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A Randomized Clinical Trial of the Treatment Effects of Massage Compared to Relaxation Tape Recordings on Diffuse Long-Term Pain

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Key Words
Chronic pain · Massage · Mental relaxation · Post-treatment effects

Abstract
Background: Long-term musculoskeletal pain is a common problem in primary health care settings that is difficult to treat. Two common treatments are mental relaxation and massage. Scientific studies show contradictory results. Furthermore, many studies lack long-term follow-up even though it is a chronic disorder. The purpose of this randomized clinical trial was to assess possible effects of massage as compared to listening to relaxation tapes in conditions of 'diffuse' and long-term musculoskeletal pain. ***Methods:*** 129 patients from primary health care suffering from long-term musculoskeletal pain were randomized to either a massage or mental relaxation group, and assessed before, during and after treatment. ***Results:*** During treatment there was a significant improvement in the three main outcome measures: self-rated health, mental energy, and muscle pain only in the massage group as compared to the relaxation group. However, at the 3-month post-treatment follow-up, there was a significant worsening in the outcome measures (time × group effect $p < 0.05$) back to initial rating levels in the massage group as compared to no changes in the relaxation group. ***Conclusion:*** Massage, but not mental relaxation, is beneficial in attenuating diffuse musculoskeletal symptoms. Beneficial effects were registered only during treatment. This lack of long-term benefits could be due to the short treatment period or treatments such as these do not address the underlying causes of pain. Future studies of long-term pain should include longer treatment periods and post-treatment follow-up. It might also be worthwhile assessing the long-term benefits from booster treatment after the initial intense treatment period.

Introduction

Long-term pain is defined by the International Association for the Study of Pain as 'pain which has persisted beyond normal tissue healing time', taken, in the absence of other criteria, to be 3 months [1]. Long-term pain and other musculoskeletal syndromes constitute an ever-increasing challenge to health care in general and especially to primary health care. In addition to human suffer-

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ing, long-term pain also constitutes an economic burden to society. These patients consume a disproportionate amount of health care resources and have high sickness absenteeism [2, 3]. It has been estimated that 10–15% of the population suffer from long-term pain for which they seek health care services. More women than men are affected, and prevalence increases with age [3, 4].

Due to the difficulties of finding effective treatments, patients and health care professionals commonly use an array of possible treatment regimens. Two common methods used are mental relaxation and massage. Scientific studies addressing the efficacy of such treatment methods have reported contradicting results. Some prospectively controlled studies have reported statistically significant positive effects on long-term pain from either massage or mental relaxation [5–14]. However, others, using similar designs, have failed to find any beneficial results [15, 16]. In most of these prospectively controlled studies complimentary methods, e.g. massage and mental relaxation, have been compared to other forms of complimentary methods, e.g. hypnosis, acupuncture, exercise or groups receiving no special treatments [5, 15, 17, 18]. However, many of these studies lack long-term post-treatment follow-up data, only few studies describe the patient population in sufficient detail, account for dropouts, describe the randomization procedures adequately, or base sample size on power calculations. The few studies reporting true post-treatment results in general fail to find any significant or lasting effects after the initial 2–4 weeks after completion of treatment [13, 16, 17]. In many studies there is a lack of detailed description of the treatment methods used. Such lack of specifications and design issues make it difficult to reproduce many of the previous studies [18]. Finally, there is a lack of randomized clinical trials involving primary health care patients suffering from long-term diffuse pain disorders. However, these patients consume a large proportion of health care, and the physician is often at a loss as to efficient treatment strategies.

The purpose of the present study was to assess the possible effects of massage as compared to relaxation tapes in conditions of 'diffuse' and long-term pain. In addition, the duration of possible effects was evaluated by long-term post-intervention follow-up. The outcome measures that were compared over time were: self-rated health, mental energy, consumption of medicine, and muscle pain.

