

Relaxation for the relief of chronic pain: a systematic review

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Relaxation for the relief of chronic pain: a systematic review

The effectiveness of relaxation techniques in the management of chronic pain was determined in this systematic review of published randomized controlled trials. Reports were sought by searching MEDLINE, psycLIT, CINAHL, EMBASE and the Oxford Pain Relief Database. Studies were included in this review if they were randomized controlled trials of relaxation techniques in chronic pain. Studies which investigated the effects of relaxation in combination with other interventions were not considered. Nine studies involving 414 patients met the predefined inclusion criteria and are critically appraised in this review. Meta-analysis was not possible, due to lack of quantitative data in the primary studies. Studies involved patients with a range of chronic pain conditions. The McGill Pain Questionnaire was the most common pain outcome used. Whilst four studies were able to show a significant difference for the pain outcomes in favour of relaxation for the pre- and post-treatment assessments, few statistically significant differences were reported in favour of relaxation when between treatment comparisons were used. Only three studies reported statistically significant differences in favour of relaxation (judged as a significant difference for at least 1 of the pain outcomes) compared to the other treatment groups. In rheumatoid arthritis the McGill Pain Questionnaire scores were significantly lower for patients receiving relaxation compared to those who were in the routine treatment control group. In ulcerative colitis significant differences were reported for six of seven different pain outcome measures in favour of progressive muscle relaxation compared to patients in the waiting list control group. In one of the two cancer pain studies, relaxation taught by nurses produced significantly lower pain sensation scores compared to the control group. Two studies reported significant differences in favour of the experimental control groups rather than for relaxation. There is insufficient evidence to confirm that relaxation can reduce chronic pain. Many of the studies both positive and negative suffer methodological inadequacies. Recommendations for future research into the effectiveness of relaxation techniques for chronic pain are made.

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BACKGROUND

Relaxation strategies are a common component of multi-modal chronic pain management programmes (Owens & Ehrenreich 1991, Jessup & Gallegos 1994, Linton 1994,). There are now several published meta-analyses on the effectiveness of multi-modal interventions (Mullen *et al.* 1987, Malone & Strube 1988, Flor *et al.* 1992,), but these do not examine the specific effects of relaxation on pain. Relaxation techniques have become especially popular, either as a sole or combination intervention together with biofeedback, in the treatment of headache and migraine (Jessup & Gallegos 1994). The results of meta-analysis and systematic reviews in headache and migraine show conflicting results (Blanchard & Andrasik 1982, Holroyd & Penzien 1986, Hyman *et al.* 1989, Holroyd & Penzien 1990). Others promote the use of simple relaxation techniques that can be learnt by nurses who can then teach skills to patients who can use these techniques as necessary at home (Pearce 1993). However, the evidence on which this recommendation is based is unclear and the precise role of relaxation in the management of pain is uncertain (McCaffery *et al.* 1994). It may have an effect on coping rather than having specific effects on pain (Craig 1994).

A recent review into the effectiveness of relaxation and behavioural therapies in chronic pain does not add to existing knowledge (NIH Technology Assessment Panel 1996). Although the authors of this report conclude that there is strong evidence to support the use of behavioural and relaxation interventions in chronic pain, they do not provide the evidence on which they base these conclusions. These recommendations are based on the results of a consensus meeting, a method which is open to potential bias. Although the published report hints at a systematic and a thorough search of the literature, the methods used to do this are not reported, other than to briefly mention the use of MEDLINE and details of the search strategy used. Neither are the specific inclusion and exclusion criteria for the review given. Therefore these methods cannot be replicated by others. The final and perhaps most concerning aspect of this review is the lack of information and detail on the primary studies used. There are no details of these primary studies given in the tables, results or even the reference list. Details of the bibliography are reported to be held on a WEB Site address. It has not been possible to access this list or any other source of primary references from this site.

The aim of this paper is to establish the effectiveness of relaxation strategies in managing chronic pain by means of a systematic review of published randomized controlled

trials. The findings of this review will provide direction for future research in this important area of nursing research.

