

# Efficacy of Massage Therapy in Chronic Pain: A Pragmatic Randomized Trial

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## ABSTRACT

**Background:** Although classic massage is used widely in Germany and elsewhere for treating chronic pain conditions, there are no randomized controlled trials (RCT).

**Design:** Pragmatic RCT of classic massage compared to standard medical care (SMC) in chronic pain conditions of back, neck, shoulders, head and limbs.

**Outcome measure:** Pain rating (nine-point Likert-scale; predefined main outcome criterion) at pretreatment, post-treatment, and 3 month follow-up, as well as pain adjective list, depression, anxiety, mood, and body concept.

**Results:** Because of political and organizational problems, only 29 patients were randomized, 19 to receive massage, 10 to SMC. Pain improved significantly in both groups, but only in the massage group was it still significantly improved at follow-up. Depression and anxiety were improved significantly by both treatments, yet only in the massage group maintained at follow-up.

**Conclusion:** Despite its limitation resulting from problems with numbers and randomization this study shows that massage can be at least as effective as SMC in chronic pain syndromes. Relative changes are equal, but tend to last longer and to generalize more into psychologic domains. Because this is a pilot study, the results need replication, but our experiences might be useful for other researchers.

## INTRODUCTION

In Germany, as well as in some other European countries, notably Scandinavia, classic or Swedish massage is a standard therapy in many chronic pain conditions such as low-back pain or shoulder-neck syndrome. This is because of a long therapeutic tradition that dates back to the last century (Westhof and Ernst, 1992). The theoretical foundations stipulate that the passive movements of massage and mobilization, stretching, and activation of muscles and subdermal tissue enhance blood flow

and metabolism, thus reducing tension and enabling the reduction of substances involved in the generation and prolongation of pain. Sometimes general, unspecific regulatory processes are also thought to be involved, as well as psychosomatic connections (Dogs, 1988; Haberzettl and Kemmerich, 1990; Sarno, 1976), which could be psychoneuroimmunologic pathways mediated by the immunocompetent cells of the skin (Montagu, 1982; Werner et al., 1997). However, these are only broad and speculative ideas with no accepted theory currently available to make effects of touch and massage cogently

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plausible. Many experimental studies have demonstrated that a host of physiologic parameters change after massage (Walach et al., 1995; Walach, 1996). However, there is no clear-cut theory emerging from this research. What we see is an array of differentially changing parameters depending on site, type of massage, subject of treatment, duration and frequency of treatment, pretreatment level of parameter, to name but a few of the modifying variables. While the effects of massage, in a broad and general sense, have been demonstrated in experimental studies, it is by no means clear whether these effects also relate in an understandable and systematic way to clinical improvement. This clarity can only be achieved by clinical trials (Brandmaier and Walach, 1998; Walach, 1995). As reviews have shown, there is only some evidence in favor of the clinical efficacy of massage, often stemming from methodologically flawed studies (Brandmaier and Walach, 1998; Ernst, 1998; Ernst and Fialka, 1994; Vickers, 1996). Most of the randomized studies have used massage as a control group for other therapeutic interventions, and hence have not really studied a strong version of massage, but more or less massage as a placebo (Hsieh et al., 1992). Therefore, it is not valid to use evidence from these studies in reviews (e.g., as in Ernst, 1999). Although some methodologically convincing randomized studies have been conducted (Field et al., 1986, 1992, 1997a, 1997b; Scafidi et al., 1990, 1993; Wheeden et al., 1993), and some evidence exists as to the efficacy of vibratory massage in pain syndromes (Lundeberg 1983, 1984a, 1984b, 1985; Lundeberg et al., 1984, 1987, 1988), none of these studies addressed the question of whether classic massage is effective in those conditions in which it is mainly used, namely, in chronic pain.