Methods

Participants

Patients fulfilling the study criteria of long-term pain [1] were carefully examined by their primary care physician and asked if they wanted to participate in a study concerning the efficacy of two different treatment methods for long-term pain. After informed consent was obtained, all of the 129 patients, initially asked as to their willingness to participate, enrolled in the study. A criterion for patient involvement in the study was that the condition was not due to any specific disease treatable by, for example, surgery. Pain should have existed for at least 3 months. Patients were consecutively randomized into either of the two study groups: massage and tape-recorded mental relaxation. A certified physiotherapist invited the referred patients to an introductory visit in her office. The participants were characteristic of the long-term pain patient commonly seen in primary health care settings. Many of them suffered from depression and had several other diagnoses. Some of the participants had a history of unemployment and many were immigrants.

Methods

At the first visit, individual patients received information about the aim of the study. Information was given about the design of the study as well as the specifics of the treatment. Finally the patients were asked to fill out the first questionnaire. In cases of language difficulties, a translator was hired.

The certified physiotherapist, specialized in massage, treated patients in the massage study group. In the massage group, patients received 6–10 sessions, each lasting 30 min. The patients were treated 1–3 times a week. Patients who participated in less than 6 treatments were considered dropouts. Patients in the massage group received an average of 7 treatments. Patients in this group typically exhibited severe sensitivity/touch-allodynia, due to the long-term pain. The massage was therefore adapted to meet the pain threshold of the patients. Under no circumstances was the massage considered painful or uncomfortable. Exceptions were made in the cases where patients showed distinctive myofascial trigger points, which were treated by 'trigger point technique', implying that the therapist applied pressure at these tender areas which could be uncomfortable but not unbearable.

Patients in the relaxation tape group were instructed by the same physiotherapist as in the massage group to listen to a progressive relaxation [19] audiotape twice a week during 5 weeks. In short, the tape instructed the participants to systematically tense and relax the muscle groups of the body accompanied by slow and regular breathing. A calendar was given to follow frequency of training. In order to ensure that the participant learned the proper relaxation technique the physiotherapist guided the patients through a relaxation exercise at the first visit.

At the final treatment in the massage group, and after 5 weeks in the relaxation tape group, the patients filled out the second questionnaire. In the relaxation tape group the audiotape and calendar were returned on this occasion. Three months after the last treatment, a final questionnaire was mailed to the patients.

Questionnaire

Each patient thus filled out a questionnaire on three separate occasions: before the first intervention, immediately after the termination of the intervention period, and at the 3-month follow-up. The questionnaire covered the following areas: age, gender, smoking hab-

its, country of birth, marital status, and profession. In addition, self-rated health and the two scales mental energy and muscle pain were used.

The mental energy scale comprised items concerning a person's mental and cognitive well-being. The muscle pain scale consisted of items concerning musculoskeletal pain. Both scales have been used in a large number of prior studies [20]. The constructed scales all had Cronbach's α of >0.7 with individual factor loading of 0.5 or higher. Each scale consisted of a number of questions to which participants were asked to respond on a 3- or 4-graded scale concerning the frequency of occurrence or intensity of specific symptoms. Higher scale scores indicate a more positive outcome. The scales mental energy and muscle pain and most of the questions have previously been validated and used [21]. In addition, there was one single question, using a 5-graded response scale, concerning the subjects' assessment of their own health status.

Statistics

The statistical program SPSS 10.0 was used for data analysis. Changes over time (group × time) were assessed using two-way analysis of variance (ANOVA, Greenhouse-Geisser). Stepwise forward multiple linear regression analyses were carried out to test linear models predicting four different and specific outcome (that is dependent) measures (perceived health status, mental energy, consumption of medicine, and muscle pain). New variables were created based on the changes in the outcome measures between the three assessment periods. These variables were labelled, e.g. Dhealth21 (change in self-rated health between the first and second measure, i.e. t2 – t1), and Dhealth23 (change between the second and third measure, i.e. t2 – t3). This principle was applied to all three major outcome measures (perceived health status, mental energy, and muscle pain, respectively). Significance levels were set at a two-tailed p value of <0.05. Using mental energy and muscle pain scales as outcome measures, the sample yielded a β of 0.10 (Power.90), using an α of 0.05, for detecting a 15% difference between study groups. Intention-to-treat was the basic principle for analyzing the results. In the time × group analyses, only participants with a complete set of variables were included.

