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Improving the Multidisciplinary Treatment of Chronic Pain by Stimulating Body Awareness

A Cluster-randomized Trial

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Background: Because of methodological flaws and a lack of theoretical foundation of body awareness (BA) in previous effect studies of interventions directed to stimulate BA, it is impossible to attribute treatment effects to this specific component of a multidisciplinary treatment. Therefore, this study evaluated short-term and long-term effects of a multidisciplinary pain rehabilitation program with and without psychomotor therapy (PMT), which focused on BA (measured by the scale of body connection) as a primary target of intervention.

Methods: Ninety-four patients clustered in 20 treatment groups were cluster randomized, using a biased-coin design, to multidisciplinary treatment as usual with or without PMT. Outcome variables were health-related quality of life, disability, and depression. BA, catastrophizing, and self-efficacy were measured as potential process variables. Assessments were performed at baseline, directly after treatment, and at 3, 6, and 12 month follow-ups. The data were analyzed by linear mixed-model analysis according to the intention-to-treat principle.

Results: Data of all 94 patients were used for analyses. After treatment, significant differences favoring PMT were found between conditions on depression (regression coefficient [RC] = −5.01; 95% confidence interval [CI], −8.81 to −1.21), BA (RC = 0.23; 95% CI, 0.04 to 0.42) and catastrophizing (RC = −4.76; 95% CI, −8.03 to −1.48). These differences were no longer significant for depression at the 3-month follow-up and for catastrophizing at the 6-month follow-up.

Conclusions: No clinical meaningful differences were found between treatment conditions in the primary outcome measures health-related quality of life and disability. However, this is the first long-term RCT that has shown that PMT improves BA in patients with

chronic pain and shows good effect size and a significant decrease for catastrophizing.

Key Words: health-related quality of life, body awareness, psychomotor therapy, chronic pain, rehabilitation

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Patients with chronic pain report that pain has a serious impact on their daily activities, social and working lives, affecting their emotional status and ability to maintain independent living.^{1,2} The biopsychosocial model of pain is a widely accepted perspective of the understanding and treatment of chronic pain. As a result, a proliferation of multidisciplinary pain management programmes has occurred. The main goal of these programmes, consisting of a combination of physical and psychological treatment such as exercise, relaxation, occupational therapy, and cognitive-behavior therapy, is to decrease disability due to pain, to decrease depression, and improve health-related quality of life (HRQOL). Although these multidisciplinary programmes appear to have positive outcomes on HRQOL, disability, and depressive symptoms in the short term, the effects do not always last.³ Moreover, it is not clear which components or combination of components are most beneficial, which might make these programmes inefficient.⁴ One component that is incorporated more and more in these multidisciplinary programmes is aimed at improving body awareness (BA). Studies have shown that treatments aimed at developing BA or treatments incorporating a component aimed at developing BA in patients with chronic pain might enhance treatment effects.^{1,5–10}

BA has been defined in various ways in the literature.¹¹ This study defines BA as a multidimensional construct involving sensitivity and attentiveness to internal body signals (eg, muscle tension, heartbeat, and fluttering in the stomach), overall body states (eg, strained, relaxed), and of the body response to changes in the environment or emotions (eg, acceleration of breath when you get scared or tightening of muscles when someone gets too close to you).^{12,13}

By improving BA, patients learn to recognize and use body signals other than pain and to determine their physical and mental states.¹⁴ Being aware of the relation between physical and mental states in different contexts may lead to a better understanding of this bodily information, thereby increasing confidence in one's body and oneself.^{15,16} Learning to interpret body signals without negative thoughts and concomitant feelings were found to decrease catastrophizing.¹⁷ Furthermore, acting according

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to this information from the body was suggested to increase self-efficacy.⁸ Both catastrophizing and self-efficacy have been shown to be important prognostic and/or mediating factors in treatment outcome on HRQOL, disability, and depression.^{18,19} In this study we hypothesized that BA, catastrophizing, and self-efficacy are potential process variables affecting the main outcome variables HRQOL, disability, and depression.

However, many studies on the effects of BA interventions were preliminary studies and therefore suffered from methodological flaws, such as lack of randomization^{6,7,9} or control groups.⁸ Moreover, a theoretical foundation for BA or the BA intervention was often lacking. Furthermore, whether the intervention actually changed BA was often not measured, or the contribution of the BA component was not separately analyzed. These different issues make it impossible to attribute effects to this specific component of treatment.

Therefore, a cluster-randomized trial was conducted to evaluate short-term and long-term effects on HRQOL, disability, and depression of a multidisciplinary pain rehabilitation program with and without specific treatment to enhance BA (eg psychomotor therapy [PMT]). PMT is an experiential treatment focuses on BA as a primary target of the intervention.

