Pain 90 (2001) 83–90

PAIN

www.elsevier.nl/locate/pain

A cognitive-behavioral group intervention as prevention for persistent neck and back pain in a non-patient population: a randomized controlled trial

Steven J. Linton*, Marianne Ryberg

Department of Occupational and Environmental Medicine, Örebro Medical Center, 701 81 Örebro, Sweden

Received 15 February 2000; received in revised form 27 June 2000; accepted 20 July 2000

Abstract

Given the demand for interventions that may prevent the development of persistent musculoskeletal pain problems, we investigated the effects of a cognitive-behavioral program in a group of non-patients with neck or back pain symptoms. Two hundred and fifty-three people selected from a population study were invited to participate. These people had experienced four or more episodes of relatively intense spinal pain during the past year but had not been out of work more than 30 days. Participants were randomly assigned to either a cognitive-behavioral group intervention or a treatment as usual comparison group. The experimental group received a standardized six-session program, provided by a trained therapist according to a manual. A significant overall analysis at the 1-year follow-up showed that the cognitive-behavioral group produced better results on 26 of the 33 outcome variables. Group comparisons indicated that the cognitive-behavioral group, relative to the comparison group, had significantly better results with regard to fear-avoidance beliefs, number of pain-free days, as well as the key variable of sick leave. Participation in the cognitive behavioral group reduced the risk for long-term sick leave during the follow-up by threefold. Thus, despite the strong natural recovery rate for back pain, the cognitive-behavioral intervention produced a significant preventive effect with regard to disability.

Keywords: Cognitive-behavioral program; Back pain; Sick leave

1. Introduction

An overview of the literature suggests a clear need for preventive strategies that include psychological techniques. On the one hand, psychological factors have been strongly linked to the development of costly chronic back disability (Linton, 2000; Turk, 1997; Weiser and Cedraschi, 1992). In addition, psychological techniques, specifically cognitive-behavioral programs, have been found to be helpful in treatment situations (Compas et al., 1998; Morley et al., 1999). In view of the extraordinary suffering and costs associated with the development of a persistent problem (Goossens and Evers, 1997; Linton, 1998; van Tulder et al., 1995; Williams et al., 1998), several government agencies and researchers have highly recommended early, preventive measures. However, to date few studies have examined the specific effects of psychological preventive interventions.

Some early, secondary preventive efforts have nevertheless shown promise. For example, Waddell et al. (1997) reviewed 10 trials of early interventions for acute back pain mainly in primary care settings and found that programs that encouraged maintaining daily activities produced better results than various control conditions. One reason for this success may be that these programs dealt with the fear and anxiety often associated with acute pain and believed to generate 'fear-avoidance' behaviors that may produce disability (Vlaeyen and Linton, 2000). More recently, Von Korff et al. (1998) have found that a lay-led, cognitive-behavioral program for patients with acute back pain significantly reduced worry and disability at follow-up relative to a treatment as usual control. Therefore, there is reason to believe that early, preventive interventions might be viable.

However, there has been some debate concerning the time point for preventive interventions that reflects on the relative lack of investigation in 'non-patient' populations. For example, Frank et al. (1996a) argue that, statistically speaking, interventions prior to about 8 weeks sick leave have little value since the natural recovery rate is high.

* Corresponding author. Tel.: +46-19-602-2456.
E-mail address: steven.linton@orebroll.se (S.J. Linton).

0304-3959/01/$20.00
PII: S0304-3959(00)00390-0

Indeed, Sinclair et al. (1997) found that an early intervention program based on exercise, mobilization and education administered throughout Ontario produced little benefit in relation to 'usual' care. Still, from a psychological point of view the foundation for fear, anxiety, and other processes that may generate disability (Turk, 1996; Vlaeyen and Linton, 2000; Waddell, 1998), is probably activated quite early on. Consequently, very early, psychologically-oriented prevention might be valuable. Nevertheless, there are relatively few attempts at prevention in non-patient populations, and most attempts have involved ergonomic, education or exercise techniques rather than psychological ones (Linton and van Tulder, 2000; van Poppel et al., 1997). Indeed, the results of these preventive interventions, according to these reviews, have been sobering. Hence, research on the specific effects of psychological preventive interventions in non-patient populations is desirable.