All participants were free to withdraw at any time during the study without any explanation or further consequences. In addition, they were allowed to continue the massage/relaxation tape sessions, should they so decide, without having to fill out any additional questionnaires.

The study was approved by the Ethics Committee of the Karolinska Institute. Analyses were undertaken to answer two questions: (a) whether patients with various long-term pain syndromes show beneficial effects by the used interventions, i.e. a time effect, and (b) whether any significant differences occurred between the two study groups over time, i.e. group × time effects. The main outcome measures of interest were scorings on the muscle pain and mental energy scale, respectively, as well as self-rated health.

Results

A total of 129 persons were referred by a primary health care physician to participate in the study. 12 persons dropped out after a few treatments or did not attend any of the treatments. Age and gender characteristics were similar in both study groups, with a higher representation of female participants (table 1).

Table 1. Background characteristics of respondents

Variable	Massage (n = 62)[1]		Mental relaxation (n = 55)[1]	
	n	% of total	n	% of total
Age (range)				
≤44 (11–44) years	31	26.5	31	26.5
≥45 (45–77) years	29	24.8	26	22.2
Gender				
Male	10	8.5	9	7.7
Female	52	44.5	46	39.3
Marital status				
Married/common-law spouse	34	29.4	28	24.1
Single	38	24.1	26	22.4
Nationality				
Nordic (Swedish, Danish, Norwegian, Finnish)	27	23.1	27	23.1
Other nationalities	35	29.9	28	23.9
Smoker				
Yes	25	21.4	22	18.8
No	37	31.6	33	28.2

No statistically significant differences were found between the two groups in the above variables.

[1] n = 117, data on 12 non-compliers are missing.

During treatment, there was a significant improvement in all three main outcome measures: self-rated health, mental energy, and muscle pain in the massage group as compared to no changes in the relaxation tape group (table 2). At the follow-up 3 months after conclusion of the intervention, the massage group had deteriorated significantly as compared to no changes in the relaxation tape group (fig. 1–3).

Stepwise forward linear regression analysis was carried out to identify predictors of the three main outcome measures. Adjustments were made for age, gender, marital status, nationality, smoking habits, as well as baseline values for the three main outcome measures. The new variables, e.g. Dhealth 21, i.e. the difference in subjective health ratings between the first and the second measurement, were used as dependent variables for changes over time.

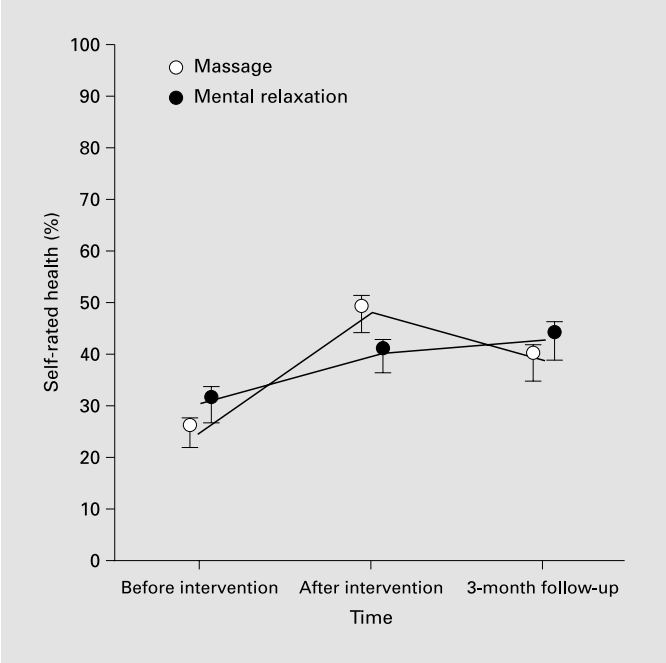

Fig. 1. Self-rated health (± SEM). Massage as compared to mental relaxation. Higher scores are more positive. Time effect ($p < 0.001$), group effect (p = nonsignificant), time × group ($p < 0.03$).