METHODS

Participants

Patients with chronic musculoskeletal pain, such as nonspecific low back pain, postwhiplash syndrome, and fibromyalgia, who were referred for pain rehabilitation treatment to an outpatient center for pain rehabilitation in Amsterdam, The Netherlands, were screened for eligibility. First the rehabilitation physician and psychologist screened

patients whether or not they were eligible for the routine pain rehabilitation treatment. To be eligible for treatment within this center, the patient (1) had to experience limitations in several life areas (eg, social, cognitive, mobility, household, work, etc.); (2) had to be motivated to participate in treatment to learn to cope with pain (instead of pain reduction); (3) had no psychiatric diagnosis which could interfere with the treatment; and (4) did not insist on further somatic diagnostic procedures.

Procedures

All consecutive patients eligible for regular pain rehabilitation treatment in the period from November 2007 through March 2010 were invited to participate in the study by letter in combination with a telephone call. Patients who were willing to participate signed an informed consent. Cluster randomization was used to assign treatment groups of 4 to 6 patients to one of 2 multidisciplinary treatment interventions, either treatment as usual (TAU) for the rehabilitation center or the same care to which PMT was added. A staff member not involved in the treatment performed randomization according to a “biased-coin” design²⁰ for 20 groups, 10 groups for each treatment condition. The results of the biased-coin procedure were put in 20 sequentially numbered sealed envelopes. The logistic planner of the treatment opened a sealed envelope to know if the group would or would not receive PMT. Approval for this research was obtained from the Medical Ethical Committee of the VU University Medical Center in Amsterdam.

Assessments were accomplished at baseline, directly after the 12-week group treatment program (or during the last week of treatment), and at 3, 6, and 12-month follow-up (Fig. 1). At each assessment time, the patient received a set of questionnaires to fill out at home. The patients and therapists were aware of the treatment group assignment.

FIGURE 1. Flowchart of patients. PMT indicates psychomotor therapy.

Interventions

TAU consisted of a multicomponent group treatment package and included the following elements: relaxation²¹ (6 × 1.5 h), graded activity based on the program of Fordyce et al²² on 1 aerobic fitness device (33 × 1 h), rational-emotive therapy²³ (9 × 1 h, 6 × 1.5 h), occupational therapy (6 × 1.5 h), chronic pain education (3 × 1.5 h), sports (in the swimming pool [5 × 1 h] and in the sports hall [5 × 1 h]), partner education (3 × 1.5 h), and coaching (4 × 1 h), a total of 94 hours. The different components of treatment were spread across 3 d/wk during 12 weeks. Two follow-up group sessions of 1.5 hours were offered after 3 and 6 months to evaluate the patients' goals, which they had set at the end of the 12-week group program. Each patient was given the opportunity to share his or her experiences of the last 3 months in relation to their goals. Reasons for not achieving goals and solutions were explored. In the first follow-up session new goals were set when necessary. These follow-up sessions were led by a psychologist and a physical therapists or occupational therapist and were in the same group as during treatment. The group size was between 4 and 6 patients. The aim of the treatment was to improve HRQOL and decrease disability and depression.²⁴

Patients in the TAU + group PMT received 10 sessions of 1.5 hours in addition to TAU. PMT is an experiential-based therapy in which behaviors, feelings, and thoughts are explored using movement and body-oriented techniques and verbal reflection on self-experiences.²⁵ In this specific PMT group program the focus was on 2 main topics: body experience, and interaction and communication. The main focus is that the patient first learns to be aware of different physical sensations (increasing BA), for example, in exercises in which patients make contact with different materials and other people, or when patients are feeling and expressing emotions. Secondly, the patient learns to interpret these signals without negative thoughts and concomitant feelings (decreasing catastrophizing), for example, by focusing only on the internal body sensations and describing them in a more distant and objective manner and/or normalizing the feelings the patient has in the specific context. Thirdly, the patient learns to use this information from the body to act accordingly (thereby increasing self-efficacy), for example, communicating about what you feel, your boundaries, and asking for help in miscellaneous exercises.²⁶

PMT was explicitly directed to the 3 factors: BA, catastrophizing, and self-efficacy. However, TAU also contains elements more or less directed to these factors. For example, within the relaxation module there was some attention to BA, in the sports module and in occupational therapy patients were asked to act according to their body signals (increasing self-efficacy), and in the rational-emotive therapy catastrophizing thoughts were discussed.

Measures

Pain intensity was measured for baseline characteristic purposes on an 11-point numerical rating scale. Patients were asked for the usual and least pain felt in the last week. The arithmetic mean of usual and least pain was suggested to be the most valid measure for average pain intensity²⁷ and was therefore used in this study. Higher scores reflect more intense pain.