Recently, Linton and Andersson (2000) demonstrated that a cognitive-behavioral group intervention was helpful as an early intervention for those with subacute or recurrent spinal pain. This randomized study compared a cognitive-behavioral therapy (CBT) intervention with treatment as usual coupled with extra information encouraging active coping. The results showed that the risk of being on long-term sick leave was nine times less for the CBT group relative to the comparison groups. Taken together with the encouraging results of Von Korff et al. (1998), a CBT oriented group format might be valuable for a non-patient population.

The aim of this investigation was to evaluate the preventive effects of a cognitive-behavioral therapy group intervention for people reporting neck or back pain, but with virtually no sick leave in a randomized controlled trial. As a result, our approach was to apply cognitive-behavioral techniques as a method of helping a non-patient sample prevent the development of a more serious pain problem. As a result, our unique population consisted of candidates selected with little disability from the general population rather than patients. We hoped to reach these people before the pain was a disrupting problem, yet when the person nevertheless was interested in participating. Since prevention is often oriented toward relevant health-economic factors, our key variables were sick leave and health-care utilization. However, we have included other variables to assess the participant's pain perception, quality of life, and function. We hypothesized that the CBT intervention would result in a more favorable outcome as compared to the comparison group, i.e. that it would help prevent future disability problems.

2. Method

2.1. Overview of the design

We conducted a randomized controlled trial employing two groups with assessments at pretest and at 1-year follow-up. The experimental group received a standardized cognitive behavioral group intervention while the comparison group received the 'usual treatment' available if help was sought.

2.2. Participants

This study is part of the Södermanland Back Pain Project where 3000 people, 35–45 years old, were randomly selected from the population census register by a third party (Sema Group Infodata) and mailed a short questionnaire concerning spinal pain. From the pool of responders, the following inclusion criteria were employed: (1) worst pain during the past year $\geqslant 7$ on a 0–10 point scale; (2) $\geqslant 4$ episodes during the past year; and (3) pain in the spinal region (back, neck, or upper back). The exclusion criteria were: (1) accumulated sick leave of more than 30 days during the past year; (2) co-morbidity of handicaps or diseases that might interfere or contraindicate the intervention.

A written invitation to participate in the study was mailed to the 481 people who met the inclusion and exclusion criteria. A description of the study was supplied and they were informed about the purpose and consequences of participating in the study. Application required the person to fill in a form as well as the pretest assessment materials and return them in the provided envelope. Two hundred and fifty-three people returned the application form and a person not associated with the project team employed a table of random numbers to assign participants to the two groups. However, based on previous pilot work we anticipated that many people assigned to the intervention group would, in the end, not be able to participate because of scheduling problems as only a limited number of groups could be offered. To compensate for the difference in the expected rate of participation, a block randomization was used where six of every nine candidates were allocated to the CBT intervention group. Thus, 91 were randomly assigned to the Treatment as Usual Control group and 162 to the CBT Intervention group.

Participants were subsequently informed of which group they had been randomly assigned to and, for the experimental group, they were supplied with a reply form describing the available group schedules. As suspected, 42 people assigned to the CBT Intervention group replied that they could not attend because of scheduling problems, and 36 failed to respond to the invitation. These non-responders, as planned above, were consequently excluded from the study. We conducted an analysis of these non-participants as they had completed the pretest assessment instruments. The 78 non-participants relative to the participants were a half year older and there were slightly more males although this difference was not significant ($P > 0.05$). There were no significant differences on the key variables of average pain intensity ($P > 0.05$), pain at its worst ($P > 0.05$), and number of days of previous sick leave ($P > 0.05$). In addi-

tion, we examined the other variables in the assessment described below. The non-participants had significantly more pain-free days than participants ($P < 0.05$) at pretest, but there were no significant differences on variables, e.g. coping ($P > 0.05$), depression ($P > 0.05$), and function ($P > 0.05$). Thus there were 84 people who agreed to participate in the CBT group.

