 (0.7–1.6)	1.5 (0.8–1.9)	1.1 (0.7–1.3)	0.6 (0.3–1.1)
Physical therapy visits (0–11)	3.7 (2.3–4.8)	4.0 (2.5–5.0)	2.5 (1.5–3.6)	3.3 (2.0–4.4)	3.4 (2.2–4.1)	2.6 (1.8–3.4)
Activities of Daily Living (0–60)	42.0 (39–45)	41.8 (38–45)	42.7 (39–46)	43.5 (40–47)	45.0 (42–48)	45.6 (43–48)
Fear, mFABQ (0–24)	11.9 (10–14)	8.9 (7–10)	11.3 (10–13)	8.6 (7–10)	11.5 (10–13)	8.0 (7–9)
Catastrophizing, PCS (0–52)	18.4 (16–21)	15.8 (14–18)	17.1 (15–19)	14.7 (12–17)	17.1 (15–19)	16.4 (14–19)
Depression, HAD (0–21)	4.0 (3.2–4.8)	3.9 (3.2–4.7)	4.2 (3.4–5.0)	4.0 (3.2–4.8)	4.2 (3.5–4.9)	3.9 (3.2–4.7)
Anxiety, HAD (0–21)	6.1 (5.0–7.2)	5.1 (4.2–6.0)	6.3 (5.3–7.2)	6.0 (4.8–7.2)	5.3 (4.6–6.0)	5.3 (4.5–6.0)

CI = 95% confidence interval; mFABQ = Fear-Avoidance Behavior Questionnaire; PCS = Pain Catastrophizing Scale; HAD = Hospital Anxiety and Depression scale.

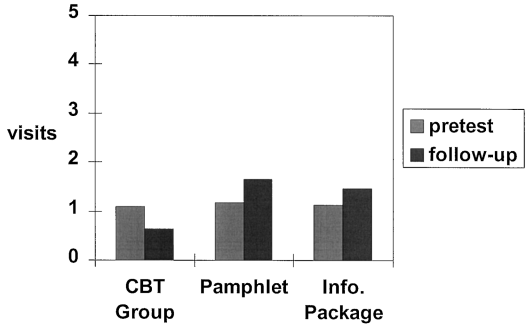

Figure 3. Average number of visits to the physician for spinal pain during the past year.

physical therapist relative to the pretest, the CBT group reported a decrease, and the difference between the groups was significant for visits to a physician ($P < 0.001$) and to a physical therapist ($P < 0.01$). Other visits remained stable for all three groups.

Sick Absenteeism and Risk for Disability

Figure 5 illustrates the average number of sick days per month for each group during baseline and the last 6 months of the follow-up period. The very low pretest level mirrors the inclusion criteria and underscores the fact that the aim of the study was to prevent long-term disability. As can be seen in Figure 5, the number of sick days increases for both information groups at follow-up evaluation and then remains relatively stable. However, the CBT group lowered its rate and remained at an average of 0.5 days per month throughout the follow-up period. To test whether this difference was significant with nonparametric statistics, because the distribution was skewed, sick leave was categorized into 0, 1 to 30, and 30 to 180 days. Although no difference between the groups was evident at the pretest, the difference at the follow-up assessment was significant ($P < 0.05$). *Post hoc* comparisons showed that the CBT group had significantly better results than the pamphlet group ($P < 0.05$), whereas neither the difference between the pamphlet and information package groups nor the difference between the CBT group and the information package group was statistically significant.

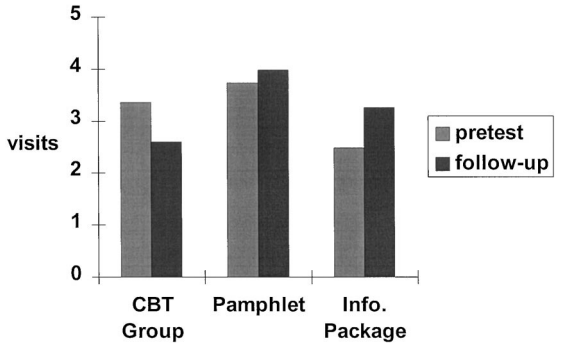

Figure 4. Average number of visits to a physical therapist during the past year at both baseline and follow-up for the three groups.

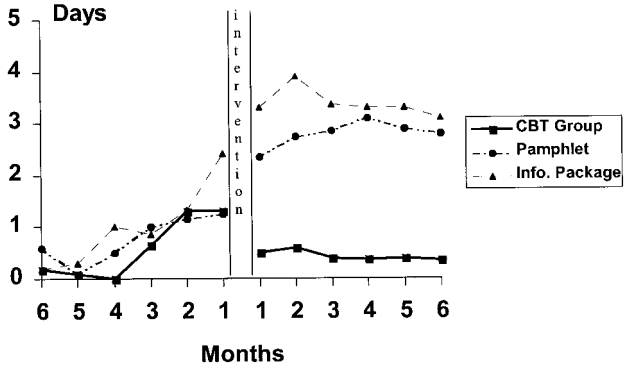

Figure 5. Average number of sick leave days per month for the three groups during the last 6 months of baseline and the follow-up.

