Combined physiotherapy and education is efficacious for chronic low back pain

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Manual therapy, exercise and education target distinct aspects of chronic low back pain and probably have distinct effects. This study aimed to determine the efficacy of a combined physiotherapy treatment that comprised all of these strategies. By concealed randomisation, 57 chronic low back pain patients were allocated to either the four-week physiotherapy program or management as directed by their general practitioners. The dependent variables of interest were pain and disability. Assessors were blind to treatment group. Outcome data from 49 subjects (86%) showed a significant treatment effect. The physiotherapy program reduced pain and disability by a mean of 1.5/10 points on a numerical rating scale (95% CI 0.7 to 2.3) and 3.9 points on the 18-point Roland Morris Disability Questionnaire (95% CI 2 to 5.8) , respectively. The number needed to treat in order to gain a clinically meaningful change was 3 (95% CI 3 to 8) for pain, and 2 (95% CI 2 to 5) for disability. A treatment effect was maintained at one-year follow-up. The findings support the efficacy of combined physiotherapy treatment in producing symptomatic and functional change in moderately disabled chronic low back pain patients. **[Moseley L (2002): Combined physiotherapy and education is efficacious for chronic low back pain. *Australian Journal of Physiotherapy* 48: 297-302]**

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Introduction

Chronic low back pain is a multifactorial phenomenon and it is not surprising that many therapeutic approaches exist. Some approaches are ineffective but manual therapy, specific muscle training, cognitive behavioural therapy and multidisciplinary pain management programs have all been supported. Distinct approaches tend to target distinct effects. For example, manual therapy (mobilisation and/or manipulation of the lumbar spine) is effective in reducing pain (Andersson et al 1999, Cherkin et al 1998, Triano et al 1995), and specific exercise programs which aim to restore normal function of the trunk muscles are effective in reducing disability and increasing performance at least in mildly disabled patients (Mannion et al 1999, O'Sullivan et al 1997). Although they may be effective in producing benefit across outcome domains, these approaches do not directly address psychosocial aspects of pain. In some patients, such aspects are thought to be enduring barriers to improvement. These patients may obtain more benefit from programs that directly address cognitive and behavioural aspects of pain.

Multidisciplinary pain management programs, which usually focus on cognitive and behavioural aspects, are primarily effective in reducing disability, promoting self-efficacy and normalising pain cognitions (Guzman et al 2001, McQuay et al 1997). Not all programs are alike; more intensive programs, although more expensive, appear to be more effective (Guzman et al 2001, Williams et al 1996). The fact that they require substantial personnel and economic resources is a limitation of multidisciplinary programs. An alternative way to target cognitive and behavioural aspects of chronic low back pain is through the targeted provision of information. Education in this manner attempts to effect change through reconceptualisation of the problem.

Employing an education approach may appear surprising because for some time, there has been a consensus that there is no clinically important effect of education programs for chronic low back pain (Cohen et al 1994). Reviews on education-based back schools appear convincing (Koes et al 1994), however, recent evidence suggests that the lack of effect is probably due to the type of information that has been presented. Studies that have employed an approach to education that emphasises cognitive-behavioural (Burton et al 1999, Linton and Andersson 2000, Symonds et al 1995) or neurophysiological (Moseley et al 2001) aspects have reported reduced disability, reduced health care utilisation, normalisation of pain cognitions, and increased self-efficacy.

Manual therapy, specific exercise training and targeted education all seem to promote therapeutic success through targeting distinct aspects of chronic low back pain. Although each of these strategies is broadly encompassed within the domain of physiotherapy, the effect of a combined physiotherapy treatment that consists of all three strategies is not known. The aim of this study was to determine the effect of such a combined physiotherapy treatment on functional and symptomatic parameters of moderately disabled patients with chronic low back pain.

Methods

Experimental design This study was a randomised controlled trial with repeated measures comparison of means. The study was approved by the Institutional Medical Research Ethics Committee and all procedures conformed with the Declaration of Helsinki.

Subjects Sixty-two subjects volunteered for the study by responding to a note that advertised the project. The note was included in the material given to each patient on initial attendance at participating physiotherapy clinics or the referring general practitioner. Subjects were included if the primary reason for presentation was a history of low back pain of greater than two months. Subjects were excluded if they were unable to understand, read and speak English, had worsening neural signs, had any neurological or orthopaedic condition that would interfere with treatment, or were awaiting surgery. Five subjects were excluded.

