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Biopsychosocial rehabilitation for repetitive-strain injuries among working-age adults

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The objective of this study was to determine the effectiveness of biopsychosocial rehabilitation for upper-limb repetitive-strain injuries among working-age adults. Studies were identified from electronic bibliographic databases, reference checks, and consultations with experts in rehabilitation. Four blinded reviewers selected randomized controlled and controlled trials. Two experts evaluated the clinical relevance of the findings. Two other reviewers extracted the data and assessed the main results and the methodological quality of the studies. Finally, a qualitative analysis was performed. Only 2 studies satisfied the criteria. They were both considered to be low-quality trials. The clinical relevance of the included studies was also unsatisfactory. The level of scientific evidence was limited, showing that hypnosis as a supplement to comprehensive treatment can decrease the pain intensity of acute repetitive-strain injury in short follow-ups. There appears to be little scientific evidence for the effectiveness of biopsychosocial rehabilitation with respect to repetitive-strain injuries.

Key terms multidisciplinary, musculoskeletal, randomized controlled trial, review, treatment, therapy, upper limb, worksite visit.

The term repetitive-strain injury (RSI) is often used to describe upper-limb disorders caused by overuse (1). Common acute RSI cases usually recover rapidly. Prolonged pain tends to develop into a combination of physical, psychological, and social disabilities. For some people the pain persists, and the disorder can result in chronic work disability similar to that observed for low-back pain. Therefore physical rehabilitation for musculoskeletal disorders has been combined with psychological, behavioral, and educational intervention (2–4). The conceptual basis for this kind of rehabilitation lies in the biopsychosocial (biological, psychological, and social) model of illness (5), which is nowadays applied in inpatient and outpatient rehabilitation. Biopsychosocial rehabilitation is often a multidisciplinary treatment program, which requires substantial staff resources and financial

resources on the part of the health care system. The indirect costs burden the employers, insurance companies, and patients as well. Therefore, there is a need to determine whether intervention that accounts for the majority of costs has a significant impact on long-term outcomes (3).

Some meta-analyses on the efficacy of multidisciplinary biopsychosocial pain treatment have been published (6, 7), but they lack information on RSI. To gain evidence on the effects of biopsychosocial rehabilitation on, especially, RSI, we have written this review from data gathered for a more general systematic review (Karjalainen et al, an unpublished manuscript of a systematic review) on the effectiveness of biopsychosocial rehabilitation with respect to common musculoskeletal disorders among working-age adults. The objective of the present

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systematic review was to investigate the effects of biopsychosocial rehabilitation in the treatment of upper-limb RSI among working-age adults.

Material

Types of studies

Only randomized controlled trials and prospective concurrent controlled trials on biopsychosocial rehabilitation were considered. However, it was agreed that, should there be 3 or more randomized controlled trials, only randomized controlled trials would be included. Studies reported in English, Dutch, Finnish, Swedish, Norwegian, German, French, or Spanish were included.

Types of participants

Working-age adults (18 to 65 years of age) suffering from upper-extremity RSI were included. Excluded were patients with acute trauma, neoplasm, and inflammatory or neurological diseases.

Types of intervention

The inpatient or outpatient biopsychosocial rehabilitation programs had to be biopsychosocial; they had to consist of a physician's consultation plus psychological, social, or vocational intervention or some combination of the three. Thus trials in which rehabilitation was exclusively or predominantly medical were excluded. For example, a program consisting solely of medical treatment and physiotherapy would not have been included, but a program with medical treatment and a workplace visit would. Electromyographic (EMG) biofeedback as the only component of physiological intervention was excluded.

Types of outcome measures

We sought the following types of outcome: (i) pain intensity (eg, visual analogue scale, ordinal scale), (ii) global status (eg, overall improvement), (iii) disorder-specific functional status (eg, the Upper Extremity Function Scale), (iv) generic functional status or quality of life [eg, SF36, 15-D, Sickness Impact Profile, Health Assessment Questionnaire, West Haven-Yale Multidimensional Pain Inventory (WHMPI) (9), Disabilities of the Arm, Shoulder and Hand Measurement Tool (8)], (v) ability to work (eg, sickness absence, return to work, number of days off work), (vi) health care consumption and costs (eg, physician's consultations, psychologist's or social worker's consultations, physiotherapy, intake of analgesics), and (vii) satisfaction with treatment.