Table 1 summarizes the background data of the participants. As the table illustrates, there were no significant differences ($P > 0.05$) between the groups at the pretest with regard to age, pain intensity, previous sick leave, employment status, and smoking. Nor were there any systematic differences with regard to pain site. There were about 8% more females in the treatment group as compared to the control group, but this difference is not significant ($P > 0.05$).

The hospital's board on research ethics approved this study.

2.3. Measures and procedure

Postal questionnaires were employed at the pretest and 12 months after the intervention that utilized items from standardized instruments. Since the intervention focused on prevention, two key variables were included to assess this. First, we measured health-care utilization. Second, we focused on sick leave since long-term problems often result in work loss. Additional items covered a range of areas including pain perception, dysfunction, and psychological factors described in detail below. Participants completed the questionnaires at home and returned them in the pre-paid, addressed envelope provided. 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 sent. If a response was not received within an additional 2 weeks at the follow-up, the person was contacted by telephone.

Table 1
An overview of the characteristics of the participants at pre-test

Variable	Treatment group		Control group	
	N	%	*N*	%
	84		91	
Gender (female)	53	63.1	50	54.9
Smokers (yes)	26	31.3	25	28.1
Gainfully employed	64	78.0	80	80.8
Education				
Compulsory school		24		23
Secondary school		48		47
University		28		29
	Mean	SD	Mean	SD
Age (years)	40.02	3.2	40.52	3.3
Pain intensity (0–10)	6.63	2.1	6.31	2.6
Sick leave (days/6 months)	2.51	9.8	2.10	6.3

2.4. Key outcome variables

The self-reported number of visits to a physician, physical therapist, specialist or hospital, and alternative care provider during the previous year was used to assess health-care utilization. Participants reported the number of visits to each of these by ticking the appropriate number from no visit to more than 10 visits. The reliability and validity of this self-report measure has not yet been established (Linton et al., 1998).

Sick absenteeism was assessed with self-report items concerning sick leave and other forms of absenteeism related to their spinal pain. All residents of Sweden are covered by a national insurance scheme that pays compensation while a person is ill. This scheme provides coverage for all people regardless of employment status (employed, unemployed, students, etc.) but payment is contingent on reporting the illness. Consequently, people may be aware of their sick leave since one must actively seek compensation by reporting the illness. Specifically participants were asked how many days of formal sick leave they had taken (that is reported in order to obtain compensation) each month during the past 6 months. Participants responded by filling in the number of days for each of the preceding, and clearly labeled months. Likewise, another question asked how many days of work they had missed because of pain, but where they were not formally classified as ill, e.g. by taking vacation. Research shows that patients are able to make relatively accurate estimates of their sick leave as compared to official documents, especially when the pain is acute and most patients take few or no sick days (Hensing et al., 1998; Linton et al., 1995).

2.5. Self-report inventories

Items from several self-report inventories were employed to complement the key outcome variables. Background variables included age, nationality, gender, smoking, height and weight. Pain perception was captured by using items about intensity, frequency and medication consumption from the Outcome Evaluation Questionnaire since they have been shown to have good reliability and validity (Keefe et al., 1992; Linton and Halldén, 1997; Linton et al., 1992). Ratings of pain intensity asked about the participant's worst pain during the past 3 months and average pain during the past week, as well as the past 3 months rated on 0–10 point scales. In addition, frequency was measured by asking the number of pain-free days they had experienced during the past week as well as during the past 3 months. We also asked for the number of days during the past week that pain medicines had been consumed.

Several psychological aspects of pain perception were assessed. Anxiety and depression were measured with the Hospital Anxiety and Depression Scale (HAD), a 14-item instrument for patients with somatic complaints, that has acceptable psychometric characteristics (Zigmond and

Snaith, 1983). The Pain Catastrophizing Scale (PCS) which has acceptable reliability and validity was used to assess the cognitive evaluation of the pain and has three subscales (rumination, magnification and helplessness) (Sullivan et al., 1995). Fear-avoidance beliefs were measured with two questionnaires. First, 12 items from the Tampa Scale of Kinesophobia (TSK) which has been shown to be a relevant measure of fear of movement/activity was employed (Kori et al., 1990; Vlaeyen et al., 1995). Secondly, a modified form of the Fear-Avoidance Behavior Questionnaire (mFABQ) was employed that contains four items from the physical activity scales (Linton et al., 1999; Waddell et al., 1993). The short forms were tested in a pilot study and shown to exceed 85 on test-retest and 83 on correlations with the scale as a whole.