While each subject was undertaking the initial assessment, an independent person allocated them to experimental group using a coin toss. This strategy ensured that allocation was concealed from the subjects until after initial assessment, and from the assessors throughout the study. Twenty-nine and 28 subjects were allocated to the physiotherapy and control groups respectively. Figure 1 presents the recruitment strategy and experimental plan.

Table 1. Subject characteristics prior to randomisation, including withdrawals and drop outs (n = 57). Continuous variables are reported as means and SDs.

	Physiotherapy treatment group (n = 29)	Control group (n = 28)
RMDQ	12.4 ± 3.7	11.9 ± 3.2
NRS pain	4.9 ± 1.8	4.7 ± 1.5
Age (yrs)	43 ± 7	38 ± 7
Height (cm)	174 ± 12	170 ± 8
Weight (kg)	72 ± 5	78 ± 8
Duration of LBP (months)	39 ± 18	37 ± 12
Female	64%	54%
Working full time	19%	24%
Working part time	32%	32%
Currently receiving compensation	44%	50%
Non-English speaking background	21%	26%

RMDQ, Roland Morris Disability Questionnaire. NRS, Numerical Rating Scale. LBP, low back pain.

Experimental protocol The following items were used as outcome measures: the 18-item Roland Morris Disability Questionnaire (RMDQ; Roland and Morris 1983) and the 0-10 Numerical Rating Scale (NRS) for pain ("How would you rate your low back pain, on average, over the last three days?"). Initial and final assessment was performed by the same two investigators, who were not otherwise involved in the study and were blinded to experimental group. One-year follow-up data were collected via telephone by separate assessors who were also blinded to experimental group. The properties of the RMDQ and the NRS for pain are thought to be maintained when administered over the phone (Cherkin et al 1998). A further question estimated the number of health visits for low back pain over the course of the follow-up period: "Since your assessment on [date of final assessment], how many times have you consulted a health care professional for your low back pain?"

Treatment protocol Each subject received two physiotherapy treatments per week for four weeks. Manual therapy treatment involved symptom management according to the discretion of the treating physiotherapist, who chose from spinal mobilisation/manipulation, soft tissue massage, and muscle and neuromeningeal mobilisation techniques, but not electrophysical modalities.

Each subject participated in specific trunk muscle training both on an individualised level on two occasions per week and through a standardised home-exercise program. This program was conducted according to the protocol described by Richardson and colleagues (Richardson and Jull 1995). Subjects were instructed to maintain the home program indefinitely. Compliance with the home program was not assessed.

Each subject participated in a one-hour education session, once per week for four weeks. The education session was in a one-to-one seminar format, was conducted by an independent therapist, and focused on the neurophysiology of pain with no particular reference to the lumbar spine. In addition, the subjects completed a short workbook which consisted of one page of revision material and three comprehension exercises per day for 10 days.

Subjects in the control group received ongoing medical management as advised by their general practitioner. These subjects were also advised not to seek physiotherapy treatment during the data collection period. Subjects in the control group were questioned after the final assessment as to what intervention, if any, they had since initial assessment and how many visits to the general practitioner they had made for their low back pain.

Analysis Two-factor repeated measures ANOVAs (group x time) were used to identify a treatment effect on the dependent variables at final assessment and at one-year follow-up. Numerical Rating Scale and RMDQ were the dependent variables. Because two separate ANOVAs were used in the analysis, the probability of a Type 1 error for the study was elevated. To adjust for this, a Bonferroni correction yielded $\alpha = 0.025$. Analysis was by intention to treat.