Search strategy for identification of studies

To identify relevant studies for the general musculoskeletal disorder review, we searched MEDLINE from 1966,

PsycLIT from 1967, and EMBASE from 1988 to April 1998. The Cochrane library CD-ROM (Issue 2, 1998) was also searched for recent studies. We also screened studies published in Finland from 1978 to 1998 using the Finnish medical database Medic and performed a Science Citation Index search. References of identified articles and reviews were also checked. We consulted 24 experts in the field of rehabilitation to identify potentially relevant studies that we might have missed. The Cochrane Musculoskeletal Injuries Group Specialized Register was also searched.

The MEDLINE search strategy, which incorporated the optimal search strategy for randomized and controlled trials by Dickersin et al (10) was used for the general musculoskeletal disorder review. It was modified for the other database searches. The search strategy can be obtained from the first author if requested.

Methods

The methods used for this systematic review on RSI were based on current recommendations (11–13). The clinical relevance of the trials was assessed using a set of criteria based on the recommendations of Shekelle et al (14) for the critical reading of clinical literature.

Study selection

Four reviewers (KK, AM, RR, HH) independently selected the trials for the systematic review. We used the latin square method, whereby each of the 4 reviewers selected the studies from among half of the papers so that the assessments of each reviewer overlapped with another's assessments. The reviewers were blinded as to the journal and authors. From the title, keywords, and abstract they determined whether or not the study met the inclusion criteria regarding design, subjects, and intervention. Disagreements were discussed in consensus meetings, and, if they remained unresolved or if it was unclear whether the article should be included, the full article was retrieved for final assessment. The same reviewers, still blinded as to authors and journal, then assessed the full text of the article to make the final decision about whether the study met the inclusion criteria. Any disagreements were again discussed in a consensus meeting.

Data extraction

Two reviewers (MvT, BK), blinded as to authors, journal and institution or origin, independently extracted the data using a standardized form.

Evaluation of effect for individual studies

We analyzed the data with MetaView 3.1 using the fixed-effects model and weighted mean differences. The mean

differences and 95% confidence intervals were calculated comparing the used interventions according to the pre-defined outcomes.

We considered a study to have a positive outcome if biopsychosocial rehabilitation showed statistically significant improvement when the results were compared with those of the reference forms of intervention for at least one of the outcome measures listed earlier. A study was judged negative if the biopsychosocial rehabilitation was less effective than the reference forms of intervention, or it was judged neutral if there was no statistically significant difference between the intervention groups with respect to the assessed outcomes.

Clinical relevance assessment

Two experts in the field of rehabilitation (AM, HH) assessed the clinical relevance of the extracted studies by evaluating whether the patients, health care setting, and interventions were described precisely enough to allow inferences about the clinical applicability of the results and the clinical relevance of the measured outcome. On this basis, they decided whether the evidence was sufficient for clinical recommendations to be made.

The following 3 questions were used to assess the clinical relevance: (i) are the patient characteristics and treatment settings described well enough to decide whether they are comparable to those you see in your own practice, (ii) are all the intervention(s) described well enough to allow you to provide the same for your own patients, and (iii) were clinically relevant outcomes measured? Each question was given a plus (+) if the methodological criterion was fulfilled, a minus (-) if the criterion was not fulfilled, and a questionmark (?) if data were not available or not sufficient.

Methodological quality assessment

Two reviewers (MVT and BK) independently assessed the methodological quality of the trials. A consensus method was used to resolve disagreements.

We used a list of criteria that has been used in other Cochrane reviews in the field of back pain (15) and selected only items reflecting the internal validity of the trials. Equal weights were applied to all 10 criteria, which have been described in detail in appendix 1.