Risk for Long-Term Disability Developing. The risk for long-term disability developing was evaluated in two ways. First, the participants with a poor outcome on sick leave at follow-up evaluation were compared with those who had a good outcome. A poor outcome was defined as more than 30 days of sick leave during the past 6 months and a good outcome as 0 to 30 days sick leave during the same period. To calculate a relative risk, the two control groups receiving information were combined and compared them with the CBT group. In the information groups, a long-term sick absence developed with 11 participants (10.4%), whereas this occurred with only 1 participant (1.1%) in the CBT group. The comparison showed that participants in the information groups had a ninefold increased risk of being on long-term sick leave as compared with the CBT Group (risk ratio, 9.3; 95%; 95% confidence interval, 1.2–70.8).

Second, each participant's own perception of a long-term disability developing were compared across an interval. An analysis comparing participants' ratings at pretest and follow-up assessment showed that the CBT group had a significant decrease ($P < 0.009$), whereas the within-group difference was not significant for the pamphlet or information package group. The between-group difference, however, did not reach significance.

Overall Analysis

Gain scores were used to rank the groups in terms of which group had the most favorable results on each of the 19 outcome variables. If there was no difference between the groups, then each group would be expected to have the most favorable result on one-third the six variables. However, the CBT intervention group had the "best" average result on 13 of the 19 variables, and this difference is significant ($P < 0.02$, Kruskal-Wallis). This analysis indicates that the CBT intervention group had the most consistent overall progress between the pretest and 1-year follow-up assessment.

■ Discussion

The results of this study show that a CBT preventive intervention may be a valuable tool in the very early stages of a spinal pain problem. Although the compari-

son groups that received usual medical treatment and specific information reported benefits, the participants in the CBT Group still had significantly fewer days off work and consumed smaller amounts of health care. This has important implications because it demonstrates that chronic problems can be prevented by providing self-help oriented interventions. Moreover, it offers a model that may be applicable to a variety of health care settings (*e.g.,* at the primary care level).

The current findings underscore the significance of an approach that aims to prevent long-term disability and that is in line with some previous reports. Because most studies are conducted within the health care field, often the aim is to "treat" or "cure" the problem. However, although most people with back pain tend to improve over the course of a few weeks, they may continue to experience pain or recurrent episodes. This creates problems for evaluation, and it is difficult to find treatments at the acute stage supersede the natural return-to-work curve.[5,31] Nevertheless, a small number of patients in pain fail to improve significantly. They may be off work and seeking considerable health care. The current study aimed to prevent this from occurring. As the sick leave data indicate, this was successful in the CBT group relative to the comparison groups because the risk for a long-term absence developing was nine times less in the CBT group.

Von Korff et al[34] reported similar results for a group intervention that focused on self-management. Two differences exist in that the current intervention was professionally whereas theirs was lay led, and the current study reported differences on absenteeism whereas they reported scores on a disability questionnaire. Together, these studies point to the possible importance of activating the patient toward constructive self-management (coping).

Other studies also have indicated that the early stages of intervention may be critical (*e.g.,* by recommending activity and self-management).[13,37] Turner,[30] in her review of education and behavior interventions in primary care, concludes that whereas further controlled studies are needed, research should focus also on specific aspects such as which patients respond, at what time point, and with what interventions. The current findings support this view.

It is noteworthy that many participants receiving information reported reading it and also improved from pretest to the follow-up assessment. The information used in this study was specifically designed for early use with people experiencing musculoskeletal pain, and the pamphlet was been reported to have a preventive effect.[28] Although the current design focused on the effects of CBT, the findings show that at least one third of the participants read the material, and that approximately one fourth reported the information to be very helpful. This may represent an encouraging benefit given the low cost and time investment, but the improvements were small relative to the those of the CBT group.

The current study does have limitations. It would have been preferable to have several follow-up points to capture transient outcomes, and ratings of expectancy also could have provided valuable insights. Finally, the 29 people who were randomized might have better assessed, but they failed ever to participate in the treatment.

In conclusion, in patients with acute or subacute problems, CBT-oriented self-management groups may be helpful in reducing disability and health care use. The findings show small but consistent differences between the groups for most variables, whereas the risk for long-term sick leave was greatly reduced by participation in the CBT group intervention.

■ Key Points

- Because chronic spinal pain develops in a small number of patients, there is a need for early, preventive interventions.
- A randomized trial was conducted to examine the effects of a coping-oriented CBT program as compared with providing information.
- The results show a ninefold reduction in the risk for the development of a long-term sick leave and significantly less health care use by the CBT group.
- Early psychologically oriented interventions may be helpful in preventing the development of chronic disability.

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