Individually Tailored Treatment Targeting Activity, Motor Behavior, and Cognition Reduces Pain-Related Disability: A Randomized Controlled Trial in Patients With Musculoskeletal Pain

Pernilla Åsenlöf,* Eva Denison,*,† and Per Lindberg*

Abstract: **This study compares the outcomes of an individually tailored behavioral medicine intervention (experimental) with physical exercise therapy (control). The experimental intervention was systematically individualized according to each participant's behavioral treatment goals and functional behavioral analyses. One hundred twenty-two patients seeking care at 3 primary health care clinics because of musculoskeletal pain were randomized. Ninety-seven completed the trial. Data were collected at baseline, immediately after treatment, and at a 3-month follow-up. Analyses of data from completers, as well as intention-to-treat analyses, showed that the experimental group experienced lower levels of disability ($P = .01$), lower maximum pain intensity ($P = .02$), higher levels of pain control ($P = .001$), and lower fear of movement ($P = .022$) as a result of treatment condition. Self-efficacy ($P = .0001$) and physical performance ($P = .0001$) increased over time for both groups. Participants in the experimental group generally reported more positive effects after treatment. Treatment fidelity was maintained during the course of the study. Activity can be resumed and pain might be managed by the patients themselves if treatment incorporates the biopsychosocial explanatory model of pain and strategies are tailored according to individual's priorities of everyday life activities and empirically derived determinants of pain-related disability.**

Perspective: ***This study shows that the biomedical and the psychosocial perspectives of the experiences and consequences of pain complement rather than contradict each other. Primary health care patients with persistent musculoskeletal pain benefit more from a systematic tailoring of treatments according to biopsychosocial factors than from a physically based exercise intervention.***

Key words: *Behavioral medicine, tailored treatment, persistent pain, behavioral goal assessment, functional analyses, primary health care.*

Individuals respond, adjust, and cope with pain in several different ways, which has increased the interest in designing interventions to match individual assets and needs. Tailoring of interventions to homogenous subgroups of patients sharing particular psychosocial needs has been suggested as an important new field for research in the area of pain management interventions,[36,43] and data provide initial support for tailored treatment protocols in temporomandibular disorders.[20,21,62] In a study by Evers et al[22] on patients with rheumatoid arthritis and a psychosocial risk profile, treatment was tailored according to patients' priorities and choices of standardized cognitive-behavioral treatment modules. This tailored approach resulted in significant short- and long-term benefits when compared with standard medical care. Interestingly, Broderick et al[12] found that individuals change their adaptational style toward pain over time. Adjustment to changing individual needs during the course of therapy would possibly render more effective interventions than treatment tailored to predefined subgroup characteristics. Furthermore, patients could benefit from tailoring of a broad range of factors relevant for adjustment and coping with pain.[36] Preferably, these are neither psychosocial nor entirely physical, but rather a combination of psychological, contextual, and physical factors identified to determine behaviors and everyday life activities in the particular individual.

There is a substantial body of knowledge supporting the benefits from interventions involving behavioral and

Received January 31, 2005; Revised March 21, 2005; Accepted March 24, 2005.

From the *Department of Public Health and Caring Sciences/Section of Caring Sciences, Uppsala University, Uppsala, and †Department of Caring and Public Health Sciences, Mälardalen University, Västerås, Sweden.

Supported by the Swedish Research Council and the Section for the Swedish Council on Technology Assessment in Health Care and Research, Uppsala County Council.

Address reprint requests to: Pernilla Åsenlöf, Department of Public Health and Caring Sciences/ Section of Caring Sciences, Uppsala University, Uppsala Science Park, S-751 83 Uppsala, Sweden. E-mail: pernilla.asenlof@pubcare.uu.se

1526-5900/$30.00

doi:10.1016/j.jpain.2005.03.008

cognitive-behavioral components for patients with persistent musculoskeletal pain (MSP).[16,51,66] Current evidence also points to the benefits of physical exercises and physical activity.[23,40,65] However, systematic reviews and meta-analyses showed that no single active treatment condition (eg, behavioral therapy, cognitive-behavioral therapy, physical exercises, or relaxation) is more effective than any other.[63,66] Multimodal treatment provided at multidisciplinary pain clinics is generally considered the most effective treatment available.[25,60] Inpatient programs are reported to be more effective than outpatient programs,[9,68] especially for those with a psychosocial risk profile and low physical performance.[29]