The maximum overall score was 10. A randomized controlled trial was considered to be of high methodological quality if at least 5 out of 10 items received a positive score and if the study had no fatal flaws. Examples of fatal flaws were withdrawals by more than 40% of the patients, total or nearly total nonadherence to the protocol, or very poor, unadjusted comparability in the baseline criteria. Any trial with fatal flaws in the study design or execution was considered inadequate and excluded from the analysis.

Qualitative analysis

The qualitative analysis involved using a rating system with 4 levels of scientific evidence for the effectiveness of biopsychosocial rehabilitation (13). The results were considered contradictory if the overall conclusions regarding the effectiveness in different studies were contradictory or inconsistent for the same diagnosis. The 4 levels were as follows: *level A*: strong research-based evidence: generally consistent findings in multiple high-quality randomized controlled trials; *level B*: moderate research-based evidence: generally consistent findings in 1 high-quality randomized controlled trial and ≥ 1 low-quality randomized controlled trials or generally consistent findings in multiple low-quality randomized controlled trials; *level C*: limited research-based evidence: 1 randomized controlled trial (either high or low quality) or inconsistent or contradictory evidence in multiple randomized controlled trials; *level D*: no research-based evidence: no randomized controlled trials.

Description of the studies

Our extensive literature searches identified only 3 articles, which were reports on 2 trials (4, 16, 17), that focused on upper-limb RSI. Another trial (18) was identified through contact with the Cochrane Musculoskeletal Injuries Group. The articles of Spence (16, 17) were later excluded due to their lack of a biomedical component in the rehabilitation scheme. We did not find any concurrent controlled trials that could be included in this review. Thus 2 trials studying RSI in the upper extremities have been included (4, 18).

Characteristics

Moore (18) examined 32 patients, with a mean age of 35.4 years, recruited from the occupational medicine department of a local medical center in California. All the patients had recently diagnosed RSI (carpal tunnel syndrome, wrist tendinitis, de Quervain tenosynovitis or cervical myofascial dysfunction) with an onset of symptoms within 8 weeks. They had no previous medical treatment for RSI, no associated medical diseases and no significant psychiatric illnesses, were nonsmokers, and their employment required operation of a keyboard. All the patients were involved in comprehensive treatment in the department (including medication when indicated, referral to physiotherapy focusing on ergonomic evaluation, self-management, soft-tissue flexibility, and strength). The study explored the extra effect of hypnosis with biofeedback and autogenics (a form of autohypnosis using self-suggestion), provided once a week for 6 weeks, compared with the results for waiting-list referents (table 1).

Spence et al (4) recruited 48 patients, with a mean age of 42 years, who had chronic pain in their upper limbs, neck, or shoulders in association with repetitive tasks at the workplace. The study focused on 3 behavioral therapies, EMG biofeedback, applied relaxation with progressive muscular relaxation and imagery methods. The biopsychosocial intervention groups were given a combination of EMG biofeedback and applied relaxation

or applied relaxation only. One reference group was given EMG biofeedback and the other waited 8 weeks for treatment (table 1).

Methodological quality

Both of the trials included in the review were rated as low in quality since they scored less than 5 out of a max-

Table 1. Characteristics of the included studies. [RSI = repetitive-strain injury, M = methodological quality scores, CE = reviewers' overall conclusions on effectiveness, + = positive if multidisciplinary intervention was effective with regard to at least 1 outcome measure, - = negative if multidisciplinary intervention was less effective than reference intervention(s), N = neutral if multidisciplinary intervention was ineffective in comparison with the reference intervention(s), EBT = emphasis on behavioral therapy, RCT = randomized controlled trial, EMG = electromyography, VAS = visual analogue scale]