Two measures of physical function were utilized. First, six items reflecting activities of daily living were employed consisting of work, walking, household chores, weekly shopping, sleep, and sitting. Participants rated their ability to do these activities on 0–10 point scales anchored by 'cannot do it because of pain' and 'can do it without pain being a problem'. These items were taken from a 10-question measure of activities of daily living was employed that has been shown to be reliable and valid (Linton, 1990). A self-administered physical function test that has been shown to be reliable and valid was also used where participants are asked to perform and record eight simple movements reflecting mobility (Hellsing et al., 1997). Although these movements are simple they are often affected by spinal pain.

2.6. Intervention

2.6.1. Treatment as Usual Comparison group

Participants in this group were free to pursue any ordinary treatment they deemed warranted, e.g. from a general practitioner or physical therapist. However, no extra resources were made available from the study. For those seeking care a typical course is an examination by a primary care physician or physical therapist. Common treatments are prescription drugs, exercise, and referrals. In fact, 37% saw a physician, 45% a physical therapist, and 37% a chiropractor or other complementary medical staff. People in this group were informed that they would be contacted for a follow-up assessment.

2.6.2. Cognitive-Behavioral Therapy Intervention (CBT Intervention group)

A six-session structured program was offered where participants meet in groups of 6–10 people, six times, once a week for 2 h. Since psychological interventions may vary greatly in content and administration, a manual available from the first author was written to standardize the intervention and the therapist was a certified behavior therapist who had received special training in administering this treatment. Moreover, the therapist met with the senior author and other psychologists offering similar courses in other settings for discussion once per week. At these meetings progress was discussed and the content of the coming session reviewed.

Sessions were organized to activate participants and promote coping. Each session began with a short review where homework, etc. was gone through. Subsequently, the therapist introduced the topic for the session and provided information for a maximum of 15 min. Participants received a problem that was to be solved with the help of a partner. Solutions were presented in the group and discussed. After a short break, the therapist introduced new skills and participants practiced them. Homework assignments were then made and these were tailored to the participant's needs. However, all participants were asked to apply all of the skills learned in their everyday life to gain some experience about it. Finally, the session was reviewed underscoring what the participants had learned, what the homework assignment would be. Participants were asked to provide feedback concerning the positive and negative aspects of the session in order to provide continual quality assessment for the group and the therapist.

Table 2 provides a summary of the content of the six sessions. A goal was that each participant would develop a personal 'coping strategy plan' at the end of the course. To this end participants developed their own goals for the program. Moreover, each session focused on a theme with associated specific skills. Themes dealt with pain management, but also with stress and management of problems that develop as a consequence of the pain, e.g. at work or at home. During sessions participants actively discussed what effect these skills might have on a fictive pain patient. In addition, they were asked to practice each skill between sessions. During the last two sessions participants worked on developing their own specific coping plan and they

Table 2
Overview of the content of the CBT intervention.

Session	Focus	Skills
1	Causes of pain and the prevention of chronic problems	Problems solving Applied relaxation Learning about pain
2	Managing your pain	Activities, maintain daily routines Scheduling activities 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 Coping skills review Applied relaxation
6	Maintaining and improving results	Risk analysis Plan for adherence

developed strategies for maintaining their program in the future.

2.7. Statistical analyses

The data from the pretest and 1-year follow-up were first summarized and examined using descriptive statistics. Change scores were calculated for each outcome variable by subtracting the follow-up value from the pretest value. This allowed direct statistical comparisons between the groups. As many of the variables had skewed distributions and since most of the scales were on an ordinal scale, nonparametric statistics were employed with a P level of 0.05 for two-tailed tests.

