Preventing Progression to Chronicity in First Onset, Subacute Low Back Pain: An Exploratory Study

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Objectives: To evaluate the effects of a behavioral medicine intervention, relative to an attention control, in preventing chronic pain and disability in patients with first-onset, subacute low back pain (LBP) with limitations in work-role function.

Design: A 2-group, experimental design with randomization to behavioral medicine or attention control groups.

Setting: Orthopedic clinic at a Naval Medical Center.

Participants: Sixty-seven participants with first-onset LBP of 6 to 10 weeks of duration and impairment in work function, of whom 50 completed all 4 therapy sessions and follow-up 6 months after pain onset.

Intervention: Four 1-hour individual treatment sessions of either behavioral medicine, focused on back function and pain education, self-management training, graded activity increases, fear reduction, and pain belief change; or attention control condition, focused on empathy, support, and reassurance.

Main Outcome Measures: The primary outcome was proportion of participants classified as recovered, according to pre-established clinical cutoffs on standardized measures, signifying absence of chronic pain and disability at 6 months after pain onset. Secondary analyses were conducted on pain, disability, health status, and functional work category. Intervention credibility and pain belief manipulation checks were also evaluated.

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0003-9993/09/9004-00581\$36.00/0 doi:10.1016/j.apmr.2008.10.032 **Results:** Chi square analyses comparing proportions recovered at 6 months after pain onset for behavioral medicine and attention control participants found relative rates of 52% versus 31% in the modified intent-to-treat sample (P=.09) and 54% versus 23% for those completing all 4 sessions and 6-month follow-up (P=.02). At 12 months, 79% of recovered and 68% of chronic pain participants still met criteria for their respective groups (P<.0001). Recovered participants also had higher rates of functional work status recovery at 12 months (recovered: 96% full duty and 4% light duty; chronic pain: 61% full duty, 18% light duty, and 21% medical discharge, respectively; P=.03).

Conclusions: Early intervention using a behavioral medicine rehabilitation approach may enhance recovery and reduce chronic pain and disability in patients with first-onset, subacute LBP. Effects are stronger for participants attending all 4 sessions and the follow-up assessment.

Key Words: Behavioral medicine; Health status; Pain; Preventive health services; Rehabilitation.

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OW BACK PAIN is among the nation's most costly medical conditions, with direct costs exceeding \$26.3 billion. LBP is the fifth most common reason US patients consult physicians and the second most frequent health problem in primary care. Although most patients with acute LBP recover within 4 to 6 weeks, those who do not account for the bulk of individual and economic burden. Prevention is therefore a public health research priority.

Patients with acute (less than 3 months), subacute (6–12 weeks), and chronic (at least 3 months) LBP exhibit different physiologies, courses, and treatment responses. The subacute phase has been recommended as an optimal intervention window. A previous study prospectively examined patients with first-onset LBP of 6 to 10 weeks and found that 78% had daily pain and disability after 6 months, and 72% had these symptoms after 1 year. 10

Psychosocial variables, such as beliefs, moods, or coping, impact the transition from acute to chronic pain and disability in LBP¹¹⁻¹³ and may exercise greater impact than biomedical or biomechanical variables. ¹⁴ Therapies that target psychosocial factors have therefore been recommended in recent national

List of Abbreviations

вмі	body mass index
DDS	descriptor differential scale
LBP	low back pain
PAIRS	pain and impairment relationship scale
QWB	quality of well-being
SIP	sickness impact profile

clinical guidelines for back pain treatment.¹⁵ Group cognitive-behavior therapy for patients with LBP in primary care has reduced long-term disability and absenteeism relative to minimal and active controls. ¹⁶⁻¹⁹ These studies did not differentiate patients with subacute from chronic or acute conditions. Evidence suggests that psychosocial factors emerge as potent influences on chronicity development at the subacute stage,²⁰ and that pain of this duration, unlike acute pain, is highly predictive of chronicity¹⁰; therefore, targeting subacute LBP specifically should maximize therapeutic impact.

Only a handful of psychosocial intervention studies have selected for subacute LBP. In a Norwegian study of patients sick-listed for 8 to 12 weeks, 21 cognitive therapy improved disability at 18 weeks, whereas exercise reduced pain significantly but had higher dropout. A randomized study of disability applicants 4 to 8 weeks on compensation for back pain²² found physician consultation plus weekly telephone sessions, focused on increasing activity, reduced pain and disability 2-fold relative to usual care at 6 months, but did not increase return to work. An intervention focused on activity increase and fear reduction among sick leave patients with new or recurrent back pain of 4 to 12 weeks^{23,24} resulted in improved 1-year return to work and 5-year employment and sick leave relative to usual care. These subacute LBP studies suggest the usefulness of psychosocial intervention yet are limited by either the use of usual care controls or a follow-up assessment interval of less than 6 months, and the use of subjects with previous pain episodes.