METHODS

Randomization has become the gold standard in pain research methodology when the purpose of the study is to compare the relative effectiveness of two or more interventions. Randomization methods can be relatively simple and such methods have been described elsewhere (Altman 1991). Non-randomized trials are believed to overestimate treatment effects and in randomized controlled trials inadequate concealment of randomization produced an overestimation of odds ratios by up to 40% (Schulz *et al.* 1995).

Published randomized controlled trials (RCTs) which reported the use of a relaxation strategy as an active treatment, which was compared with at least one other active or control treatment, in patients with either chronic cancer or chronic non-malignant pain conditions were actively sought. Reports were included only if they used at least one pain outcome measure. Studies in which a relaxation technique was studied in combination with another pain intervention, such as cognitive behaviour therapy, biofeedback, hypnosis or imagery were not actively sought. Combination studies were not included in this review as it seemed appropriate to look at all multi-modal studies together in one separate review. Unpublished studies were not actively sought and authors of published studies were not contacted for additional information. Reports of RCTs in headache or migraine were not considered, neither were studies in acute pain conditions or laboratory experiments. Studies with treatment groups of less than 10 subjects were excluded (L'Abbe *et al.* 1987). Abstracts and review articles were not considered.

A number of different methods were used to identify eligible reports. These included searching of the following electronic databases using both Knowledge Server Version 3.25 and WINSPIRS Version 2.32 as the search platforms: MEDLINE (1966–6/1996), psycLIT (1974–6/1996), CINAHL (1982–6/1996), EMBASE (1980–6/96) and the Oxford Pain Relief Database (19506/1994) (Jadad *et al.* 1996). The Oxford Pain Database is a computerised reference database containing the reference citations of over 13 000 randomized controlled trials for pain interventions. This database was developed from an optimized search of MEDLINE and the hand-search of 40 biomedical journals.

The search for this review was done in two stages. Initially the word 'relax' and variants of the word relaxation were used as free-text search terms in searching, including combinations of these words, and without

restriction to language. MeSH headings were found to be inadequate in identifying appropriate studies and thus were not used in a deliberate attempt to maximize recall, even though this meant over-selection of potential studies. The second stage of the electronic search including searching for studies including imagery, hypnosis, visualization and cognitive therapy, using a variety of free text combinations of these terms in attempt to maximize yield. Additional reports were identified from the reference lists of retrieved reports, published review articles and textbooks.

Each study which could possibly meet the inclusion criteria was read by both authors independently. Studies were scored for methodological quality using a modified 3-item scale (Jadad *et al.* 1996). Studies which were described as randomized were given one point, and a further point if the method of randomization was given and was appropriate (use of random number tables, for instance). Where the method of treatment allocation was unconcealed (alternate allocation, for instance) the report was excluded. The double blinding of relaxation studies was anticipated to be difficult, because of the nature of the intervention, therefore this item from the Jadad *et al.* (1996) scale was omitted. Studies which described the number and reasons for withdrawals were given one point. Included studies could thus have a maximum score of 3 and a minimum score of 1.

Information from each study was extracted systematically, to obtain the following details on: the pain condition, site of pain, number of subjects approached and the number who entered into the study, aims of the study and its design. Additional information on the pain outcomes, psychological outcomes, and treatment groups (experimental and control) was summarized (Table 1). If available, details of the type of relaxation technique, frequency of its use, when and by whom and instructions to patients were extracted from each study. Any withdrawals and adverse effects were noted and the overall findings were summarized. Study interventions were considered to be effective if p -values < 0.05 were reported for at least one pain and/or psychological outcome. Post-hoc subgroup analysis in the original study reports were not considered.

RESULTS

The results for the included studies are presented in Tables 1a and b. The details of the studies excluded are shown in Table 2. Quality scores of the included studies ranged between 1 and 3. Both authors independently rated all nine studies, and agreement between the scores was 9/9.