After examining the descriptive data, a series of analyses were conducted. First, an overall analysis employing all of the outcome variables was used to ascertain whether any substantial systematic changes had occurred between the groups. If the intervention has no effect on the outcome, then the probability of having the 'best' average score on any given dependent variable would be the same for the Comparison group and the CBT Intervention group. To test this idea, average gain scores were examined on each of the 33 variables and the results ranked according to which group had the most favorable outcome. Subsequently, the probability of the distribution of ranks was calculated for significance using a Chi-Square analysis. This provides a measure of the consistency of the results.

After determining the overall analysis above, the data were statistically examined for changes within and between groups. Within-group comparisons were achieved with the Friedman two-way analysis of variance. Between group analyses were calculated with the Mann–Whitney U-test.

3. Results

3.1. Participation rate

Of the 175 people that began participation in the study, two people could not be included as one was diagnosed as having cancer (control group) and the other moved abroad (CBT group). The participation rate was 92% as 160 people completed both the pretest and the follow-up assessments and these data were used in the data analyses. Of the 13 dropouts, five were in the Comparison group and eight in the CBT Intervention group.

Attendance at all of the intervention sessions was recorded. The mean participation rate was 4.1 (SD = 1.64) of the six sessions. Twenty-three percent attended all of the sessions, while 20% attended two or fewer of the sessions. The relationship between attendance and outcome was not statistically significant and therefore we have not adjusted for this variable in the analyses. We did include all subjects in the data analysis who completed the questionnaires regardless of attendance.

3.2. Overall analysis

An overview of the results is presented in Table 3. As described above, gain scores were used to rank the groups as to which group had the most favorable result on each variable. If there was no difference between the groups, then each group would be expected to have the most favorable result on half of the variables, i.e. 16 variables. In fact, the CBT Intervention group had the 'best' average result on 26 of the 33 variables and this difference is highly significant (Chi-Square = 19.63, $P < 0.001$).

Table 3
Summary of some of the results for self-rated pain, psychological and physical function for the two groups.

Variable	CBT Treatment group				Comparison group			
	Pre-treatment		12 month follow-up		Pre-treatment		12 month follow-up	
	Mean	SD	Mean	SD	Mean	SD	Mean	SD
Tampa Scale of Kinesophobia (TSK)	11.17	6.46	11.49	6.72	10.45	6.40	12.12	6.74
Pain Catastrophizing Scale (total)	16.64	9.44	17.41	8.70	16.91	9.53	18.46	9.74
Rumination (PCS)	6.71	3.84	6.91	3.22	6.49	3.64	7.04	3.48
Magnification (PCS)	3.61	2.35	3.39	2.17	3.46	2.64	3.77	2.73
Helplessness (PCS)	5.81	4.47	7.10	4.58	6.42	4.93	7.66	4.83
mFABQ 1	11.08	6.37	9.58	6.55	11.01	6.68	9.93	6.06
FABQ 2	17.21	8.38	15.97	8.30	17.63	9.01	16.95	7.86
Physical function test	7.88	1.82	7.68	2.31	7.68	1.80	7.15	2.22
HAD: anxiety	6.17	3.82	5.50	3.49	6.42	4.24	6.17	4.26
HAD: depression	4.84	3.46	4.41	3.77	4.74	3.29	4.56	3.78
Activities of daily living	46.00	11.22	44.84	11.61	47.56	10.00	45.34	11.38
Mean pain (past week)	5.41	1.67	4.53	1.67	5.58	1.78	4.67	1.78
Worst pain (past 3 months)	8.03	0.99	7.11	1.72	8.13	1.03	7.07	2.08
Consumption of medicine	0.84	1.75	0.81	1.47	1.18	1.94	1.14	2.11
Pain-free days	27.22	28.43	37.63	33.63	35.21	32.62	35.11	32.56
Health-care visits	3.69	5.45	4.51	6.25	5.25	7.48	6.62	8.19

Thus, this analysis indicates that the CBT Intervention group consistently had the most favorable overall progress between pretest and the 1-year follow-up.