Study	Method	Participants	Intervention	Outcomes	Notes	CE	M
Spence et al, 1995 (4)	RCT	34-to-60-year-old patients (N=48) with chronic pain in the upper limbs, neck or shoulders in association with repetitive tasks at work; 85% women and 15% men; average duration of pain = 5.7 years	Intervention: EMG biofeedback plus applied relaxation (N=12); reference group 1 = applied relaxation (N=12), progressive muscular relaxation and imagery methods; reference group 2: applied EMG biofeedback (N=12); reference group 3: patients on a waiting list (N=12); duration of therapy 4-6 weeks in out-patient setting, 8 sessions of 1.5 hours each	Pain Intensity (self-monitored pain index): baseline: 21.1 for intervention group, 24.4 for reference group 1, 17.3 for reference group 2, and 20.3 for reference group 3; after rehabilitation 17.7 for intervention group, 16.7 for reference group 1, 13.9 for reference group 2, 21.3 for reference group 3; at 6 months: 17.7 for intervention group, 13.4 for reference group 1, 11.4 for reference group 2; disorder-specific functional status (West Haven Yale Multidimensional Pain Inventory): baseline: 2.6 for intervention group, 2.4 for reference group 1, 2.0 for reference group 2, 2.3 for reference group 3; after rehabilitation: 2.6 for intervention group, 2.5 for reference group 1, 2.1 for reference group 2, 2.3 for reference group 3; at 6 months: 2.4 for intervention group, 2.4 for reference group 1, 2.3 for reference group 2; other: health care consumption and costs (medication use), psychological aspects (depression, pain beliefs)	Dropouts: 10 (20.8%); EBT; small sample size; waiting list not a good reference group	N	1
Moore & Wiesner, 1996 (18)	RCT	32 patients with recently diagnosed RSI (carpal tunnel syndrome, wrist tendinitis, de Quervain tenosynovitis or cervical myofascial dysfunction); onset of symptoms within 8 weeks; 93% women and 7% men; mean age = 35 years	Both the intervention and reference groups: comprehensive treatment in the department (medication and referral to physiotherapy focusing on ergonomic evaluation, self-management and soft-tissue flexibility and strength); intervention group: basic relaxation training and hypnosis once a week for 6 weeks (1st week: basic relaxation and hypnosis; 2nd week: modified biofeedback; 3rd week: autogenics self-suggestion; 4th, 5th and 6th weeks: further practice); recommendation to practice 2 times a day for 20 minutes using recorded tapes (N=15); waiting-list referents (N=17)	Pain Intensity (VAS): mean change at 6 weeks: -5.7 (SD 1.6) for intervention group, -2.1 (SD 2.5) for reference group; other outcome: temperature change; only mean changes reported	Dropouts: 2 (6.3%); both forms of intervention multidisciplinary; only 6-week follow-up	+	3

imum of 10 points in the methodological quality assessment scheme described in appendix 1.

The results of the quality assessment for individual items are presented in table 2.

Clinical relevance

Moore (18) satisfactorily described the intervention and the setting from which the patients were recruited, but the proportions of patients according to a more specific diagnosis (eg, epicondylitis, wrist tenosynovitis, carpal tunnel syndrome) within RSI remained unclear. In addition, the study did not report what type of treatment the waiting-list reference group received while it waited for the same treatment as the studied intervention group. The only outcome measured in the study of Moore (18) was the intensity of pain in 6 weeks of follow-up. Spence et al (4) measured relevant outcomes but did not adequately describe the setting, patient characteristics, or intervention.

Results

Outcome

Moore (18) recorded pain, measured by a 10-cm visual analogue scale (VAS), in both groups. After 6 weeks of follow-up, there was a greater and statistically significant reduction in the mean decrease in pain rating in the intervention (hypnosis) group than in the reference group (mean difference -3.6 cm, 95% confidence interval -5.1 to -2.0 cm).

According to the assessed outcomes (Self Monitored Pain Index and WHYMPI) in the study of Spence (4), the 2 biopsychosocial interventions were not more effective than the 2 reference interventions after 8 weeks of follow-up. After 6 months, data on the waiting-list referents could not be used, but in the comparisons between the other groups no statistically significant differences were found, although there was a trend showing that applied relaxation could have been more effective than any of the other forms of intervention. The sample size was too small to show a statistically significant effect, however.