Nine studies involving 414 patients met the predefined criteria for this review. Eight studies used a parallel group design and one study used a cross-over design (Graffam &

Johnson 1987). Two of the studies involved oncology patients (Graffam & Johnson 1987, Sloman *et al.* 1994). The other seven (Okeson *et al.* 1983, Funch & Gale 1984, Shaw & Ehrlich 1987, Dulski & Newman 1989, Seers 1993, Donaldson *et al.* 1994, Gunther *et al.* 1994) were in a variety of different chronic non-malignant pain conditions including low back pain (2), rheumatoid arthritis (1), temporomandibular joint dysfunction (1), fibromyalgia (1), and ulcerative colitis (1). The most common form of relaxation was progressive muscle relaxation (6) with tape recordings and regular home practice. Of the 414 patients, 196 received relaxation. Sample sizes for the relaxation only groups ranged from 12 to 30. Treatment periods varied, as did the frequency and duration of relaxation.

Four studies used a waiting list control (Shaw & Ehrlich 1987, Dulski & Newman 1989, Seers 1993, Sloman *et al.* 1994). Of these only one used an attention control (Seers 1993). Only one study made a direct comparison of two different relaxation techniques (Sloman *et al.* 1994): taped and live relaxation. However, the method used in the live relaxation was not reported. Active treatment controls included biofeedback, education, imagery, routine care, occlusal splint and hydro-galvanic baths as shown in Table 1a.

A range of different pain outcomes were used in the studies, the McGill Pain Questionnaire (MPQ) being the most common. All but one study used more than one different subjective patient rating to assess pain. The other study used single investigator ratings of pain on palpation in patients with temporomandibular joint dysfunction (Okeson *et al.* 1983).

The results were generally presented as means or medians. Few studies presented the results as individual patient data. Only two studies specifically assessed anxiety and or depression (Funch & Gale 1984, Seers 1993), although some studies did look at other psychological and functional/activity outcomes. Assessments commonly involved pre- and post-treatment clinic assessments and self-report patient diaries. Only three studies examined the long-term use of relaxation, that is 4 months or more (Funch & Gale 1984, Seers 1993; Donaldson *et al.* 1994). The longest follow-up was made by telephone at 4 years (Donaldson *et al.* 1994).

No analysis of pooled data was possible due the inadequate reporting of original data and likely heterogeneity. None of the studies reported any complications as a direct result of relaxation.

Studies in chronic non-malignant pain

Within treatment study comparisons

Of the five studies in chronic non-malignant pain that reported within group (pre-post test) differences two showed that relaxation had a significant difference for at least one pain outcome and/or other outcomes (Dulski & Newman 1989, Seers 1993) and three did not.

Table 1 Randomized controlled trials of relaxation alone in chronic pain

Author	Pain condition/site of pain/entry criteria	Number of patients	Study design	Treatment groups	Pain & other outcomes	Results for main pain outcomes (statistical tests significance at 0.05 level)	Withdrawals & dropouts	Authors overall comment	Our comment & quality score
<i>Studies in chronic non-malignant pain</i>									
Donaldson <i>et al.</i> (1994)	Low back pain > 1 year 18-55 yr	36	RCT, parallel group Assessment pre- and post-treatment 90 days Telephone follow up at approx. 4 yr	1. Progressive muscle relaxation training (modified) 10 × 35 min sessions n=12 2. Single motor biofeedback training n=12 3. Educational n=12	1. McGill PQ 2. VAS pain intensity (average score/group & change (0-5)) 3. MMPI 4. EMG	Within group: sd for education & biofeedback NSD for relaxation Between groups: NSD for McGill PQ, or VAS At follow up biofeedback sig. lower McGill PQ scores than relaxation	No dropouts at 90 days 26/36 available at 4-year assessment	No effect for relaxation Assessor blind to treatment allocation	Complicated analysis, one way ANOVA for-between treatment effects QS=3
Dulski & Newman (1989)	Rheumatoid arthritis Females	60	RCT, parallel group Assessment pre- and post-treatment No long-term follow-up	1. Progressive muscle relaxation (Jacobson & Benson) relaxation 10-120 min. => BD × 4 weeks n=30 2. Routine-treatment control n=30	1. McGill PQ 2. Analgesic consumption 3. Stanford arthritis disability & discomfort scale 4. Daily diaries × 4 weeks	Within treatment: sd for control & relaxation groups for McGill PQ Between treatment: sd between treatments for McGill PQ	43/60 completed & analysed 15/60 failed to return for post-test assessment 2/60 did not receive instructions	Positive result in favour of relaxation. Compared to routine treatment	sd in baseline pain between groups QS=2
Funch & Gale (1984)	Temporo-mandibular joint dysfunction => 2 yr	57	RCT, parallel group One week baseline run in period with patient diaries Assessment pre- and post-treatment Long-term telephone follow up at 1 yr	1. Relaxation (3 × 20 min tapes taught in clinic & practised daily × 12 weeks) n=27 2. Biofeedback relaxation (20 min daily sessions) n=30	1. Derived average weekly pain score (pain intensity 0-6, TDS) 2. Investigator rating change in pain (0-7) 3. Wallstones' Locus of Control 4. Taylor manifest anxiety 5. Involvement in therapy (0-5)	NSD between treatments	Not described in detail, but not all available for long term assessment	NSD overall	QS=1