We therefore set out to study this question in a randomized but pragmatic trial. We wanted to determine whether massage is a useful therapy in those conditions for which it is normally prescribed in Germany, namely in noninflammatory rheumatic conditions and headache. These are somewhat broad diagnostic categories that comprise all sorts of chronic pain, predominantly in the back, the adjacent large limbs and joints, and also radiating to the

head. All these conditions are traditionally treated by massage, at least in Germany, but without much evidence from randomized trials. We compared massage treatment to standard medical care in general practice, which could be anything from prescribing medication to giving advice on posture and exercise, excluding the prescription of physiotherapy and massage. Originally we had planned to run a three-armed trial, comparing massage to standard medical care and an automated massage by over-water pressure massage (Muetzell, 1988), in order to control for the purported psychologic effect of touching (Güthlin and Walach, 1997). However, when we started the trial, health cost reimbursement policy in Germany changed as a result of economic pressure, and we had tremendous difficulties recruiting doctors and patients. Doctors were limited in massage prescribing and therefore were reluctant to prescribe massage for study reasons. Thus, we had to change our original protocol, which called for a randomized allocation, to arms. Because the automated massage was situated at a location in Freiburg and we could not get enough patients locally, we had to broaden the area of recruitment, and consequently were unable to carry out the third comparison as a randomized treatment arm. We publish here the data from the randomized comparison of massage therapy and standard medical care.

## MATERIALS AND METHODS

### *Design*

The design of the study was a pragmatic parallel, randomized, open comparison trial, comparing classic massage with standard medical care (SMC) at three measurements: pretreatment, post-treatment, and at 3-month follow-up. We proceeded according to a preformulated protocol, which was submitted to the sponsor, with the exception mentioned above. Methodological details and results are described in full in a report, which is available on request from the authors (Walach et al., 1999). We prepared numbered, opaque, sealed envelopes according to the results of a random-

ization procedure run on SPSS software (SPSS, Inc., Chicago, IL) and forwarded these, together with instructions, to doctors who had expressed a willingness and openness for participation. Because doctors were reimbursed only at a basic rate (30 DM/15 \$ per patient), we recruited doctors known to be favorably disposed toward massage and with a genuine scientific interest. The doctors approached all suitable patients and informed them about the study. If a patient was willing and gave written informed consent the doctor opened the next sequentially numbered envelope, and according to the result either began treatment or sent the patient to one of the licensed massage practitioners who had agreed to participate.

*Patients: inclusion and exclusion criteria*

Patients had to have a long-term diagnosis (i.e., > 6 months) of what is known in Germany as noninflammatory rheumatic pain. This diagnostic entity comprises chronic pain in different locations, mostly in the lower back, neck, and shoulders, as well as chronic headaches. Patients had to be between 18 and 65 years old. Exclusion criteria were inflammatory processes, fever, neoplasms, skin diseases, abuse of alcohol, legal or illegal drugs, pregnancy, hemophilia, arteriosclerotic diseases, including ischemic heart disease or myocardial infarction, diseases that call for anticoagulating therapy, skin diseases or morbus Sudeck.

*Treatment*

Patients randomly assigned to SMC received whatever treatment the doctor prescribed. In most cases this was pharmacologic therapy, but could, in theory, also have been advice on exercise and posture, or the like. While in a strictly experimental efficacy study a standardization of this procedure would have been optimal, this was neither possible nor desirable in this practical context of primary care, where massage is normally used and where a pragmatic comparison was the goal. The doctor was free to prescribe whatever seemed best, and there were no regulations. Massage therapy similarly followed the usual therapeutic routine in Germany: 10 sessions of massage therapy, 20 minutes each, with usually two sessions

per week (i.e., a 5-week course). The only difference was that heat packs were explicitly excluded. Massage treatment was individual, but normally consisted of what is known as classic or Swedish massage, a complete massage of the back, using the classic grips of effleurage, petrissage, vibration, friction, and tapotement. The sequence, location, and intensity of massage movements was completely at the discretion of the massage therapist. Again, from an experimental point of view, one could object to this lack of standardization but because a pragmatic comparison of what is done in practice was our goal, we opted for individualized massage as the intervention of choice.

*Measures and outcome criterion*

All measures were patients' self-reports by questionnaires, which were handed out by the doctor but returned by the patients to the study secretary in stamped envelopes. Thus, data collection was independent of the person treating the patients. The predefined, main outcome criterion was self-rated "pain during the last 2 weeks" on a nine-point rating scale, which was measured at intake, post-treatment, and at 3-month follow-up, like all other measures.