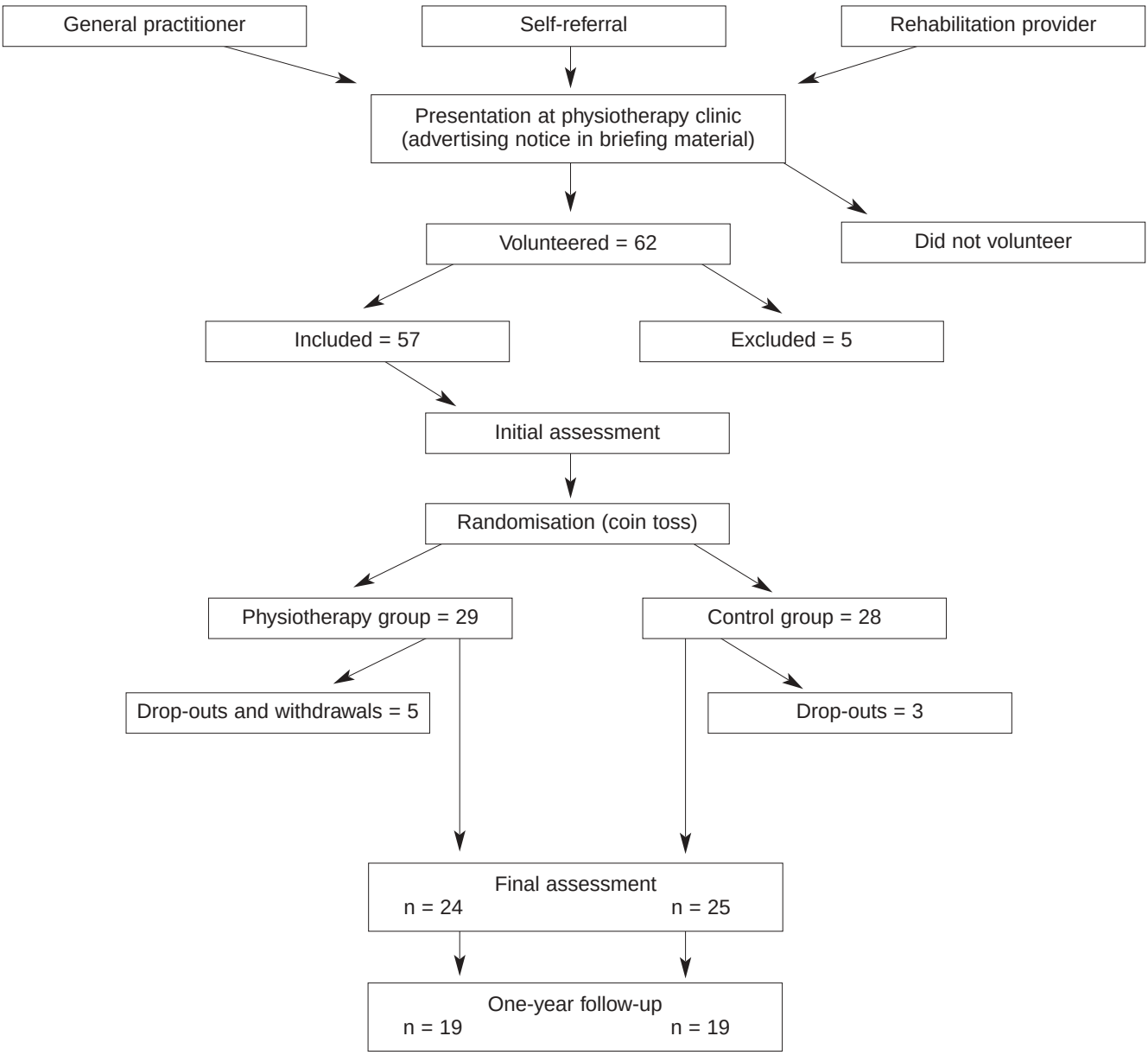

Figure 1. Recruitment and experimental plan.

For those dependent variables in which the group x time interaction was significant, treatment affects were estimated from the difference in group means. For NRS and RMDQ, the number needed to treat (NTT) in order to gain a clinically significant change was also determined. The threshold for a clinically significant change in NRS and RMDQ was set *a-priori* at 2 points and 4 points, respectively. These values were selected according to estimates in the literature, (eg Stratford et al 1994, Turk and Melzack 1992).

Results

Subject details Table 1 shows the subject characteristics. There were no pre-treatment differences between the groups in any of these measures or in the dependent variables ($p > 0.31$). On final assessment, the mean number of visits to the general practitioner was 4 (SD 2). Eighteen of the subjects in the control group indicated that they had been prescribed physical exercises by their general practitioner previous to the initial assessment, but only six

subjects had these exercises reviewed during the data collection period. Six subjects indicated that they had received weekly manipulations from their general practitioner and nine subjects indicated that their pain relief medications had been increased or altered during the data collection period. Two control subjects received weekly analgesic injections during the data collection period.