Table 1 (Continued)

Author	Pain condition/site of pain/entry criteria	Number of patients	Study design	Treatment groups	Pain & other outcomes	Results for main pain outcomes (statistical tests significance at 0.05 level)	Withdrawals & dropouts	Authors overall comment	Our comment & quality score
<i>Studies in chronic non-malignant pain</i>									
Gunther <i>et al.</i> (1994)	Fibromyalgia	25	RCT, parallel group Assessment pre- and post-treatment No long-term follow-up	1. Progressive muscle relaxation (Jacobson 4 session/3 weeks, then OD × 2 weeks) <i>n</i> = 13 2. Hydro-galvanic baths (twice weekly × 5 weeks, × 20 min + 30 min rest) <i>n</i> = 12	1. McGill PQ 2. % pain intensity (different time points) 3. Presence of other symptoms 4. Sleep (1–3) 5. 79-item pain behaviour assessment	Between treatment: <i>sd</i> pain in the mornings less for bath therapy No other <i>sd</i> between treatments	None reported	Only <i>sd</i> was for pain in the morning in favour of baths	Pain intensity scores appeared lower post-treatment for both groups, but statistical tests not reported. <i>sd</i> for pain in morning reported in favour of relaxation in results (incorrectly) QS = 2
Okeson <i>et al.</i> (1983)	Temporo-mandibular joint dysfunction	24	RCT, parallel group Assessment pre- and post-treatment Follow up 4–6 weeks	1. Relaxation (tape, Modified Jacobson instructed to use daily) <i>n</i> = 12	1. Investigator rating pain on palpation (0–3)	Between treatment: <i>sd</i> for mean total pain on palpation in favour of splint. <i>sd</i> for mean maximal & comfortable inter-incisal distance for splint	None reported	Splint more effective than relaxation	Problem of sensitivity Main pain outcomes — investigator rating of pain on palpation QS = 1
Seers (1993)	Chronic non-malignant pain > 3 months age = > 18 yr	75	RCT, parallel group Assessment pre- and post-teaching Follow-up 1 & 4 months	1. Taught progressive muscle relaxation & applied relaxation (× 1/week × 4 weeks) <i>n</i> = 27 2. Attention control <i>n</i> = 28 3. Waiting list control <i>n</i> = 20	Clinic assessments & diaries 1. McGill PQ 2. Numerical rating scale 0–100 3. Quality of life — sickness impact profile 4. Coping strategies 5. Self-efficacy 6. Hospital anxiety & depression scale	<i>sd</i> relaxation pre & post-test for McGill PQ, anxiety, disability (SIP), NSD for any pain outcomes between treatments	8 dropped out, 2 excluded 4 lost to follow-up	<i>sd</i> for pain, anxiety & disability in favour relaxation	Some evidence that relaxation reduced pain (pre-post assessments), no significant differences for pain between treatment groups QS = 3