Additionally, we measured medication (pain medication, sleep medication, or tranquilizers, and frequency of use: daily, sometimes during the week, once per week, never), pain intensity and pain experience using a validated German questionnaire, the Hamburg Pain Adjective List (HSAL) (Hoppe, 1991); general well-being using the German version of the Profile of Mood State (POMS) (Bullinger et al., 1990); depression using the German version of the Center for Epidemiological Studies—Depression (CES-D) scale (ADS) (Hauzinger and Bailer, 1991); anxiety using the German version of the State-Trait-Anxiety Inventory (STAI-G) (Laux et al., 1981); and body concept using the Frankfurt Body Concept Scales (Frankfurter Körperkonzeptskalen FKS; Deusinger, 1998). We hypothesized that depression and anxiety as pain-related psychologic constructs should show changes accompanying symptomatic improvement, and that more generalized differential effects of treatments could be visible in the other psychologic measures.

### Problems

At the time that we launched the trial, public opinion among doctors in Germany became hostile toward massage to the extent that reimbursement of massage therapy was strictly limited, with leading professionals actively campaigning against massage in general and our study in particular. This resulted in problems in recruiting doctors and patients. Therefore, we were unable to adhere to 30 patients per group, and had to reduce our three-armed design to a two-armed one (see Introduction).

### Statistics

Analysis was done according to intention-to-treat. Missing data were interpolated by grand mean estimations at the first measurement, by last-value-carried-forward algorithms at post-measurement, and by interpolations of pre-measurements at follow-up. Thus, we always opted for the most conservative interpolation. If preconditions for analysis of variance were met, analysis was done by analysis of variance (ANOVA) according to a 3 (measurement points)  $\times$  2 (groups) – design. Otherwise we used nonparametric methods. In that case we tested the general trend of time by Friedman analysis, followed by single Wilcoxon tests, and tested for group differences using Mann-Whitney *U* tests. We calculated standardized mean differences as effect-size within groups for the most important parameters, by subtracting 3-month follow-up data from pretreatment data and dividing by the larger standard deviation, thus calculating an equivalent of the well-known *d* statistic for within-group change (Glass et al., 1981; Rosenthal, 1994). All analyses, except effect-size estimates, which were done by hand, were run on STATISTICA for Windows Version 5 (StatSoft GmbH, Hamburg, Germany).

## RESULTS

### Patients

Nineteen (19) patients were randomly assigned to receive massage and 10 were to receive SMC. This uneven proportion reflects the fact that more patients withdrew their consent

to participate when they learned that they had been randomly assigned to receive SMC. Basic sociodemographic information on these patients is given in Table 1.

### Pain

ANOVA revealed a significant difference between groups ( $F_{1/22} = 14.4$ ;  $p = 0.001$ ) and a significant change over time ( $F_{2/44} = 3.4$ ;  $p < 0.05$ ), with no significant interaction. The data are presented in Figure 1. *Post hoc* tests (Tukey Honest Significant Difference for unequal *n*) revealed that the main effect of the group factor was the result of a difference of the groups at 3-month follow-up ( $p = 0.003$ ), because the groups were neither significantly different at pretreatment nor at post-treatment. The main effect of time was the result of the difference between pretreatment and post-treatment ( $p < 0.05$ ).

### Psychologic measures

*Pain experience (Hamburg Pain Adjective List—HSAL)*. There were no significant effects in this variable.

*Depression (CESD-ADS)*. There was a significant main effect of time ( $F_{2/44} = 6.1$ ;  $p < 0.005$ ), a significant interaction ( $F_{2/44} = 4.1$ ;  $p < 0.03$ ), and no main effect of treatment groups. *Post hoc* tests (Tukey Honest Significant Difference for unequal groups) revealed that while the SMC-treated group did not exhibit significant change over time, the massage-treated group changed significantly ( $p < 0.002$ ).