Pain and disability Final assessment was performed 29 ± 6 days after the initial assessment. There was a mean reduction of 2.9/10 and 1.4/10 on the NRS for pain, and 8.2/18 and 4.3/18 points on the RMDQ, for the physiotherapy treatment and control groups respectively (Figure 2). Thus, the mean improvement effected by physiotherapy treatment was 1.5 points on the NRS for pain (95% CI 0.7 to 2.3) and 3.9 points on the RMDQ (95% CI 2.0 to 5.8). The repeated measures ANOVAs indicated a significant treatment effect on NRS and RMDQ ($p < 0.01$ for both). The number needed to treat (NNT) to gain a clinically significant change was 3 (95% CI 2 to 8) for the NRS and 2 (95% CI 2 to 5) for the RMDQ.

Twelve-month follow-up Nineteen subjects in each group (67% of total sample) were contactable at one year (mean ± SD = 352 ± 28 days) for follow-up. There were significant treatment effects on NRS and RMDQ, and on the number of health care visits for low back pain during the follow-up period (Figure 2). The treatment effect was 1.9 for pain (95% CI 1 to 2.8) and 3.9 points on the RMDQ (2.3 to 5.8) corresponding to numbers needed to treat of 2 (95% CI 1 to 4) and 2 (1 to 3) respectively. During the one year since final assessment, subjects from the physiotherapy group made a mean ± SD 3.6 ± 2 health care visits for their low back pain, which was fewer than the control group, who attended a mean ± SD 13.2 ± 5 health care visits ($p < 0.001$). Thus the effect of treatment was to reduce the number of health care visits by a mean of 9.6 (95% CI 6.9 to 11.9).

Withdrawals, dropouts and side effects Four and three subjects, from the physiotherapy group and control group respectively, dropped out of the study and could not be contacted. One subject from the physiotherapy group withdrew due to urgent surgery unrelated to low back pain. Twenty-four and 25 subjects completed the physiotherapy and control programs respectively. The pre-treatment data for those subjects included in the follow up showed no differences between the experimental groups (*t*-test, $p > 0.21$).

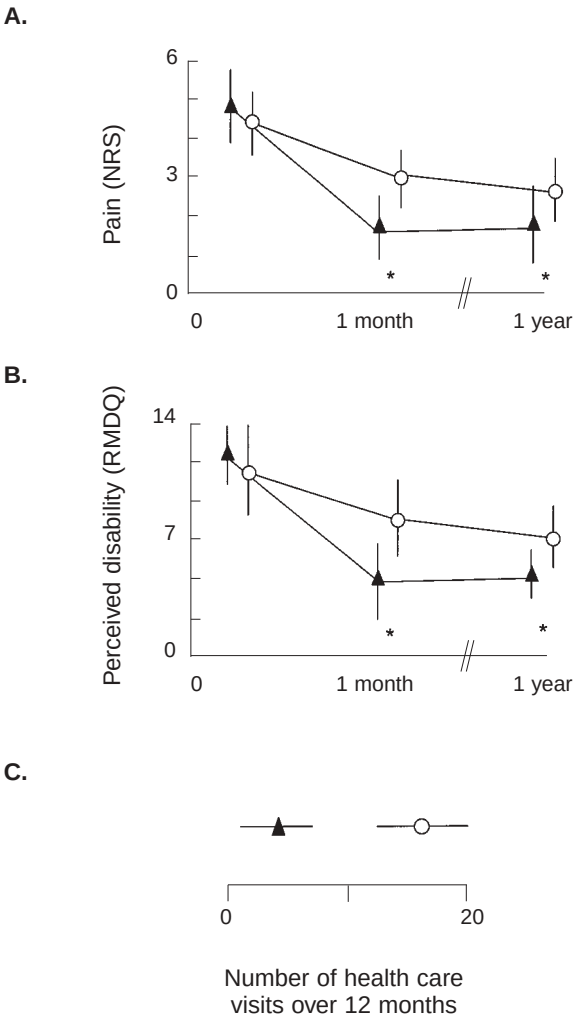

Figure 2. Group means and SDs for A, Numerical Rating Scale for pain; B, perceived disability; and C, the number of health care visits during the 12 month follow-up, for the physiotherapy treatment (filled triangles) and control (open circles) groups. Asterisks denote statistical significance ($p < 0.025$).

Discussion

These findings show that a combined physiotherapy treatment consisting of manual therapy, specific exercise training, and neurophysiology education is effective in producing functional and symptomatic improvement in chronic low back pain patients. This is evidenced by a significant treatment effect and substantial effect size for pain and disability, both of which appear to be maintained for at least one year.