Study	Population	Sample Size	Intervention	Comparison	Outcomes	Results	Notes
<i>Studies in chronic non-malignant pain</i>							
Shaw & Ehrlich (1987)	Ulcerative colitis > 6 months age 20-60 yr	40	RCT, parallel group Assessment pre- and post-treatment 6-week follow-up	1. Progressive relaxation 75 min sessions x 6 Tapes for home practices OD n=20 2. Attention control (waiting list with weekly telephone calls) n=20	1. McGill PQ 2. Zung pain & distress scale 3. Present pain intensity (1-10) 4. Duration of pain episode 5. Pain relief (1-10) 6. Analgesic consumption	Between treatment: SD for 6/7 pain outcomes McGill words, pain intensity, pain frequency, pain relief, pain distress, number taking anti- inflammatory drugs post-treatment	sd in favour of relaxation Positive result in favour of relaxation QS = 1
<i>Studies in cancer pain</i>							
Graffam & Johnson (1987)	Oncology patients 18-80 yr	30	RCT, cross-over treatments given on sequential days Assessment pre- and post-treatment	1. Progressive muscle relaxation (15 min tape) n=15 2. Pleasant guided imagery (15 min tape) n=15	1. VAS pain intensity (0-10) 2. VAS pain distress (1-10)	Within treatment: SD for both treatments for pain intensity & distress NSD between treatments	NSD between treatments 67% preferred relaxation SD in baseline pain for the 2 treatments. No long-term data QS = 2
Sloman <i>et al.</i> (1994)	Oncology patients	67	RCT, parallel group Assessment pre- and post-treatment	1. Progressive muscle relaxation + imagery (tape) BD x 3 weeks + PRN n=20 2. Live relaxation (taught by nurses) n=20	1. VAS pain intensity 2. McGill PQ (short form) 3. Analgesic consumption	Within treatment: SD for both active treatments vs control for current pain intensity overall pain intensity, pain sensation, non opiate PRN Between treatment: NSD between experimental groups except pain sensation, which was significantly lower in live relaxation group	Both active treatments effective Positive effect for taped & nurse-taught relaxation, NSD between relaxation groups QS = 2

OD = once daily, BD = twice daily, McGill PQ = McGill Pain Questionnaire, sig = significant, QS = quality score, NSD = no statistically significant difference, PRN = as required, SIP = sickness impact profile, OD = once a day, MMPI = Minnesota Multiphasic Personality Inventory.

Table 2 Excluded randomized controlled trials of relaxation in chronic pain

Author & date of publication	Total patients studied	Details	Reason for exclusion	Overall outcome
Achterberg <i>et al.</i> (1981)	24	RCT, parallel group 2 phase (phase 2 not RCT Assessments pre- & post-treatment (after 6 & 12 sessions) No post-study long-term follow-up. Biofeedback to increase skin temperature (12 × 30 min sessions/6 weeks) <i>n</i> = 12 vs biofeedback to decrease skin temperature (12 × 30 min sessions/6 weeks) <i>n</i> = 12 vs biofeedback technology (Model 302) NB: all patients had disease information & taped relaxation pre-biofeedback with home practice = >BD	RCT, combination treatment	Biofeedback + relaxation reduced pain, but NSD between specific types of biofeedback
Altmaier <i>et al.</i> (1992)	45	RCT, parallel group. Assessments pre- and post-treatment. 6-month follow-up. Standard 3-week inpatient physical rehabilitation programme (BD sessions: physio, aerobics, education, counselling, etc.) <i>n</i> = 21 vs standard 3-week inpatient rehabilitation programme + operant conditioning (including daily relaxation group training, home practice, biofeedback 5 × 1 h cognitive skills) <i>n</i> = 24	RCT, combination treatment	Both treatments are effective, but no advantage when adding other components. Improvements in pain & function not maintained at 6 months
Arathuzic (1994)	24	RCT, metastatic breast cancer, 3 treatments: relaxation + visualization, <i>n</i> = 8 vs relaxation + visualization + cognitive coping skills <i>n</i> = 8 vs standard care control <i>n</i> = 8	RCT, less than 10 per treatment, combination treatment	NSD pain, distress, mood, SD for ability to decrease pain (perception)
Bernal i Cercos <i>et al.</i> (1995)	48	RCT, anxiety or untreated somatoform disorders, anti-depressive + relaxation <i>n</i> = 31 vs control <i>n</i> = 17. Spanish English Abstract	RCT, combination treatment, not all subjects had pain	Positive result in favour of relaxation in patients with pain, not anxiety
Biedermann <i>et al.</i> (1987)	24	RCT, back pain > 6 months, 3 treatment groups involving different EMG biofeedback, <i>n</i> = 8/treatment group	RCT, combination treatment, less than 10 patients per treatment group	NSD between study treatments. SD within treatment
Brooke & Stenn (1981)	174	RCT, myofascial pain, <i>n</i> = 174, 4 treatment groups: physiotherapy vs occlusal splint vs biofeedback + relaxation vs relaxation, number of subjects/treatment group not given	RCT, abstract	NSD between study treatments
Burkhardt <i>et al.</i> (1994)	99	RCT, parallel group. Assessments pre- & post-training. Follow-up 6 & 12 weeks post-training, Long-term follow-up 4–8 months post-training. Education (including relaxation strategies: 6 week self-management course, with training 6 × 1.5 h sessions) <i>n</i> = 31 vs education (including relaxation + physical training (6 h exercise) <i>n</i> = 33 vs waiting list control <i>n</i> = 35	RCT, combination treatment	Both treatments effective