3.3. Key variables

3.3.1. Work absenteeism

A key variable for prevention was absenteeism since it dominates the economic picture and provides a concrete long-term outcome. The average number of sick leave days per person and month is shown in Fig. 1 and illustrates a more favorable outcome for the CBT group. The data encompass a 6-month period before the intervention as well as a 6-month period at follow-up. Thus there is a period of 6 months separating the pretest and the follow-up data.

The figure illustrates that sick leave was virtually null during the first 4 months and then increases mirroring our selection criteria. The follow-up shows that both groups have, on the average, more days of sick leave than at baseline. However, for the CBT Treatment group the level remains stable with the last month of baseline while the Usual Treatment Comparison group has an increased level, a difference that is statistically significant (Mann–Whitney *U*-test, $U = 2441$, $P = 0.032$). In fact, while there is virtually no difference during baseline, the treatment group has the lowest amount of sick leave on each of the 6 months during follow-up. The absolute value of the difference during baseline varies between about one-half to one and a half days per month. The number of self-reported days of work loss due to back pain when the person was not sick listed (e.g. utilized vacation day) was assessed as a control. However, such leave was seldom used and there were no differences between the groups.

Risk for developing 'disability' was evaluated by comparing those with a poor as opposed to a good outcome on sick leave at follow-up. We defined a poor outcome as those with 14 days of sick leave during the past 6 months and a good outcome as those participants having 0–13 days sick leave during the same time period. In the Control group 15% developed a long-term sick absence while in the CBT group 5% did. The comparison showed that participants in the treatment as usual group had a threefold increased risk of being on long-term sick leave as compared to the CBT group (OR = 3.33; 90%CI = 1.19–10.2).

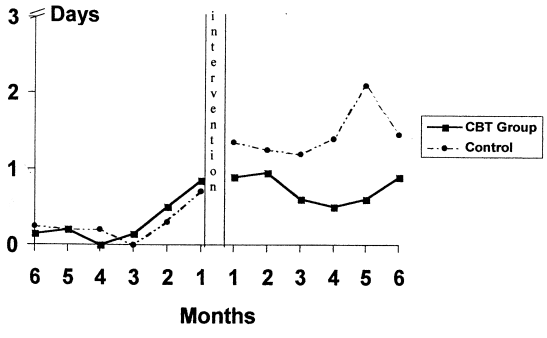

Fig. 1. The average number of sick leave days per person and month.

3.3.2. Health-care utilization

The number of self-reported health-care contacts at pretest and follow-up were analyzed to determine possible group differences. No significant between-group differences were observed over the course of the study.

3.4. Other variables

A review of Table 3 reveals that most participants had relatively mild problems at pretest, which is consistent with the selection procedure. Since this study focuses on prevention, the most important results pertain to a worsening (rather than improvement) in these variables.

3.4.1. Pain experience

The outcome for pain experience was evaluated by ratings of pain intensity and the number of pain-free days. As seen in the table, both groups experienced improvement in their pain. For average pain during the past 3 months, the within-group analyses was significant for the CBT Treatment group ($P < 0.05$) and for the Treatment as Usual Control ($P < 0.05$). The CBT group also noted a significant improvement in the number of pain-free days between the pre- and follow-up assessments ($P < 0.05$). No other within-group differences were significant for either group. One between group analysis produced a significant result, namely that the CBT Treatment group had a significantly larger increase in the number of pain-free days than did the Control group ($P < 0.05$).

3.4.2. Physical function

Physical function was assessed with two instruments. The self-administered physical function test indicated that both groups had relatively high scores on the pretest and showed little change between pre- and follow-up for either group. The Activities of Daily Living scale scores were also relatively high and showed little change over the course of the study for either group.

3.4.3. Psychological factors

A variety of measures were employed to capture the psychological aspects of pain and its consequences. However, many of these variables showed relatively normal scores on the pretest and little change between pre- and follow-up values. The CBT Treatment group did have a significantly larger improvement on the mFABQ than did the Treatment as Usual Control group ($P < 0.05$) There were no significant findings for the remaining variables (PCS, TSK, FABQ, HAD, CSQ).