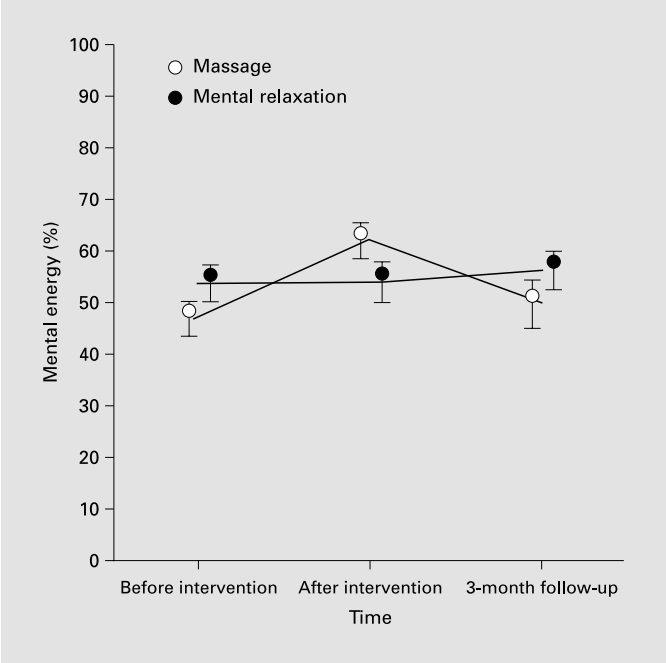

Fig. 2. Mental energy (± SEM). Massage compared to mental relaxation. Higher scores are more positive. Time effect ($p < 0.001$), group effect (p = nonsignificant), time × group ($p < 0.01$).

Table 2. Mean and SD: 2-way ANOVA

	Massage			Mental relaxation			2-way ANOVA	
	mean	SD	n	mean	SD	n	F	p
Self-rated health, %							3.6	<0.03
Before intervention	28.7	23.4	41	33.5	25.1	47		
After intervention	50.6	25.9	41	42.5	22.7	47		
3-month follow-up	39	24.4	41	43.1	25.4	47		
Mental energy, %							5.9	<0.01
Before intervention	49.7	24.8	41	53.5	26.7	48		
After intervention	64.2	23.1	41	55.1	27.6	48		
3-month follow-up	49.2	30.4	41	55.6	26	48		
Muscle pain, %							5.8	<0.01
Before intervention	45.6	22	41	49.5	24.1	48		
After intervention	60.1	25	41	51.6	30	48		
3-month follow-up	45.3	27.1	41	50.3	27.7	48		

In addition to treatment group (massage being more beneficial than relaxation tapes), being born in a Nordic country, lower initial muscle pain and lower baseline health predicted improvement in self-rated health during treatment (table 3). Altogether this model explained 38% of the explained variance. Treatment group, lower initial mental energy and being born in a Nordic country explained 29% of the increase in mental energy.

Treatment group, being born in a Nordic country, higher baseline health and baseline mental energy, more

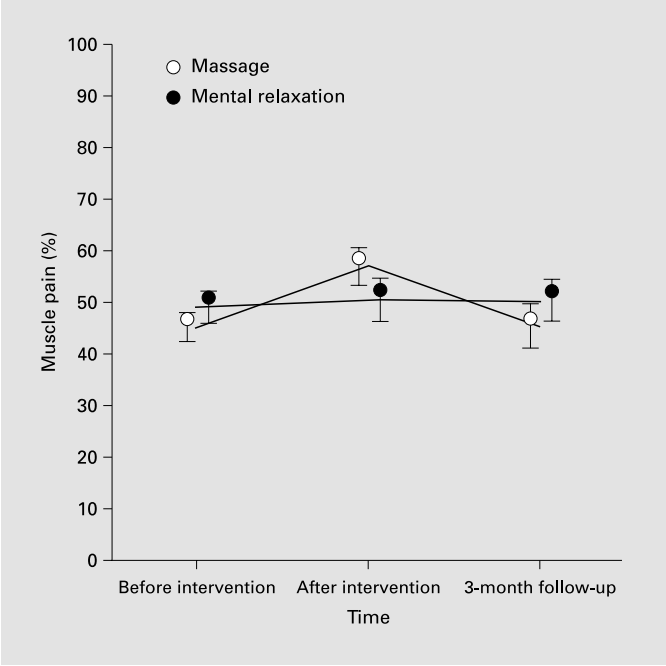

Fig. 3. Muscle pain (± SEM). Massage compared to mental relaxation. Higher scores are more positive. Time effect ($p < 0.001$), group effect (p = nonsignificant), time × group ($p < 0.01$).

initial muscle pain predicted improvement in muscle pain during active treatment. Altogether, the model explained 25% of the variance.