Table 2 (Continued)

Crockett <i>et al.</i> (1986)	21	RCT, chronic facial pain, 3 treatment groups: dental splint + physio $n=7$ vs biofeedback + relaxation $n=7$ vs TENS $n=7$	RCT, combination treatment, less than 10 per treatment group	NSD between treatment groups. SD within treatment for pain intensity & frequency
Fialka <i>et al.</i> (1996)	18	RCT, upper limb reflex sympathetic dystrophy, 2 treatments, autogenic training with relaxation $n=9$ vs control $n=9$	RCT, combination treatment, less than 10 per group	NSD for pain outcomes, SD for skin temperature between treatments
Guthrie <i>et al.</i> (1991)	102	RCT, parallel group. Assessments pre- & post-training, Long-term follow-up 1 year. Active psychological treatment \times 3 months (including relaxation tape) $n=53$ vs standard medical treatment $n=49$	RCT, combination treatment	active psychological treatment superior to standard medical treatment on a variety of outcomes
Lavigne <i>et al.</i> (1992)	8	RCT, juvenile rheumatoid arthritis, 2 treatments: immediate treatment including relaxation $n=4$ vs delayed treatment (including relaxation) $n=4$	RCT, less than 10 per treatment group, combination treatment	NSD within treatment pain scores. Too small to make valid conclusions
Linton & Gotestam (1984)	20	RCT, chronic back pain, 3 treatments, waiting list control $n=5$ vs applied relaxation $n=8$ vs applied relaxation + operant conditioning $n=7$	RCT, less than 10 per treatment group	Active treatment groups significantly better than control
Linton <i>et al.</i> (1985)	28	RCT, chronic pain, 3 groups: cognitive behaviour therapy + relaxation $n=8$ vs routine care $n=10$ vs waiting list control $n=10$	RCT, combination treatment, less than 10 per treatment group	Behaviour therapy treatment significantly better than other treatments
Lorig & Holman, (1989)	589	RCT, arthritis, self-management course including relaxation 3 treatments: bi-monthly newsletter $n=130$ vs 6 week reinforcement course $n=260$ vs no reinforcement control $n=153$	RCT, combination treatment, not clear whether relaxation was used during study	NSD between groups, within treatment 0–20 month pain reduced by 20%
Nicholas <i>et al.</i> (1991)	58	RCT, low back pain, 6 treatments: cognitive therapy $n=10$ vs cognitive therapy + relaxation $n=8$ vs behaviour therapy $n=10$ vs behaviour therapy + relaxation $n=9$ vs attention control $n=10$ vs no attention $n=11$	RCT, combination treatment, less than 10 subjects in each group	Relaxation made no difference to cognitive or behavioural therapy
Peniston & Kao (1985)	8	RCT, chronic pain, 2 groups, EMG biofeedback + relaxation $n=4$ vs control with pharmacological interventions $n=4$	RCT, less than 10 per treatment group, experimental pain model	Groups too small to make valid statistical conclusion
Puder (1988)	71	RCT, parallel group, 7-day baseline monitoring period, Assessments pre- & post-treatment (active w10, 14, 20 & 24. Control weeks 10, 20, 24. Follow-up 1 & 6 months. Cognitive behaviour therapy including progressive muscle relaxation therapy (group sessions) 10 weeks treatment \times 2 hr $n=32$ vs Delayed waiting list control $n=39$	RCT, combination treatment	Active treatment significantly better than control. Benefit maintained at 6 months