4. Discussion

Despite the strong natural recovery rates know for spinal

pain, this study demonstrated a preventive result from the application of a cognitive-behavioral intervention that reduced the risk for disability threefold. Unlike other studies, our participants were selected from a population-based sample, rather than from a clinic, and had very little disability. Indeed, relatively few of the participants developed further problems as reflected in the sick leave data. Nevertheless, the CBT group showed the most stable improvements in the overall analyses. In addition, the CBT group demonstrated a significantly better result for sick leave relative to the Treatment as Usual Comparison group, reducing the risk of sick leave greater than 2 weeks by more than threefold. With regard to other variables, the CBT group reported a significant decrease in fear-avoidance beliefs and an increase in the number of pain-free days in relation to the Comparison group. The results of this study suggest that early preventive interventions may be of genuine value.

Even though we selected people with very low levels of sick leave, we were able to show that the intervention was of value in reducing future problems. Indeed, although early interventions are not always successful, our results are in line with some studies showing that early self-management oriented interventions are beneficial (Linton and Andersson, 2000; Linton and Götestam, 1984; Von Korff et al., 1998). As most people with back pain tend to get better rather quickly, it is especially difficult to demonstrate results that are superior to the natural recovery curve (Frank et al., 1996b; van den Hoogen et al., 1998). Moreover, in the present study, given its focus on prevention, we had restricted statistical power due to the limited numbers of participants. Despite these difficulties, our results nevertheless showed significant differences particularly with regard to sick leave.

The overall analyses showed that the CBT group had the most stable changes although the size of the changes in the psychological and disability variables was often relatively small probably due to the low risk at baseline. Indeed, the overall analysis did show that the CBT group had the best improvement on a majority of the variables. The fact that the size of the differences between groups was small for the psychological and disability variables mirrors that most participants had very small problems and the scores on the various questionnaires were often normal or near normal, thus setting a ceiling for possible observed improvements. Our aim was to prevent the development of disability for the small group of participants who do not get better. As this group represents but a small percent of the group as a whole, the effect on group averages was expected to be limited.

One implication of our findings is that the time point for intervention as well as the selection criteria may be important determinants for the preventive effect observed. Clearly, selecting people from the general population generates a sample with, comparatively speaking, limited problems where only a very small percent develop problems in the course of a year. Thus, selecting those clearly at risk would offer the advantage of better efficiency and fewer people to treat. Providing this CBT intervention as a primary preventive intervention for all members of the general public or a particular workplace, for example, would probably not provide the desired effect. For that reason, there is a need for future research to develop risk analyses that may be applied early (such as at occupational or primary care settings) as well as investigations to evaluate the effect of CBT prevention at these various levels of risk.

This study does have some methodological limitations. First, the participants in the present investigation were selected based upon their pain experience in a general population survey and are not representative of ordinary primary care patients. In fact, most of them were not under active medical care when recruited into the study. In addition, participation was strictly voluntary and over half of those fulfilling the inclusion criteria did not participate. Thus, our sample is selective and our results may not generalize to other populations. Second, the people declining treatment after randomization were not included in an 'intent to treat' analysis. We anticipated that a fair number of people would not be able to attend the group treatments because of scheduling problems. Further, an analysis comparing the non-participants with the participants did not show any significant differences on any of the key outcome variables or the other variables included in the pretest assessment package. Although there were no statistical differences, the non-participants may nevertheless have differed and biased the results. Finally, although we were able to demonstrate significant differences between the groups, there was little difference between the groups on some variables. This may be related to normal levels at baseline or to the fact that most people with spinal pain improve. However, it might also reflect limitations in the size or breadth of the intervention effect.

We conclude that the CBT preventive intervention provided to a sample of people with back pain from the general public with little disability produced a significantly better result relative to the treatment-as-usual comparison group for sick leave. Thus, early preventive interventions may be helpful. However, more research is needed to determine the most opportune sample and time point for intervention.

Acknowledgements

We would like to extend our sincere gratitude to Ing-Liss Bryngelsson and Lotta Wahlström for their expert help in analyzing the data and to FINSAM, Sörmland for economic support.

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