TABLE 1. SOCIODEMOGRAPHIC DATA  
ACCORDING TO GROUPS

	Massage	SMC
Age <sup>a</sup>	39.4 (15.0)	53.3 (6.6)
Gender: female	17 (89.5%)	9 (90%)
Pain rating (1 = no pain; 9 = very strong pain) <sup>a</sup>	5.9 (1.4)	7.1 (1.9)
Limitation (1 = very strong; 5 = none)	2.9 (1.0)	2.4 (1.1)
Painkillers daily	4 (22%)	2 (20%)

<sup>a</sup>Significant difference ( $p < 0.05$ ).

SMC, standard medical care; means (standard deviation) or frequencies (percent).

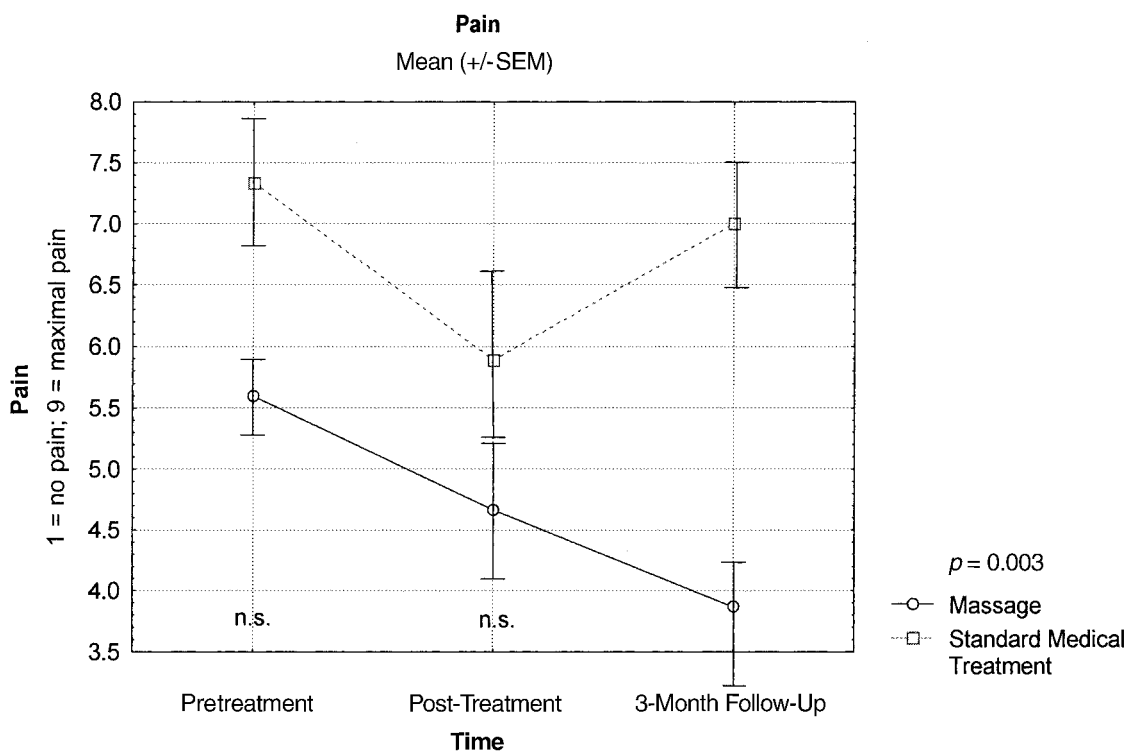


FIG. 1. Main outcome criterion pain: mean,  $\pm$  standard error of mean (SEM) at baseline, post-treatment, and at 3-month follow-up for massage and standard medical care. n.s., not significant.

from pretreatment to post-treatment and from pretreatment to 3-month follow-up, the change obviously taking place between pretreatment and post-treatment (Fig. 2).

*Anxiety (STAIG).* There was a significant interaction ( $F 2/44 = 3.4; p < 0.05$ ) and a main effect of time approaching significance ( $F 2/44 = 2.9; p = 0.063$ ). *Post hoc* tests revealed that the interaction was the result of a significant decrease of anxiety in the massage-treated group only from pretreatment to post-treatment, remaining stable until follow-up.