Table 2 (Continued)

Shearn & Fireman (1985)	105	RCT, parallel group, Assessment pre. Follow-up 4 (8?) months. Stress management + relaxation (10 weekly 90 min sessions of relaxation) $n=35$ vs mutual support $n=35$ vs no treatment control $n=35$	RCT, combination treatment	Only SD was # of painful joints
Stam <i>et al.</i> (1984)	61	RCT, parallel group. assessments pre-, intra- & post-treatment. Follow up 4–6 weeks post-treatment. Hypnosis + cognitive coping $n=12$ vs standard progressive relaxation + cognitive coping $n=15$ vs waiting list control $n=14$	RCT, combination treatment	NSD between active treatments, but relaxation better than control after 2 weeks
Stuckey (1986)	24	RCT, low back pain > 6 months, 3 treatments: EMG biofeedback $n=8$ vs relaxation $n=8$ vs control $n=8$	RCT, less than 10 per treatment	Relaxation was more effective in reducing pain & EMG
Turk <i>et al.</i> (1993)	80	RCT, 2 phase. (phae 2 not RCT). Assessments pre- & post-treatment. Follow-up 6 months. Intra-oral device 6 weeks $n=30$ vs biofeedback, assisted relaxation & stress management weekly $\times 1$ h $\times 6$ weeks $n=30$ vs waiting list control $n=30$	RCT, combination treatment	Long-term biofeedback sig. better than intra-oral device
Turner & Jensen, (1993)	102	RCT, parallel group. Assessments pre- & post-treatment. Follow-up 6 & 12 months. Progressive muscle relaxation training + imagery & daily practice with tapes 2 h/week $\times 6$ weeks $n=24$ vs progressive muscle relaxation + cognitive therapy $n=25$ vs waiting list attention control $n=23$ vs waiting list control $n=30$	RCT, combination treatment	NSD between treatments, all effective
Turner (1982)	46	RCT, chronic back pain, progressive muscle relaxation vs cognitive behaviour therapy vs waiting list control	RCT, less than 10 in control group	NSD between groups

Between treatment study comparisons

Two of the seven studies reported significant differences between treatments for at least one pain outcome in favour of relaxation at the early post treatment assessment (Shaw & Ehrlich 1987, Dulski & Newman 1989). None of the three studies with a longer term follow-up ($= > 4$ months) reported any significant difference in favour of relaxation.

Where relaxation was compared to other interventions, one study (Okeson *et al.* 1983) reported significant differences for two of the pain outcomes used, favouring the oral splint device over the relaxation treatment. Similarly, in fibromyalgia the morning pain scores were significantly lower for the hydro-galvanic bath group compared to relaxation (Gunther *et al.* 1994). Two studies compared biofeedback to relaxation: Donaldson *et al.* (1994) reported significantly lower pain scores at the 4-year follow-up, using the McGill Pain Questionnaire for the biofeedback, but not the relaxation group. However, this finding was not replicated at a 2-year follow-up by Funch & Gale (1984).

Studies in cancer pain

Within treatment comparisons

The two oncology studies were both concerned with short-term effects of relaxation. Again significant within treatment differences were reported for some pain outcomes in both studies.