Grading of the scientific evidence

The large heterogeneity of the study population, the interventions, the outcomes, and the follow-up times of the 2 studies indicated that statistical pooling would have been inappropriate, even if possible. According to a qualitative analysis, the evidence of the effectiveness of biopsychosocial rehabilitation for RSI was graded as limited. This limited evidence showed (i) a positive effect of hypnosis combined with comprehensive treatment in comparison with comprehensive treatment alone after 6 weeks of follow-up and (ii) no differences in effect between applied relaxation, EMG biofeedback plus applied relaxation, and the waiting-list conditions after 8 weeks and 6 months.

Discussion

Included studies and results

RSI of the upper extremities is usually considered to be associated with repetitive tasks at work. Therefore, workplace visits with an ergonomic evaluation could be expected to be included in biopsychosocial rehabilitation, as was done in the study of Moore (18). However, because a worksite visit was also part of the control intervention, the effectiveness of worksite visits could not be assessed. We think that relying on the positive result of hypnosis on pain intensity after 6 weeks of follow-up is debatable, and it would be interesting to see whether a positive effect would be maintained for a longer period after treatment.

Behavioral treatments are a fundamental feature of biopsychosocial rehabilitation for chronic musculoskeletal disorders. However, there were no studies comparing behavioral or biopsychosocial programs with non-biopsychosocial programs. The study of Spence et al (4) could have provided evidence of the effectiveness of different types of behavioral treatments for RSI for use in decision making with respect to combining effective behavioral treatments with other rehabilitation programs for RSI patients. However, the results did not favor using applied relaxation or EMG biofeedback plus applied relaxation in rehabilitation, but they did indicate a need for larger studies.

Table 2. Methodological quality scores of the included studies.^a

Author	Year	Method of randomization	Concealment of treatment allocation	Blinding of patients	Blinding of therapists	Blinding of observers	Similarity of baseline characteristics	Co-interventions avoided or equal	Compliance	Withdrawals <20%	Intention-to-treat analysis	?	Total +
Moore	1996	?	+	-	-	-	?	?	?	+	+	4	3
Spence	1995	?	?	-	-	-	+	?	?	-	-	4	1

^a Each quality item was rated positive (+) if the methodological criterion was fulfilled, negative (-) if the criterion was not fulfilled, and unclear (?) if data were not available. The maximum score was 10; studies with a total of >5 were considered to be of high methodological quality.

Definition of repetitive-strain injury

The definition of RSI encompasses a range of upper-extremity disorders, which are often manifested during manual handling tasks. If the diagnoses vary, as in the 2 studies included in this review, it may be difficult to generalize the results to a setting in which the spectrum of the diagnoses is different. We think that a single diagnostic entity would be a far more fruitful starting point as an intervention study for RSI. Unfortunately, we did not find any studies of this kind for this review. However, we think that biopsychosocial rehabilitation may have a role in the treatment of any diagnosis included in RSI, when we are dealing with working age adults. In the acute stage, intervention in the workplace may speed up recovery, and, if the pain becomes chronic, psychosocial rehabilitation may help the patient cope with the situation.

Definition of biopsychosocial rehabilitation

In this review, we required each intervention to be executed by a professional of the discipline in question. A psychologist should be involved with psychological or behavioral treatment, but, on the other hand, a social worker, an occupational health nurse, or an occupational physiotherapist could perform social intervention. An occupational health nurse or physiotherapist specialized in the field of occupational health care could provide the vocational intervention.

We considered that a physician needed to be part of the rehabilitation procedure, in order to enhance the reliability of the diagnosis, and a physician should have made a differential diagnosis to exclude diseases that did not belong to the study domain. Furthermore, we considered treatment provided by physiotherapists or nurses as relevant from the viewpoint of biomedical rehabilitation. We defined biopsychosocial rehabilitation as rehabilitation that contains at least 2 biopsychosocial components. Therefore, programs that included a physician's intervention and traditional physiotherapy were not included. Trials were not excluded if any psychological, social, or vocational intervention was used in addition to physiotherapy.