*Mood (POMS).* There was no change in depressed mood and no difference between groups, as measured by POMS. Vitality changed significantly from pretreatment to post-treatment and remained stable (main effect time:  $F = 2/44 = 6.5; p < 0.004$ ), with no significant differences between groups and no significant interaction. Tiredness showed a significant main effect for time ( $F 2/44 = 3.6; p < 0.04$ ) and a significant interaction ( $F 2/44 = 3.9; p < 0.03$ ). *Post hoc* tests revealed that the significant

time effect is the result of a change from pretreatment to post-treatment ( $p < 0.03$ ), and the significant interaction is due to the fact that only the massage group shows a marked improvement of seven points ( $p < 0.003$ ) which remains stable until follow-up, while the SMC-treated group showed no change. There was no significant change in depressed mood (POMS) over time, nor was there any difference between the groups.

*Body Concept (FKKS).* There were no significant effects or differences in the scales health and well-being, body care, body contact, acceptance of body. The scale bodily efficiency changed significantly over time (main effect  $F 2/44 = 3.6; p < 0.04$ ), because of a change in both groups from pretreatment to follow-up (HSD:  $p < 0.03$ ), as well as "acceptance by others," which showed a steady, significant increase over time (main effect  $F 2/44 = 4.7; p < 0.02$ ), which in *post hoc* tests was visible from pretreatment to post-treatment ( $p < 0.05$ ) and even more so from pretreatment to follow-up ( $p < 0.02$ ).

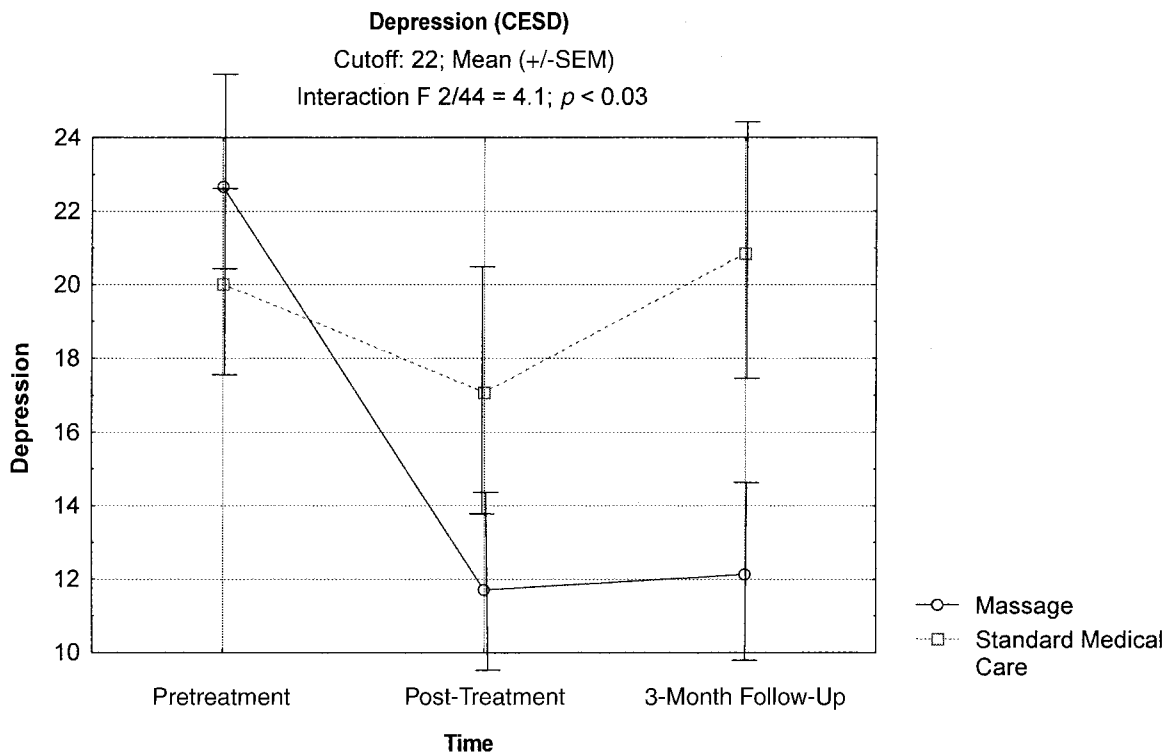


FIG. 2. Depression (Center for Epidemiological Studies—Depression/ADS): mean  $\pm$  standard error of mean (SEM) at baseline, post-treatment, and at 3-month follow-up for massage and standard medical care, n.s., not significant.