Outcome variables were HRQOL, disability, and depression. HRQOL was measured by the *RAND-36*²⁸ (Dutch version²⁹), which is considered to be the same as

SF-36.³⁰ This is a self-report measure of general health and quality of life, comprising 36 items sorted in 8 categories of health, which can be represented by 2 summary component scores. The physical component consists of physical functioning (10 items), role limitations physical (4 items), bodily pain (2 items), and general health perception (5 items). The mental component consists of social functioning (2 items), role limitations emotional (3 items), mental health (5 items), and vitality (4 items). One item measures the perceived health change over the last year. All raw scale scores were summarized and linearly converted to a scale ranging from 0 (poor health) to 100 (excellent health), with higher scores indicating higher levels of functioning or well-being. The calculation of the summary component scores is based on weights of the general US population, because no Dutch values were available. A score < 50 means that the patient scores below the reference group. Only the 2 summary component scores were used in this study. A 3- to 5-point change was considered to be a minimal clinical important difference.³¹

Disability was measured by the *Pain Disability Index*³² (Dutch version by Pain Management and Research Centre, University Hospital Maastricht, 1999), a 7-item self-report measure of pain-related disability. Ratings are made on an 11-point scale, with higher scores indicating more pain-related disability. An 8.5-point change was considered clinically important.³³

Depression was measured with the *Beck Depression Inventory*³⁴ (Dutch version³⁵), consisting of 21 four-statement items. Each item is scored on a 0 to 3 scale with 0 indicating absence of the symptom and 3 the most intense statement. Higher scores reflect higher levels of depression. A cut-off score of 21 was used.³⁶

Potential process variables were BA, pain self-efficacy, and catastrophic thinking. BA was measured by the *Scale of Body Connection*,¹³ a self-report measurement containing 2 subscales, body awareness (BA) (12 items) and body dissociation (BD) (8 items). The original version showed good reliability and validity.¹³ For the purpose of this study this questionnaire was translated into Dutch and only the subscale BA was used for analysis. BA is a multifaceted concept, not only involving the ability to identify and experience inner sensations of the body (eg, a tight muscle) and the overall emotional/physiological state of the body (eg, relaxed and tense), but also attending to bodily information in daily life, and noticing bodily changes/responses to emotion and/or environment. Ratings are made on a 5-point scale, with higher scores reflecting higher BA. Cronbach α for the total sample at baseline in the present study was acceptable ($\alpha = 0.80$).

The *Pain Self-Efficacy Questionnaire*³⁷ (Dutch version³⁸) is a 10-item self-report measure of pain self-efficacy beliefs. Ratings are made on a 7-point scale, with higher scores reflecting stronger self-efficacy beliefs.

The *Pain Catastrophizing Scale*³⁹ (Dutch version⁴⁰) is a 13-item self-report measure of the tendency of the patient to engage in catastrophic thinking. Ratings are made on a 5-point scale, with higher scores reflecting more catastrophic thoughts.

Statistical Analyses

The primary analysis was an intention-to-treat analysis to evaluate the effect of additional PMT. Data analyses were performed by linear mixed-model analysis in MLwiN 2.26 (Centre for multilevel modeling, University of Bristol,

2012). Three levels were defined, time of measurement (ie, posttreatment, 3, 6, and 12-mo follow-up) was clustered within patients and patients were clustered within therapy groups (cluster randomization). The following analyses were performed: (1) for both groups separately the linear development over time from baseline to 12-month follow-up; (2) the overall intervention effect over time; and (3) the intervention effect at the different time points. The effect of the intervention was adjusted for the baseline value of the outcome or process variable of interest, and besides crude analyses (only adjusted for baseline) also adjusted analyses (adjusted for patient characteristics which were significantly different between conditions $P < 0.20$) were performed. Besides the significant differences between the conditions, Hedges g^{41} was also calculated.

RESULTS

Participants

A total of 114 chronic pain patients, who were all consecutively found eligible for group treatment, were asked to participate and 94 gave their informed consent. After cluster randomization, 45 patients received TAU and 49 patients PMT. Figure 1 shows a flowchart of the study. Compliance with treatment was high, with only 3 patients discontinuing treatment. A remarkable difference is seen in drop-out for posttreatment measurement between TAU ($n = 12$) and PMT ($n = 4$). However, the opposite is observed for the 3-month follow-up measurement, where 14 patients within PMT and 4 patients within TAU dropped out. Reasons for lost to follow-up (TAU $n = 17$; PMT $n = 25$) were not known in 57% (TAU: 53%; PMT: 60%) of the cases. Missing value analysis indicated that patients who did not fill out follow-up questionnaires had higher pain intensity at baseline and turned out to be more frequently non-Dutch. Recruitment ended because of changes in clinical treatment procedures.