To consider EMG biofeedback as a behavioral treatment is controversial. In this review we excluded studies in which EMG biofeedback was the only component of psychosocial rehabilitation. The study of Spence (4) was included because the intervention for the biopsychosocial rehabilitation groups contained applied relaxation provided by a psychologist and applied relaxation combined with the EMG biofeedback.

Validity of the review

A challenging part of conducting a systematic review is finding all relevant papers. We identified only 1 relevant

trial by searching the electronic databases. Because our original literature search did not focus especially on RSI, it is possible that we may have missed some studies on RSI. One additional study was identified through contacting the Cochrane Musculoskeletal Injuries Group. However, we believe that we found most of the existing relevant papers.

The study selection was primarily based on abstracts. To ensure that every relevant study was selected, we retrieved the full article for further assessment if there was any doubt about the study fulfilling the inclusion criteria. Retrieving full copies of all articles would have been extremely time consuming and expensive. Furthermore, the electronic database search also produced many irrelevant articles for our purposes, such as case reports and letters.

To avoid bias, we blinded the reviewers with regard to authors, institute of origin, journal, and acknowledgments. At the study selection stage blinding demanded much work, but it may have reduced any selection bias.

When assessing the methodological quality of the individual trials, we only included the items reflecting internal validity (15, 19). We did not quantify the importance of each validity item, as the weights can be considered arbitrary.

Clinical relevance of the included studies

Intervention studies are intended to be applicable in clinical practice. Assessment of the applicability of the results demands that patient characteristics and interventions be described precisely enough for readers to make clear inferences about which patients can be treated, how they can be treated, and by whom (or in what setting). Pertinent outcome measurements are also important for clinical relevance.

In both of the randomized controlled trials included in this review, patients on waiting lists served as a reference group, and their use posed a drawback in that waiting-list referents can only provide short-term results. The study of Moore (18) was designed to have only 6 weeks of follow-up, and therefore the use of waiting-list patients was understandable. Still, clinically, a longer follow-up would have been more relevant, even for acute RSI patients. Spence et al (4) concentrated on chronic RSI patients, and, therefore, the value of a 4–6 weeks waiting-list reference group is questionable because data could not be used in the 6 months' comparison.

Methodological quality of the studies

The low methodological quality was mainly due to an insufficient description of the method of randomization and a lack of blinding. Blinding patients and therapists in randomized controlled trials on rehabilitation is usually not possible, but a feasible alternative is to evaluate

baseline expectations of both patients and therapists for the intervention and reference groups.

The information reported in the articles was insufficient for 8 out of 20 (40%) methodological quality items. This rate of insufficiency may hopefully improve in the future, now that many journals have accepted the CONSORT statement on the quality of reporting randomized controlled trials (20).

Level of the scientific evidence for the effectiveness of intervention

Methods for structured systematic reviews are constantly evolving. Using different methods for grading the evidence may lead to different conclusions.

Proposed studies

Any trials that would unequivocally fulfill the criteria of truly biopsychosocial rehabilitation could not be included in this review. We think that, at the acute phase of RSI symptoms, it would be important that the rehabilitation focus on worktasks, as well as biomedical treatment. In the chronic stage more comprehensive rehabilitation paying attention to biomedical, psychological, social, and occupational factors may be needed for the patients to continue working. In the near future, we would like to be able to investigate these types of trials, which would fulfill the methodological and clinical requirements of a high-quality study. The study population should be large enough (at least 50 patients for each treatment) to be able to show statistically significant differences in clinically meaningful changes in relevant outcome measures. For example, at least a 15-mm reduction in the intensity of pain, as measured with a 0–100 mm VAS, or a statistically significant reduction in days on sick leave due to RSI. Because RSI is a heterogeneous group of disorders, to study a single diagnosis (eg, lateral epicondylitis) would be preferable. Biopsychosocial intervention could be compared with usual care or with some treatment that is commonly used but has not been shown to be effective. The pertinent follow-up of the patients is dependent on the duration of the disorder and on the duration, content, and intensity of the intervention. Arbitrary recommendations for follow-up may vary for acute patients from 6 to 12 months and among chronic pain patients from 1 year to a couple of years.