With this randomized, controlled pilot study, we sought to evaluate the efficacy of a behavioral medicine intervention relative to an attention control in preventing chronic pain and disability at 6 months in patients with first-onset, subacute LBP. Participants were recruited from a treatment-seeking sample in a closed health care system and had all been assigned to light duty status because of pain-related functional limitations at study onset. The intervention was based on established behavioral pain treatment models²⁵ and emphasized self-management training, systematic graded activity increases, fear reduction, and pain belief change.

Nonspecific effects, including provider attention, expectations, and treatment believability, are threats to internal validity in clinical research studies. ²⁶ To address these concerns, this study used a nonspecific attention control, equated for number and duration of sessions, which provided active listening, empathy, support and nondirective assurance, including suggestion that the patient consult with the orthopedic team as needed to manage pain and recovery. As with the experimental arm, the attention control condition was also assessed for credibility and palatability. Therapists, patients, and assessors were not informed about the nature of alternative conditions or hypotheses, and treatment sessions were monitored to ensure fidelity to condition.

In line with previous work in categorizing both acute and chronic back pain^{27,28} and using procedures for defining clinically significant change,²⁹ we established cut scores for measures of pain and disability in patients with subacute LBP for the purposes of evaluating comparative treatment outcomes in clinically meaningful terms. Values below the cutoffs are considered statistically similar to 0, and these patients are classified as resolved, indicating the individual is like a member of a healthy population. The primary study outcome was the proportion of participants classified as resolved versus chronic pain at 6 months after pain onset. It was hypothesized that the behavioral medicine intervention would increase the proportion resolved relative to the attention control. Supplemental analyses examined the hypotheses of greater improvement in pain

beliefs at 6 months in the behavioral medicine group relative to attention controls, and lower pain and disability, better health status, and less impairment in work function at follow-up in the resolved group relative to chronic pain.

METHODS

Participants and Setting

The Committee on Investigations Involving Human Subjects and the Scientific Review Committee at the participating institutions approved this research protocol. Participants were identified through systematic review of patients seeking consultation at an orthopedic clinic in a closed health care system. Primary care physicians referred to orthopedic clinic patients whose back pain persisted for 4 to 6 weeks despite conservative care and who demonstrated impaired work function. With clinic permission, a research nurse approached patients with first-onset back pain of 4 to 10 weeks for consent to be evaluated for enrollment.

Study inclusion criteria were (1) age 18 to 50 years, (2) first-onset back pain (thoracic vertebra 6 or below) present daily for at least 6 but less than 10 weeks, (3) no other major medical illness or pain disorder, and (4) not a candidate for acute surgical intervention. Participants were excluded for (1) prior episodes of daily back or other pain lasting 1 week or longer, (2) being prescribed medications known to affect mood or function (eg, antidepressants, anxiolytics), (3) major surgery within the preceding 12 months, and (4) back pain secondary to serious medical disorder (eg, neoplastic disease, osteomyelitis, fracture).

Potential participants had to be able to attend the first intervention session within 1 week of group assignment to ensure the sample still represented a subacute pain phase. The research battery was administered promptly after informed consent and repeated 6 and 12 months after pain onset by research assistants not involved in other aspects of the study and blind to condition. Participants received their usual medical care during the study.

Usual Medical Care

Usual medical care was provided to both groups according to the Agency for Health Care Policy and Research Guidelines at that time. ³⁰ It consisted of 1 outpatient visit, which included (1) history, back examination, screening laboratory assessment for red flags; (2) discussion of physical findings; (3) a prescription for low-impact aerobic exercise; (4) general health recommendations; and (5) brief education regarding the benign natural history of back pain, and a *Readers Digest* article, "Good News for Bad Backs." Follow-up visits occurred if requested or were indicated.

Behavioral Medicine Intervention

The experimental intervention was a modification of a behavioral medicine chronic pain program³²⁻³⁴ revised in pilot work to fit a subacute sample. It consisted of 4 weekly, 1-hour individual sessions, led by a master's-level clinician trained for the study in behavioral pain management and rehabilitation methods. Sessions followed a systematic protocol, which included instruction and demonstrations by the clinician, and take-home assignments and schedules (eg, exercise and activity). The overall course of treatment was based on (1) education about back function and pain, (2) systematic graduated increases in physical exercise to quota with feedback, (3) planning and contracting activities of daily living, (4) self-management and problem-solving training to cope with pain,

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