Baseline patient characteristics of the 2 groups are shown in Table 1. Most patients had a medium to high level of education, and a small percentage (TAU: 13.3%; PMT: 16.3%) had paid work. A total of 78.7% (TAU: 81.8%; PMT: 76%) of the patients used some kind of pain medication and 44.7% (TAU: 43.2%; PMT: 46%) used medication for other indications than pain. During treatment no changes were made in medication prescription. Main diagnoses were neck pain (38.8% and 17.8% for PMT and TAU, respectively), back pain (22.4% and 24.4% for PMT and TAU, respectively) and generalized pain (16.3% and 24.5% for PMT and TAU, respectively). Group composition was not dictated by pain diagnoses and no adjustments were made in treatment for different pain diagnoses. For the purpose of analysis, pain diagnoses were summarized in 3 categories (ie, neck pain, generalized pain, and localized pain other than neck). The PMT group had more patients with neck pain and TAU patients more frequently reported localized and generalized pain ($P = 0.08$). The TAU group was significantly older (mean = 45.5 y vs. mean = 38.6 y; $P = 0.004$), consisted of significantly more men (28.9% men vs. 8.2%; $P = 0.009$) and had more patients with pain duration > 5 years, whereas the PMT group had more patients with a pain duration of 1 to 2 years ($P = 0.042$). These patient characteristics, pain diagnosis, age, sex, and pain duration were included in the multilevel analyses as covariates.

TABLE 1. Baseline Characteristics of the Patients, Cluster Randomized to Treatment as Usual (TAU) and Treatment as Usual With Psychomotor Therapy (PMT)

	TAU (n = 45)	PMT (n = 49)	P
Women (%)	71.1	91.8	0.009
Age (mean [SD])	45.4 (11.1)	38.6 (11.1)	0.004
Marital status (%)			0.362
Married/living together	44.5	49.0	
Single	28.9	38.8	
Divorced	13.3	4.1	
Other	13.3	8.1	
Education level* (%)			0.770
Low	17.8	20.4	
Middle	42.2	30.6	
High	37.7	49.0	
Unknown	2.2	0	
Paid work (yes %)	13.3	16.3	0.717
Pain diagnoses (%)			0.077
Generalized pain†	24.5	16.3	
Localized pain	57.7	44.9	
Neck pain‡	17.8	38.8	
Pain duration (%)			0.042
3 to 12 mo	4.4	4.1	
1 to 2 y	8.9	32.7	
2 to 5 y	31.1	28.6	
> 5 y	55.6	34.7	
Pain intensity (NRS 0-10) (mean [SD])	5.78 (1.73)	5.51 (1.76)	0.459
Depression (mean [SD])	18.68 (9.00)	20.23 (7.85)	0.390
HRQOL physical component (mean [SD])	31.51 (7.17)	32.42 (6.72)	0.526
HRQOL mental component (mean [SD])	39.59 (12.29)	39.89 (10.45)	0.899
Disability (mean [SD])	40.34 (10.34)	40.00 (9.00)	0.869
Pain catastrophizing (mean [SD])	24.10 (11.53)	20.10 (10.21)	0.089
Pain self-efficacy (mean [SD])	30.70 (10.72)	32.77 (10.25)	0.351

*Educational level is based on the Dutch school system, where low education is primary school and lower vocational education, middle is mediocre vocational education and higher secondary education, and high is higher vocational education and university.

†Including fibromyalgia.

‡Including postwhiplash syndrome.

HRQOL indicates health-related quality of life; NRS, Numeric Rating Scale; PMT, psychomotor therapy; TAU, treatment as usual.

P-values are given for the differences between the 2 groups.

Effect of Interventions

No significant differences between the treatment groups on the outcome or process variables were found at baseline. Figure 2 displays the change over time in the outcome measures and the process variables for both treatment groups. Figure 2 shows marked differences in the changes for most variables between PMT and TAU between baseline and posttreatment, whereas treatment groups converge during follow-up.

Table 2 shows the results in terms of linear development over time for both groups separately as well as the results in terms of the overall intervention effect. Both groups show significant changes over time on all variables except for the physical component of HRQOL in the TAU group. The change in the physical component was < 3 points, that is, the minimum change score to indicate clinical relevance, at any point in time for the TAU group. The

FIGURE 2. Graphic representation of means and SDs of outcome measures and process factors over time for treatment as usual (TAU) and treatment as usual with psychomotor therapy (PMT).

TAU group changed > 5 points in the mental component between baseline and the 6-month follow-up. The PMT group reached the minimum of 3 points on both physical and mental components at several follow-up moments. Almost all patients scored < 50 on both component summary scores of the RAND-36 at baseline and also during follow-up.