Between treatment differences

One of the studies (Sloman *et al.* 1994) reported statistically significant differences in favour of both relaxation techniques compared to the no treatment control group. No significant differences were detected between the two relaxation groups, but there were significant differences for pain sensation for the live relaxation only, vs no treatment control. In the other study (Graffam & Johnson 1987) no statistically significant differences were found between progressive muscle relaxation and pleasant guided imagery for either pain distress, or pain intensity. Significant differences were reported, however, in the baseline pain scores of the two treatment groups.

DISCUSSION

The results of this review suggest that there is little evidence to support the effectiveness of relaxation in the relief of chronic pain. Most of the studies included in this review reported significant differences between the pre- and post-treatment assessments, suggesting sensitivity for the outcome measures used. However, few between treatment differences were found between relaxation and the experimental and control treatment groups. Whilst pre- and post-test differences suggest change over time, between treatment differences are necessary to give an indication of relative effectiveness. Only three of nine studies reported significant differences in favour of relaxation compared to the control treatments, for at least one of the pain outcomes used (Shaw & Ehrlich 1987, Dulski & Newman 1989, Sloman *et al.* 1994); two in chronic pain and one in cancer pain. Two studies reported significant differences in favour of the active control treatments rather than relaxation (Okeson *et al.* 1983, Gunther *et al.* 1994).

Before starting the review, it was decided to exclude studies of a small sample size: less than 10 subjects per treatment arm. This may be considered too tough a hurdle by some. However, studies of inadequate sample size can lack the power needed to detect changes and result in either false positive and or false negative results. An interesting observation is that only one study (Seers 1993) examined for this review reported pre-hoc power calculations to determine the necessary sample size. The largest treatment group in the included studies was 30 per group, and it is not known whether they had the power to detect any change that may have existed. Researchers need to be aware of the problems with small samples and should take statistical advice at the developmental stage of clinical studies, to ensure that the results will have sufficient power.

Both the negative and positive studies included in this review had methodological problems which must be considered when making any general conclusions about the clinical use of relaxation in this context. The methodological quality of the included reports appeared to be low, however, this may be because of in house styles of health journals rather than because of inadequacies in the design of the primary studies. Some of the studies had limitations, such as Okeson *et al.* (1983) who used an investigator's assessment of pain on palpation. In this study no formal assessments of pain were made by the patient at any time, so in consideration of this the findings of this should be viewed with caution. In addition, this was the only assessment made of pain, whereas all the other studies in this review used two or more measures of pain. It is interesting to note that when multiple pain outcomes were used, often only one of them showed a significant difference. The judgement as to whether a study gave a positive or negative result in terms of pain relief used in this review could be

considered as over-generous, as this was based on at least one statistically significant difference for one outcome at a single assessment time.

The randomized controlled studies which were excluded from this review are summarized in Table 2. The main reasons for exclusion were that they were studies of relaxation used in combination with other interventions, such as biofeedback and multi-modal pain programmes.

More well designed and executed studies with adequate sample sizes are needed to examine the effect of different methods of relaxation on chronic pain. The relaxation methods used need to be reported in detail so that they can be reproduced by others in future research and in the clinical setting. The relaxation techniques used need to be clearly defined in terms of their nature, training, frequency and duration of use (dose and regimen). Professional background of the person or people teaching the relaxation and their experience in using relaxation would also be useful. Adequate control groups need to be used in order to measure the specific effects of relaxation on pain. This may require attention control and waiting list control groups. There is insufficient evidence to show which methods of relaxation are effective or otherwise. A comparison of different types of relaxation and ways of teaching it (for example, group vs one-to-one, tape vs live) would be a helpful addition to knowledge in this area. Relaxation strategies may not have a direct effect on pain, but may be useful in the management of other aspects of chronic pain such as coping and anxiety which may have an impact on patients' overall well-being and quality of life. Such outcomes could be usefully included in future research, to allow the wider impact of relaxation on chronic pain to be evaluated.

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