A substantial part of the pain intervention research is conducted at pain clinics including chronic and dysfunctional patients, whereas most persons with benign MSP are managed in primary health care (PHC).[61,70] Results derived from pain clinics hardly generalize to the PHC population because of the fact that patients managed in PHC are less dysfunctional.[17,61] Because psychological and psychosocial factors are involved both at the onset and in the development of persistent and disabling pain,[42,67] such factors are important to address throughout the course of pain and at different health care instances to enhance adaptive coping and self-management. However, treatments integrating physical activity and psychosocial factors are not routinely included in PHC management.[19,41]

Recently, we developed an individually tailored behavioral medicine intervention targeting physical, behavioral, and psychosocial factors of relevance for pain adjustment. Intervention strategies were organized in a cognitive-behavioral framework including 7 phases. Treatment strategies within each of the phases were then individually tailored according to each patient's behavioral goals (ie, frequent and important everyday life activities) and physical, psychological, and psychosocial determinants of disability. An initial series of experimental single subject studies showed positive effects in patients with persistent pain treated in a PHC setting (data in press).

The present study evaluated the experimental effects of the individually tailored behavioral medicine intervention in patients with MSP with a duration of 4 weeks or more. The intervention was compared with physical exercise therapy by using pain-related disability as the main outcome measure. It was hypothesized that both interventions would reduce disability, but the individually tailored behavioral medicine intervention was assumed to be more effective in comparison to physical exercises. Effects on pain, physical performance, self-efficacy, fear of movement/(re)injury, and participants' global ratings of improvements and treatment satisfaction were also studied.

Materials and Methods

Study Design

Data reported here originate from the experimental part of a clinical intervention study, designed to evaluate the effects of the new individually tailored behavioral medicine intervention. Focus was on patients with persistent MSP consulting physical therapists in PHC settings. A two-armed trial was designed, including 2 different active conditions. Participants were randomly allocated to the individually tailored behavioral medicine intervention (experimental group) or to physical exercise therapy (control group). The study involved 3 PHC clinics to increase external validity. Eight physical therapists were recruited to provide treatment in either of the 2 conditions. To control for the anticipated dose-response effects,[24] 8 to 10 supervised sessions were obliged for participants in both conditions.

A number of measures covering physical, cognitive, behavioral, and psychosocial dimensions but also participants' overall evaluation of treatment were included in the research protocol. For the present report of the experimental part of the trial, data collected at baseline (before randomization), immediately after treatment, and 3 months after treatment were included. Participants were not allowed to encounter any new or additional treatment for their pain condition during this period. A CONSORT diagram[50] in Fig 1 shows the participant flow through recruitment, baseline measurement, and the immediate post-treatment and 3-month follow-ups.

In addition, measurements of the independent variables, ie, strategies for enhancing treatment fidelity,[10] were conducted during the course of the intervention. The study was approved by the local ethics committee at the faculty of medicine, Uppsala University, Sweden.

Participants, Setting, and Procedures

Participants were recruited among persons seeking care at 3 physical therapy clinics in PHC from February 2003 to February 2004. A university town with 190,000 inhabitants and one urban community with 20,000 provided the setting for the study. To be eligible, participants had to be between 18 and 65 years of age, be literate in Swedish, and have experienced persistent musculoskeletal pain for more than 4 weeks. The wide duration criterion was based on recent data showing that pain duration does not account for any variances in the present main outcome measures in similar PHC samples.[18] Patients with recent traumas (eg, whip lash–associated disorders), rheumatic, neurologic, or malignant diseases were not considered. Patients who had attended physical therapy treatment during the past 6 months were not eligible. Patients were also excluded if they had ongoing medical or psychological treatment for depression. Demographic and background characteristics, including information about previous treatment, previous overall treatment effects, and the contribution of previous treatment attempts to enhance self-management of pain are reported in Table 1. There were no statistically significant differences between the 2 groups in demographics and background characteristics.

Participants were recruited by 3 administrative assistants at the physical therapy departments, who also gave oral information about the study according to a stan-