Across all time points the groups differed significantly on depression, BA, and catastrophizing. However, after correction for differences in patient characteristics at baseline, the difference between the groups on depression was not significant. Baseline depression scores were just below the cut-off score for depression in chronic pain patients: about 50% of all patients scored 21 or higher on the Beck Depression Inventory, at the 12-month follow-up this was around 17%. No significant interaction between group and time were found, indicating that treatment effects were not significantly different over time.

Table 3 shows the results of the analyses in terms of the intervention effect at the different time points. Depression, BA, and catastrophizing showed significantly greater changes in the PMT condition than TAU directly after treatment. As regards BA, this significant difference increased even further at the 12-month follow-up (Fig. 2 and Table 3). Differences in depression and catastrophizing between treatment groups were no longer significant at the 3- and 12-month follow-up, respectively. The difference in catastrophizing between conditions was not significant in the corrected model although a significant difference was found in the uncorrected model at the 6-month follow-up.

Differences between both treatments in HRQOL, disability, and self-efficacy were not significant at post-treatment or during any of the follow-up moments in the corrected model. However, a significant difference was demonstrated in the uncorrected model for the physical component of HRQOL and self-efficacy between the

TABLE 2. Overall Time and Condition Effects

	Overall Time Effect TAU RC (95% CI)	TAU Pre-Post Hedges <i>g</i> (95% CI)	Overall Time Effect PMT RC (95% CI)	PMT Pre-Post Hedges <i>g</i> (95% CI)	Overall Condition Effect RC (95% CI)	
					Uncorrected	Corrected*
PDI	-1.58 (-2.43 to -0.73)	-0.33 (-0.82 to 0.16)	-1.83 (-2.64 to -1.01)	-0.73 (-1.17 to -0.28)	-1.57 (-5.20 to 2.06)	0.04 (-3.93 to 4.02)
RAND-36, PCS	0.25 (-0.27 to 0.77)	0.14 (-0.31 to 0.59)	0.96 (0.37 to 1.55)	0.32 (-0.09 to 0.73)	2.05 (-0.52 to 4.63)	1.11 (-1.69 to 3.91)
RAND-36, MCS	1.49 (0.57 to 2.41)	0.02 (-0.43 to 0.47)	1.04 (0.45 to 1.95)	0.32 (-0.08 to 0.73)	0.16 (-3.39 to 3.72)	-1.10 (-4.95 to 2.74)
BDI	-1.04 (-1.62 to -0.45)	-0.30 (-0.80 to 0.21)	-1.54 (-2.12 to -0.96)	-0.92 (-1.35 to -0.48)	-2.98 (-5.50 to -0.46)	-2.37 (-5.10 to 0.35)
SBCBA	0.04 (0.00 to 0.08)	0.42 (-0.10 to 0.94)	0.11 (0.07 to 0.15)	0.79 (0.33 to 1.26)	0.23 (0.08 to 0.38)	0.24 (0.09 to 0.40)
PSEQ	1.20 (0.43 to 1.97)	0.28 (-0.18 to 0.74)	1.27 (0.516 to 2.03)	0.78 (0.36 to 1.20)	3.13 (-0.29 to 6.54)	1.85 (-1.94 to 5.64)
PCS	-1.52 (-2.17 to -0.86)	-0.32 (-0.80 to 0.17)	-1.70 (-2.34 to -1.06)	-0.73 (-1.15 to -0.31)	-4.11 (-6.87 to -1.33)	-3.61 (-6.53 to -0.68)

*Model corrected for age, sex, pain duration, and pain diagnosis.

BDI indicates Beck Depression Inventory; CI, confidence interval; PCS, Pain Catastrophizing Scale; PDI, Pain Disability Index; PMT, Psychomotor Therapy; PSEQ, Pain Self-Efficacy Questionnaire; RAND-36, MCS, Mental Component Summary of RAND-36; PCS, Physical Component Summary of RAND-36; RC, regression coefficient; SBCBA, Scale of Body Connection subscale Body Awareness; TAU, treatment as usual.

treatment groups at the 12-month follow-up and directly after treatment, respectively. A clinically important change (8.5 points) for disability was seen only at the 3-month follow-up for the PMT condition.

DISCUSSION

The primary aim of this randomized controlled study was to show short-term and long-term effects of a multidisciplinary rehabilitation program that included PMT as compared with the same program without PMT (TAU). Both treatment conditions (TAU and TAU + PMT) were effective on outcome and process variables, except for TAU on the physical component of HRQOL. The effects directly after treatment within the treatment conditions were roughly maintained at the 12-month follow-up, some increased even further and some deteriorated a little at some point in follow-up; however, none deteriorated to baseline values. Multilevel analyses showed significant differences between the 2 active treatments on the outcome variable depression and on all process variables directly after treatment.