### Drugs

Because patients were generally not heavy users of drugs, we collapsed all categories of drugs and frequency in one summary variable per measurement point: any drugs taken versus no drugs taken. Although neither Friedman analysis over the time course, nor Mann-Whitney  $U$  tests for group differences showed any significance, it was obvious that patients in the massage group took less medication (47% at pretreatment, 40% at post-treatment, 47% at follow-up) than patients in the SMC-treated group (66% at pretreatment, 78% at post-treatment, 78% at follow-up), with patients in the massage-treated group keeping medication stable and patients in the SMC-treated group increasing their use.

Effect sizes for within-group change are given in Table 2.

## DISCUSSION

Originally we had planned to include at least 30 patients per group and compare classic mas-

sage not only to SMC, but also to an apparatusive massage that would control for the effect of human touch. We had to change our original plans, because we met with opposition from medical authorities as a result of economic cuts. We finally had to end the study without having reached our goal. Therefore, we only report on those patients who had been included according to the protocol after randomization, and on the core comparison between classic massage and SMC. The study was designed as a pragmatic randomized controlled study but became a pilot study in the end. The drawbacks are clear: the groups are

TABLE 2. EFFECT SIZES  $d$  OF CHANGE FROM PRETREATMENT TO FOLLOW-UP PER GROUP

	Massage	SMC
pain rating	0.85	0.15
depression	0.83	-0.01
anxiety	0.43	-0.12

Difference expressed as the difference prefollow-up, divided by the larger standard deviation minus sign indicates aggravation

SMC, standard medical care.

not completely comparable at baseline, despite randomization, presumably either because of differential attrition, the small number of patients, or because of a combination of both factors. It is important to note, however, that this effect was not so strong as to invalidate our analysis. This points to the general problem of conducting randomized controlled trials in the field of general practice, where either practitioners or patients, or both, have sometimes strong preferences, refuse to be randomly assigned, or withdraw consent in the event that randomization goes against their preference. Patients in the SMC-treated group were demographically different from the massage-treated group, and it is likely that the difference also applies to other variables not measured. However, even if differential outcome should be confounded by initial differences of groups, this does not damage the results. In practice, where there are also differential preferences for treatments, the question also arises whether the treatment is effective for those patients choosing a particular treatment. Patients in the massage-treated group had less severe pain at baseline than patients in the SMC-treated group. However, this initial difference was not the reason for the significant between-group difference. As is clearly visible in the statistical analysis presented in figure 1, this is because of the reduction of pain in the massage-treated group that continues until follow-up, as opposed to the course of pain in the SMC-treated group, which approaches its baseline value at follow-up.

Our conclusions are not so much based on isolated single significances as on this recurrent pattern in our data. While the amount of change is comparable in both groups in nearly all parameters at post-treatment, it is only the massage-treated group that tends to maintain its improvement in nearly all variables that were sensitive to change. This is apparent, apart from pain, in depression, anxiety, and tiredness. We have quantified this by calculating effect sizes for the most important parameters: pain, depression, and anxiety. Although effect sizes as unit-less, standardized measures of effects are usually used to quantify differences between groups, they can also be used as standardized within-group mea-

asures of change (Kirsch, 1998; Kirsch and Sapirstein, 1998; Zwingmann et al., 1997). In that case they indicate the amount of change over time independent of the measure used. The effect sizes we found for change from baseline to follow-up as presented in table 2 are substantial for massage in pain ( $d = 0.85$ ) and depression ( $d = 0.83$ ), in Cohen's (Cohen, 1977) terminology, medium-sized for massage in anxiety ( $d = 0.43$ ), and small for SMC in pain (0.15), or nonexistent for SMC in depression and anxiety. The effect sizes we found compare favorably to recent data reported from a German rehabilitation program for back pain patients, measured with the German SF-36 (Zwingmann et al., 1998). Although these patients were certainly more severely ill than those in our sample, the relative change achieved in this hospital, which is representative of a good German rehabilitation program for back pain, lies in the range from  $d = 0.17$  to  $d = 0.74$ .