Factors predicting worsening with regard to muscle pain following termination of treatment were also studied. The model tested included treatment group, age, gender, self-rated health, mental energy and muscle pain. Significant predictors of worsening in self-rated health at the 3-month follow-up were higher self-rated health at the end of treatment, lower baseline mental energy, not being born in a Nordic country and lower baseline consumption of sedatives. This model explained 44% of post-treatment follow-up decrease in health. Treatment group did not remain a significant predictor in the final model. Worsening in post-treatment follow-up mental energy was explained by baseline and post-intervention values of mental energy (23%). The post-treatment follow-up increase in muscle pain was predicted by treatment group, not being born in a Nordic country, lower post-intervention mental energy, higher post-treatment muscle pain and higher intake of antidepressants (39%).

Discussion

The present study assessed short- and long-term effects on musculoskeletal pain of massage compared to listening to a relaxation tape. For all three outcome measures (self-rated health, mental energy and muscle pain), massage was significantly more effective during treatment, even after controlling for other possible factors. However, following termination of treatment there was significant post-treatment worsening of symptoms in the massage group as compared to no changes in the relaxation tape group. In addition to the treatment group, we identified other predictors of improvement in the three outcome measures during active treatment. The beneficial effects of massage found in the present study are consistent with other reports [5, 6, 8, 9, 11, 22, 23]. Many of the techniques used in physical therapy (for example massage, manipulation, relaxation, superficial and deep heat, as well as ice packs) have been cited as efficient strategies for pain control [5]. In a previous study, comparing a standard inpatient rehabilitation program, with or without additional relaxation training, no differences were found between the two groups [16]. Prior studies of the effects of psychological relaxation techniques have reported contradictory results on long-term pain. Most studies of the effects of mental relaxation on long-term pain have compared different psychological interventions, either with one another and/or to a waiting list control group [12, 13, 17]. However, it appears that effects are only significant when the psychological interventions are compared to a control group with no intervention at all [17]. In a study by Turner [13] comparing mental relaxation tapes with cognitive behavioral therapy and passive controls, mental relaxation as well as cognitive behavioral therapy resulted in significant improvement during treatment as compared to the passive controls. However, with regard to post-treatment effects only cognitive behavioral therapy was beneficial. The difference between the present study and Turner's was that in the present study participants were instructed to listen to the tapes twice weekly as compared to twice daily in Turner's study. These findings might imply that the frequency of tape sessions is of importance for achieving beneficial effects from the treatment.

The specific type of massage applied in various studies also differs. Massage interventions can include anything from gentle stroking, tactile, Swedish, light effleurage, soft tissue massage to underwater massage. Differences in skill and personality of therapists could make a difference. Since the present study only used one therapist it cannot

Table 3. Predictors of the outcome measures

Dependent variable	Adjusted r^2 %	Standardized β	F	Significance
Dhealth21	38.2		16.427	0.000
Group (massage = 1, mental relaxation = 2)	4.6	–0.218		0.007
Nationality (Nordic = 1, others = 2)	2.2	–0.190		0.038
Baseline muscle pain	6.9	0.260		0.007
Baseline health	24.5	–0.672		0.000
Dmental energy 21	29.2		14.724	0.000
Group	7.2	–0.279		0.001
Nationality	7.2	–0.285		0.001
Baseline mental energy	14.8	–0.428		0.000
Dmuscle pain 21	25.4		7.807	0.000
Group	6.6	–0.273		0.002
Nationality	3.2	–0.225		0.026
Baseline health	4	0.235		0.023
Baseline mental energy	2.6	0.253		0.000
Baseline muscle pain	9	–0.511		0.035
Dhealth23	44.4		18.347	0.000
Health t2	23.9	0.767		0.000
Baseline mental energy	11.2	–0.263		0.004
Nationality	6.3	0.316		0.001
Baseline sedatives	3	–0.206		0.022
Dmental energy 23	22.7		13.901	0.000
Baseline mental energy	9.5	–0.426		0.001
Mental energy after intervention	13.2	0.657		0.000
Dmuscle pain 23	38.6		12.077	0.000
Group	6.1	–0.248		0.005
Nationality	3.1	0.222		0.024
Mental energy after intervention	5.3	–0.423		0.000
Antidepressants after intervention	6.9	0.265		0.002
Muscle pain after intervention	17.2	0.778		0.000