In general, the effect sizes for the several measures that we found for TAU at posttreatment were small to moderate and compatible to the effect sizes presented in reviews and meta-analyses for multicomponent treatments.^{3,4,42} The effect sizes for PMT at posttreatment were moderate to large, especially for depression (effect size = -0.92), which was considerably larger than many other studies reported (cf.^{4,42}). In a meta-analytic study, Carnes et al⁴ reported that only the psychological component of multicomponent group treatment programmes had a minor effect on depression. The present study, adding PMT to TAU, which already included a psychological component, led to a further decrease in depression. Turk⁴³ has argued that depression in chronic pain patients could be one of the factors in need of tailored treatment. Reviews have suggested that mind-body therapies can be effective in the treatment of depression^{44,45} and together with the present results we suggest that PMT might offer such tailored treatment of depression in chronic pain patients.

The main treatment focus of PMT is BA; however, BA is traditionally viewed as an exaggerated focus on physical symptoms strongly related to an unfavorable clinical outcome.⁴⁶ Also, in chronic pain this exaggerated focus on pain, hypervigilance to pain, is confirmed in several studies.⁴⁷⁻⁵⁰ A person who is hypervigilant to pain will constantly scan his or her body for threatening pain-related sensations, which has a negative impact on pain perception and cognitive functioning.⁴⁸ This heightened but selective attentional focus on pain prevents an attentional shift to a "normal" internal signal.⁵¹ By increasing the perception of normal body sensations, subjective emotion-based hypervigilance might be suppressed and perception of the sensory input might become more distant and nonjudgmental. Unfortunately, we did not measure hypervigilance in this study. This change in perception may help patients experiencing chronic pain to discriminate between different physical and mental states and to cope with and adapt to different situations more adequately, making this broader type of BA adaptive and an important focus of treatment.

Potential process factors by which PMT might affect outcome are a decrease in pain catastrophizing and an increase in self-efficacy due to increased awareness of and confidence in one's body. Indeed, as expected we found that

TABLE 3. Results of the Multilevel Analyses for the Effect of Additional Psychomotor Therapy (PMT) at Posttreatment, 3, 6, and 12-Month Follow-up

	RC Uncorrected (95% CI)	RC Corrected* (95% CI)	Hedges g† (95% CI)
PDI (0-70)			
Posttreatment	−2.09 (−6.55 to 2.37)	−0.82 (−5.55 to 3.92)	−0.28 (−0.77 to 0.21)
3-mo FU	−2.38 (−7.21 to 2.46)	−1.09 (−6.17 to 4.00)	−0.30 (−0.86 to 0.25)
6-mo FU	−0.36 (−5.23 to 4.52)	1.01 (−4.17 to 6.18)	−0.12 (−0.66 to 0.43)
12-mo FU	−1.82 (−6.88 to 3.25)	−0.48 (−5.80 to 4.84)	0.003 (−0.58 to 0.58)
RAND-36, PCS (0-100)			
Posttreatment	1.49 (−1.53 to 4.50)	0.55 (−2.63 to 3.74)	0.16 (−0.29 to 0.61)
3-mo FU	1.89 (−1.36 to 5.14)	0.95 (−2.45 to 4.36)	0.19 (−0.32 to 0.70)
6-mo FU	2.50 (−0.81 to 5.81)	1.59 (−1.91 to 5.08)	0.32 (−0.21 to 0.84)
12-mo FU	3.48 (0.03 to 6.93)	2.55 (−1.08 to 6.17)	0.28 (−0.29 to 0.82)
RAND-36, MCS (0-100)			
Posttreatment	2.13 (−2.36 to 6.63)	1.17 (−3.51 to 5.86)	0.26 (−0.19 to 0.72)
3-mo FU	−0.14 (−5.09 to 4.82)	−1.12 (−6.23 to 3.99)	0.18 (−0.32 to 0.69)
6-mo FU	−0.97 (−6.02 to 4.09)	−2.17 (−7.43 to 3.09)	0.02 (−0.50 to 0.54)
12-mo FU	−1.12 (−6.44 to 4.20)	−2.19 (−7.69 to 3.32)	−0.10 (−0.65 to 0.46)
BDI (0-63)			
Posttreatment	−5.04 (−8.65 to −1.43)	−5.01 (−8.81 to −1.21)	−0.54 (−1.05 to −0.03)
3-mo FU	−3.26 (−6.98 to 0.45)	−3.22 (−7.13 to 0.69)	−0.50 (−1.05 to 0.05)
6-mo FU	−1.59 (−5.32 to 2.13)	−1.55 (−5.47 to 2.38)	−0.25 (−0.79 to 0.29)
12-mo FU	−3.14 (−6.90 to 0.62)	−2.98 (−6.99 to 1.04)	−0.21 (−0.78 to 0.37)
SBCBA (1-5)			
Posttreatment	0.24 (0.06 to 0.42)	0.23 (0.04 to 0.42)	0.44 (−0.06 to 0.94)
3-mo FU	0.20 (0.01 to 0.39)	0.20 (−0.002 to 0.40)	0.39 (−0.17 to 0.96)
6-mo FU	0.20 (0.01 to 0.40)	0.20 (−0.008 to 0.40)	0.45 (−0.12 to 1.03)
12-mo FU	0.34 (0.13 to 0.54)	0.33 (0.12 to 0.55)	0.73 (0.12 to 1.34)
PSEQ (0-60)			
Posttreatment	4.98 (1.11 to 8.86)	3.83 (−0.32 to 7.98)	0.50 (0.04 to 0.96)
3-mo FU	2.45 (−1.70 to 6.61)	1.30 (−3.10 to 5.70)	0.21 (−0.30 to 0.72)
6-mo FU	1.24 (−2.96 to 5.44)	−0.02 (−4.49 to 4.45)	0.09 (−0.43 to 0.61)
12-mo FU	2.35 (−2.01 to 6.71)	1.07 (−3.56 to 5.69)	0.03 (−0.52 to 0.59)
PCS (0-52)			
Posttreatment	−5.50 (−8.68 to −2.31)	−4.76 (−8.03 to −1.48)	−0.42 (−0.90 to 0.06)
3-mo FU	−4.23 (−7.60 to −0.85)	−3.66 (−7.10 to −0.21)	−0.11 (−0.63 to 0.41)
6-mo FU	−3.90 (−7.33 to −0.46)	−3.17 (−6.70 to 0.36)	−0.06 (−0.59 to 0.47)
12-mo FU	−2.39 (−5.99 to 1.22)	−1.86 (−5.55 to 1.83)	0.00 (−0.58 to 0.58)