The effectiveness of the physiotherapy program is substantiated by the NNT analysis. One advantage of the NNT is that it provides a clinically relevant indication of the number of patients that need to be treated for one more patient to achieve a particular therapeutic target. In short, an NNT of 1 suggests that the desired target is achieved in every patient in the treatment group but in no patient in the control group. Thus, the closer the NNT is to 1, the better the treatment is at achieving the targeted outcome. The NNTs in the current work were 3 (pain) and 2 (disability), which are consistent with recommendations in the literature that stipulate that, for chronic pain, NNTs of 2 or 3 are indicative of an effective intervention (McQuay et al 1997).

The current results suggest that the combined physiotherapy treatment is probably more effective than the components administered in isolation. This is primarily evidenced by the fact that most of the effects of sole treatments reported in the literature are small, particularly in those studies that involved subjects with high initial disability levels. For example, manipulation has been reported to produce effects of 2/10 and 3 RMDQ points (Cherkin et al 1998), 1.6/10 (Andersson et al 1999) and 2.5/10 (Triano et al 1995); exercise has been reported to produce effects of 1.2/10 and 2.9 RMDQ points (Klaber Moffett et al 1999); and education has been reported to produce effects of (1/10 and 2.5 RMDQ points (Cherkin et al 1998), 0/10 and 1 RMDQ point (Moseley et al 2001). Even so, chronic low back pain is heterogeneous and subjects vary across studies in their chronicity, pain intensity, functional level and pain impact. This means that the validity of a comparison between the current work and other studies is limited.

For this study, it is ultimately impossible to isolate the contribution that each component treatment made to the outcome of the combined treatment. In future studies, teasing out the relative contribution of component strategies to the therapeutic effect may allow conclusions about the mechanisms involved. This may, in turn, enhance the efficacy of combined physiotherapy treatments and permit targeting of sub-groups of patients with chronic low back pain.

Considering the high economic cost of chronic low back pain, targeting of sub-groups may be beneficial. This study suggests that a combined physiotherapy treatment is a cost effective strategy when targeted at moderately disabled patients with chronic low back pain; based on A$60.00 per session, the estimated cost of the combined treatment was A$720, which compares favourably with multidisciplinary pain management programs that can cost in the order of A$4000 (Moseley 1997, unpublished data). Importantly, however, the combined physiotherapy treatment may be neither cost-effective nor efficacious in more disabled patients with chronic low back pain or in other sub-groups of patients with chronic pain. Psychosocial factors are thought to be more important in some sub-groups and there is considerable evidence in support of more intensive, albeit more expensive, strategies for such patients (Guzman et al 2001, Morley et al 1999).

One aspect of the current study that is open to criticism is the lack of a robust control group. Although "ongoing medical management" is used widely and generally accepted as suitable for clinical trials, it does not adequately remove many sources of bias. By and large, this shortcoming is ignored in the relevant literature (eg Bendix et al 1997, Deyo 1996, Hides et al 1996, Laclaire et al 1996, O'Sullivan et al 1998, van der Heijden et al 1995). However, non-treatment factors such as patient expectations (Carosella et al 1994, Montgomery and Kirsch 1997), health provider expectations (Gracely et al 1985, Shapiro et al 1954), patient-provider rapport (Egbert et al 1964), therapist enthusiasm and perceived level of expertise (Nordin et al 1998, Shapiro and Shapiro 1984) are all considered to contribute to therapeutic effect.

Bias may also be introduced by the Hawthorne effect, which is caused by knowledge that one is participating in a research study (Parson 1974). However, if the Hawthorne effect varies according to *how much* the subject is participating (this certainly seems reasonable), then in the present work, the Hawthorne effect would have been greater in the physiotherapy group. Thus, although the current findings appear potent, further trials incorporating a more robust control group probably are required to substantiate the results of the current study.

One source of bias that may limit the external validity of this work is selection bias introduced by the exclusion criterion that subjects have an ability to read, speak and understand English. Although 28% of subjects were from a non-English speaking background, broad application of the current findings to linguistically diverse chronic low back pain patients would appear problematic.

Notwithstanding the potential limitations of the current work, the results strongly suggest that the combined physiotherapy treatment, consisting of manual therapy, specific exercise training, and neurophysiology education, is effective in producing functional and symptomatic improvement in chronic low back pain patients. The effect is maintained at 12 months post-treatment and patients subsequently seek substantially fewer health care visits than those under ongoing medical care. The findings presented here are important because they support the long-term efficacy of this approach for a problematic patient group: moderately disabled patients with chronic low back pain.

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