D = Differences between measurements, e.g. Dhealth21 is the difference in self-rated health between the second and first measurement. For self-rated health, mental energy and muscle pain, higher scores indicate a more positive outcome.

differentiate treatment effects from possible therapist effects.

Various theories have been presented to explain the beneficial effects of massage. In animal studies, reduced pain sensitivity (most commonly the tail flickering test in rats) has been associated with increased levels of oxytocin, endorphins and/or enkephalins [24–28]. In a study of healthy humans, however, massage had no effects on serum levels of β-endorphins [29]. Massage might also result in lower anxiety and lower cortisol levels, an important stress hormone [30, 31]. Finally, it has been suggested that treatments such as massage may contain specific ingredients of psychotherapy. These ingredients are attention (of the therapist), opportunity to ventilate thoughts and feelings, confiding relationship with a helping person, the ritual that requires active participation, all believed to improve the patient's health [32].

In the present study, support was found for the notion that feelings related to depressive moods (lower mental energy) were related to long-term worsening in muscle pain. This finding is in line with the results of a prior study showing that depressive symptom scores might actually predict future development of musculoskeletal symptoms [33]. Thus, treatment studies of long-term

musculoskeletal symptoms need to take depressive symptoms into account.

An interesting phenomenon that has been found in this as well as other studies is the significant and negative rebound effect in the massage group following the completion of active treatment. In some cases, the condition of the patients 3 months after the completion of treatment was worse than before the first treatment. The reason for this worsening is not known. The present study identified non-treatment specific factors such as initial well-being, low mental energy, and nationality to be important predictors of such worsening. Post-treatment worsening in musculoskeletal symptoms is a common, but little understood phenomenon [13, 17]. This is a major problem since many patients are left with no long-term benefits from treatment. Perhaps massage is more efficient for acute musculoskeletal pain than long-term conditions, where pain maintenance is due to more complex mechanisms.

One advantage of this study is the 3-month post-intervention follow-up. Considering the fact that there are no general standards for how much time should elapse prior to the post-intervention follow-up, the authors chose 3 months with the motivation that it is a reasonable time for assessing the long-term efficacy of these respective treatments. It has been suggested that long-term post-intervention follow-up could be after 6 and 12 months [17]. However, we noted a negative rebound effect already after 3 months, which made it unlikely that any positive rebound effect would occur later on. The few previous studies of post-treatment effects of massage have generally also failed to show any lasting beneficial effects [7, 8, 18].

This study has several limitations that should be addressed. First, the study encompassed patients that commonly are difficult to treat. Typically, they suffer from multiple diagnoses including depression and anxiety. However, these types of patients are common among long-term pain patients in primary health care and make up a significant proportion of patients in urban health care clinics. Therefore there is great need to design treatment studies that involve them as well. Second, we had no concrete/objective evidence that the patients in fact listened to the relaxation tapes. We were obliged to trust the statements of the patients, which adds a source of uncertainty when measuring compliance. Third, the design does not enable us to distinguish the possible effects from more face-to-face time in the massage group, as compared to the relaxation tape group. Neither is it known if the observed effects are due to the massage per se or merely due to the therapist's interpersonal skills. Finally, another possible weakness in this study is that neither the therapist nor the patients were blinded. This could affect treatment outcome because of expectations or prior experience of the same treatment method.

Even though massage therapy appears to be an efficient method to treat muscle pain in the short term, there is a need for prospective long-term follow-up studies to assess possible long-term effects.

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