*Model corrected for age, sex, pain duration, and pain diagnosis.

†Baseline scores are taken into account.

BDI indicates Beck Depression Inventory; CI, confidence interval; PCS, Pain Catastrophizing Scale; PDI, Pain Disability Index; PSEQ, Pain Self-Efficacy Questionnaire; RAND-36 MCS, Mental Component Summary of the RAND-36; RAND-36, PCS, Physical Component Summary of the RAND-36; RC, regression coefficient; SBCBA, Scale of Body Connection subscale Body Awareness.

BA increased more after PMT than after TAU immediately after treatment, which was maintained at the 12-month follow-up. In addition, pain catastrophizing was reduced significantly more in the PMT group than the TAU group directly after treatment and at the 3-month follow-up. Smeets et al¹⁸ have shown that a decrease in pain catastrophizing is an important mediator of treatment. They suggested that catastrophizing may be reduced as a result of changes in motor functioning and increased possibilities to perform activities due to physical training. In the present study both treatments had the same duration and intensity of physical training, but the decrease in catastrophizing was significantly greater after PMT. PMT aims at active verbal reflection on physical sensations, enabling patients to learn to interpret their body signals without negative thoughts and concomitant feelings in different contexts, adjusting primary appraisal.¹⁷ This might result in better understanding and a more objective view of the body, increasing body confidence even more. Theoretically, this would suggest that especially the elements of magnification and rumination would decrease. In this study there was an overall condition effect on all 3 elements of catastrophizing

(magnification, rumination, and helplessness) in favor of PMT, suggesting that secondary appraisals are also changed more after PMT than after TAU.

Our results also suggest that PMT might be more effective in increasing the other process variable, pain self-efficacy. Although statistical significance was not obtained for the difference between treatments in pain self-efficacy in the corrected model, the effect size was 0.50 directly after treatment in favor of PMT, and the uncorrected regression model showed a significant difference.

We expected that if BA was significantly different between treatment conditions, this would affect the outcome variables HRQOL, disability, and depression. Emotional states like depression are largely associated with body signals like heart rate, muscle tension, breathing, and sweating.⁵² Being aware of these body signals is considered to be a key element for emotion regulation and for the sense of self.⁴⁶ A better understanding of body signals would increase the confidence in one's body and oneself, improving self-efficacy. A stronger self-efficacy is related to better physical functioning.¹⁹ Also, a decrease in catastrophizing is related to a decrease in disability.¹⁷ Although

we found the expected differential effects of the 2 treatments on BA (all assessment points), pain catastrophizing (immediately after treatment until the 3-mo follow-up) and to a lesser extent on pain self-efficacy, these differences did not result in a superior treatment effect of PMT on HRQOL or disability, neither in the short nor in the long term. This suggests that other factors may lead to improvements in HRQOL and disability as well, besides the process variables studied in the present research.