Concluding remarks

Two trials, both assessing the effectiveness of a very specific intervention, could to be included in this systematic review. We found limited scientific evidence showing that hypnosis, combined with comprehensive rehabilitation, has some positive effect in the treatment of recently diagnosed RSI and that applied relaxation has a trend towards a positive effect in comparison with EMG biofeedback combined with applied relaxation, EMG

biofeedback alone, or 8 weeks of being on a waiting list when chronic RSI patients are being treated. Drawing clinical conclusions about the magnitude and duration of the effect of any intervention for RSI was hampered by the lack of high-quality studies. We believe that no health policy decisions concerning the effectiveness for biopsychosocial rehabilitation for RSI can be made at present.

There seems to be an obvious need for good-quality randomized controlled trials on comprehensive biopsychosocial treatment programs for RSI, especially for those that would include workplace intervention. Focus on a single disease entity would enhance the generalizability of the results. In addition, more exploring studies on the effectiveness of specific components of these programs would be valuable.

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Appendix 1

Criteria used for the methodological assessment of multidisciplinary rehabilitation trials for musculoskeletal disorders

Each of the following criteria was rated as positive (+), negative (-), or unclear (?).

1. *Method of randomization*: rated positive if a random (unpredictable) assignment sequence was used.
Concealment of treatment allocation: rated positive if an independent person not responsible for determining the eligibility of the patient generated the assignment. Examples of adequate concealment procedures, also scored positive, were some form of centralized randomization scheme, numbered or coded containers, an onsite computer system providing allocations in a locked, unreadable file that could be assessed only after the characteristics of an enrolled participant were input, and sequentially numbered, sealed, opaque envelopes. Clearly inadequate were procedures such as alternation or reference to case record numbers, dates of birth, and day of the week or any such other approach. If the concealment of treatment allocation was described only as random or randomized it was rated as unclear.
2. *Blinding of patients*: rated positive if the patients were blinded regarding treatment allocation and the method of blinding was appropriate. If the blinding of patients was not feasible or if the trial was pragmatic, the credibility of the treatment modalities (forms of intervention) should have been evaluated, and the treatment modalities should have been credible and acceptable to patients.
3. *Blinding of therapists*: rated positive if the therapists were blinded regarding treatment allocation and the method of blinding was appropriate. If the blinding of therapists was not feasible or if the trial was pragmatic, the credibility of the treatment modalities (forms of intervention) should have been evaluated, and the treatment modalities should have been credible and acceptable to the therapists.
4. *Blinding of observers*: rated positive if the observers were blinded regarding treatment allocation and the blinding was evaluated and adequate. It was rated negative if only self-reported (questionnaire) outcomes were used and there were no observer outcomes.
5. *Similarity of baseline characteristics*: rated positive if, according to the reviewers, the study groups were comparable at the beginning of the study. For example, age, gender, job demands, duration and intensity of pain, functional status, and sick leaves due to repetitive strain injury were considered.
6. *Co-interventions avoided or equal*: rated positive if co-intervention was avoided in the design of the study or was equally divided among the intervention groups.
7. *Compliance*: rated positive if, according to the reviewers, compliance was measured and satisfactory in all the study groups.
8. *Withdrawal rate*: rated positive if there was less than a 20% loss of patients at the main time of outcome measurement.
9. *Intention-to-treat analysis*: rated positive if all the patients were included in the analysis as part of the intervention group allocated by randomization, irrespective of noncompliance and co-intervention. If loss to follow-up was substantial (20% or more), an intention-to-treat analysis and an alternative analysis, accounting for missing values (eg, a worst-case analysis) should have been performed.