Therefore, it seems safe to conclude that this study provides initial evidence for the fact that massage is at least as effective as SMC for the treatment of various pain syndromes, for which SMC is usually prescribed in Germany. While SMC is also effective in reducing pain on the short term, the effects are more short lived and do not generalize as readily into psychological domains as depression, anxiety, or mood.

When interpreting these data it should be kept in mind that the analysis used an intention-to-treat approach. This increases variance because of extrapolation of conservative estimates for missing data, and thus decreases sensitivity of statistical tests and estimations of effect sizes. Therefore, the estimation of effects in this analysis is rather conservative. This might be the reason that the effect seen in the single rating of pain was not visible in the pain adjective list, which theoretically should be more sensitive than a single-item measure. It is possible that the adjective list was more affected by conservative interpolations than the single-item measure because the latter had few missing data, while the adjective list had more. Because our outcome criterion was predefined in the protocol, this does not hamper our results.

The POMS scale proved rather unresponsive. Only two of the four scales showed any effects at all. This might be because POMS is a scale

designed for more short-lived changes. It could also be the case that mood, as measured by POMS, has not really changed much because the constructs affected by pain are more likely to be depression or anxiety. These latter measures did indeed show clear-cut effects, with massage obviously having a more generalizing tendency toward psychologic improvement than SMC. Only two of the six scales of the measure of body concept showed changes over time, but no differentiation between the groups. This might have been because of the interpolation procedure for missing data that increased the variation. It could also be because this scale, which is meant to measure changes in body concept in the context of psychotherapy, is not valid for this type of research. We used it because we hypothesized that differences between automated massage and massage done by a therapist could also carry effects mediated by human touch, and we wanted a measure for that. Because we did not evaluate this comparison as a result of the organizational problems described above, it comes as no surprise that this measure does not differentiate between massage and SMC, nor that it is rather unresponsive to change. We can say from these data that if massage and SMC are therapeutically effective, they are not effective because they change much about the body concept. The changes seen in "bodily efficiency" and "acceptance by others" are probably generalizations of symptom reduction.

Our study was small and hence had low power to detect differences. Thus, it is even more impressive that we were able to show differential effects of massage, in terms of effectiveness that lasted for at least 3 months, as well as in terms of psychologic effects. This trial was pragmatic in nature. We did not use strict inclusion or exclusion criteria. Patients included are a fairly representative sample of those patients seeing general practitioners in Germany and asking for a prescription of massage. Our trial showed that massage can be a useful intervention, and worthwhile in the long term because effects continue. It should be noted that this treatment effect is not confounded with pharmacologic treatment, because patients in the massage-treated group tended to use less medication, although our measure of drug use

was rather crude and also the baseline probability of using medication in this sample was rather low from the outset. Because of this flooring effect, medication was not a useful outcome parameter in this trial, although it certainly shows that the massage effect was not caused by concomitant medication.

It is also important to note that we did not address the question—and never had the intention to—whether any particular component of massage, any particular movement or way of practicing is the effective element. Although we are saying that massage appears to be at least as effective as SMC, this of course applies to the whole setting: touch, environment, personal attention, relaxing on the table, time off work, plus the specific intervention of massage. It is this general setting and not any active ingredient that we studied. To patients it probably does not matter what gives relief as long as they experience it. It might be a good complementary approach to study the important component of massage experience in a more qualitative way to understand what are the therapeutic elements in this experience.

To our knowledge, this was the first randomized trial of classic massage in what is known as noninflammatory rheumatic pain in Germany, a classic indication for massage. It therefore is more of a pilot study. It showed that massage is a promising intervention, at least as effective as SMC, and that it needs to be studied more closely.

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