Apart from the results relating to the main aim of the study, the added value of PMT, the effects of the multi-component treatment in itself may be noted. TAU in this study consisted of an intensive multicomponent program that had not previously been studied for its effects. The present study demonstrated that this treatment program has significant positive effects on depression, disability, and the mental component of HRQOL, both directly after treatment as well as in the long term (up to the 12-mo follow-up). With these good results of TAU in mind, it is difficult to make the treatment even more effective with a relatively small addition. Moreover, TAU also had an effect—albeit to a lesser extent—on the proposed process variables. Several of the components of the multi-component treatment were in fact targeting these same processes to at least some degree. Nonetheless, the treatment effects were obtained earlier in time in PMT than in TAU. Integration of thoughts, feelings (emotions and physical sensations), and behavior in movement-oriented and body-oriented activities is an important general aim of PMT^{53,54} and may act as a catalyst of TAU effects. Considering this, it would be worthwhile to investigate a less-intensive multidisciplinary treatment in combination with PMT.

Limitations

There was some discrepancy between the results of the corrected and uncorrected model. Most studies have not found age, sex, pain duration, or pain diagnosis to affect treatment response.^{55,56} However, the difference between the corrected and uncorrected model in the present study suggests that a priori differences in these variables can partly explain differences between treatment on the process variables pain self-efficacy (posttreatment) and catastrophizing (the 6-mo follow-up), and on the outcome variable depression (overall condition effect). The available literature generally supports a relation between sex and pain experience and pain behavior. Explanations for these differences have included differences between emotional and coping responses of male of female subjects. Women engage in catastrophic thinking more,⁵⁷ report lower self-efficacy beliefs,⁵⁸ report greater emotional distress, and may use more emotion-focused problem solving than men.⁵⁹ In men there seems to be a direct relationship between pain and disability, whereas in women this relationship was mediated by negative mood.⁶⁰ Especially for depression the relationship between disability and depression seems to be stronger in female than in male subjects.⁶¹ However, sex differences in the relationship between depression and pain appear to depend on the pain measures taken.⁶² It has been suggested that treatment-outcome studies should examine sex-specific effects, rather than just controlling for them. Unfortunately, no sex-specific effects could be examined in this study because there were so few male subjects involved.

Pain duration is often mentioned as a predictor of treatment outcome.^{55,56,63} Unfortunately no theoretical

explanations are given. It could be hypothesized that longer pain duration is related to more complex problems in biopsychosocial factors. For example, Quartana et al¹⁷ mentioned that longer pain duration appears to exaggerate the relationship between catastrophizing and a punishing response from the spouse/significant other. Furthermore, patients with longer pain duration probably had several treatments already, without sufficient or sustaining results. Therefore, correction has been made for these variables in this study.

Another limitation was that there was no compensation in the TAU group for the 10 times 90 minutes extra attention the PMT group received in the additional PMT sessions. This extra attention could account for the differences in effect between TAU and PMT and for effects being obtained earlier in time in the PMT group. However, clinical reality dictated that it was not possible to design and apply a suitable control treatment.

No systematic registration was kept of compliance of the different components. It is therefore not clear if there was a difference between attendance of sessions in TAU and PMT and how this influenced the results. In the TAU condition the most patients dropped out of research at posttreatment, for the PMT condition this was at the 3-month follow-up, it is not clear what caused this.

There was a significant difference in baseline pain intensity between patients who did and did not complete the follow-up measurements, which suggests selective drop-out. However, longitudinal mixed-model analysis, the method used in this study, uses all information of every person in the analysis to estimate the effects. So also persons with only 1 follow-up measurement are included. It has been proven that this method is even better than multiple imputation techniques.⁶⁴ Therefore, we expect that the chance of bias caused by selective drop-out was minimized.

Recommendations

It is necessary to investigate how the treatment exerts its effect, not only to improve the effectiveness of treatments, but also to answer the question “what works for whom?” The sample of patients in this study was heterogeneous in different variables but also in chronic pain diagnoses. Patients with different pain diagnoses were treated in the same group, which is the clinical reality in this treatment center, but is not seen very often in chronic pain treatment or research. Moreover, it was demonstrated in this study that pain diagnosis was one of the variables that might explain some of the treatment effects. To the authors’ knowledge this was the first randomized controlled study to examine the contribution of PMT as an additional component in the treatment of chronic pain, and despite some limitations, the results suggest that PMT might have beneficial effects and that this might operate through increasing BA.

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