

**Direction specific or stabilization exercises for chronic low back pain patients: a randomized controlled trial**

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**Study Design**

A randomized, controlled trial.

**Background**

The fact that much of the current research has investigated the management of low back pain, as if this was a homogenous group, could account for the lack of support for the prescription of specific exercise programmes. Identifying subgroups of patients more amenable to specific treatments has been claimed as one of the promising recent developments in back pain research. Evidence has emerged that treatment based on classification is superior to non-specific treatment, according to contemporary back pain guidelines. However, most of these trials recruited acute and sub-acute back pain patients (only one trial had 50% of the population defined as chronic). Furthermore, the role of directional preference exercises in the management of a chronic back pain population has not been specifically explored before.

**Aims**

The aim of this research project was to compare the effectiveness of directional preference exercises with a stabilisation exercise programme in the management of chronic low back pain and to follow up functional status and pain intensity at discharge from physical therapy at intervals of six months and one year later. Criteria for recruiting patients consisted of the existence of directional preference and the criteria for the clinical prediction rule for stabilisation exercises.

**Methods**

Data was gathered from adults (n=62 patients) with chronic low back pain who, on initial assessment, demonstrated a directional preference and an indication that they might respond to stabilization exercises, for at least three months. Patients were then randomized to either directional preference or stabilization exercises and treated for up to four weeks, and then followed up at six and 12 months. Outcomes used were the Numeric Pain Rating Scale (NPRS) for back and leg pain, the Roland-Morris Disability Questionnaire (RMDQ) and the Global Perceived Effect Score (GPES), measured after treatment. All data was assumed to be ordinal (RMDQ, NPRS, GPES) so non-parametric tests were used. Analysis of outcomes between groups at different time points was done using ANOVA, and all outcomes' significance was set at  $\leq 0.05$ .

**Limitation**

Contamination of the data in the stabilization group was a major limitation of the study, with many patients in this group receiving extension exercises as well.

**Results**

There was a significant difference in both groups over time in all outcomes ( $P < 0.0001$ ), but there were no significant differences between groups at any time point.

**Conclusion**

It is not clear if these results are a true comparison between directional preference and stabilisation exercises, as there was substantial contamination of the stabilisation group treatment.

**KEY WORDS:** *Chronic Low Back Pain, Directional Preference, Stabilisation Exercise*

**Introduction**

Low back pain (LBP) remains a leading cause of disability and is one of the most prevalent and costly conditions treated in primary care (Hayden et al, 2005a). In the UK, the total direct and indirect costs have been estimated at between £5 and £10 billion, with the majority of this absorbed by indirect societal costs (Maniadakis and Gray, 2000). Similar high costs exist in other countries, where data is available (Dagenais et al, 2008), and it is likely that the situation is similar in the Czech Republic. In 2004, in the Czech Republic about 19% of total work compensation was for musculoskeletal incapacity to work, compared to 40% for respiratory illness and 12% for trauma and poisoning (Říha, 2008). A minority of those with chronic or persistent symptoms appear to absorb the majority of the costs; it is estimated that 15% of the back pain population absorbs about 70% of total costs (Linton et al, 1998).

Systematic reviews, while mostly concluding that there is moderate-to-strong evidence for exercise therapy as

a treatment for CLBP, have not supported specific exercises or any particular form of exercise (van Tulder et al, 2000; Hubley-Kozey et al, 2003; Liddle et al, 2004; Hayden et al, 2005a; Slade and Keating, 2006). The beneficial role of general aerobic and strengthening exercises and the possible importance of supervised programmes has been highlighted by some reviews (Liddle et al, 2004; Hayden et al, 2005b; Slade and Keating, 2006).

The findings from large systematic results are used to formulate clinical guidelines and recommendations for best practice. The limited evidence for specific exercise prescription is therefore present in the current clinical guidelines for managing CLBP.

Routine physiotherapy intervention for any musculoskeletal problem, including CLBP, involves an in-depth assessment to identify signs and symptoms. These assessment findings are then used to formulate an appropriate treatment plan, which will frequently

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include the prescription of specific exercises that are thought to be appropriate to the patient's presentation. Thus, rather than standard management being used for all patients with CLBP, treatment is based on individual clinical presentations. For instance, in a survey of primary care clinicians, including physiotherapists, who routinely assess and treat patients with LBP, 93% did not think that LBP was one condition, but rather comprised heterogeneous sub-groups (Kent and Keating, 2004). In contrast, and this represents a major difficulty when interpreting much of the research on the use of specific exercise programmes in the management of CLBP, trials have viewed CLBP patients as a homogenous group. On the whole, previous trials have not attempted to select patients as being suitable for a particular intervention, instead simply randomising them to alternate interventions.

The fact that much of the current research has investigated the management of LBP as a homogenous group could account for the lack of support for the prescription of specific exercise programmes. This possible flaw with much of the previous research has recently been identified (Fritz et al, 2003; Long et al, 2004; Brennan et al, 2006, Browder et al, 2007), and as a result, research is developing in the area of sub-grouping of patients with LBP. Here, patients are assessed according to specific signs and symptoms and sub-classified according to these findings. The intention of these trials has been to determine if classification-based treatment produces better outcomes than standard treatment; and in these trials that has indeed been the case (Fritz et al, 2003; Long et al, 2004; Brennan et al, 2006, Browder et al, 2007).

Identifying subgroups of patients more amenable to specific treatments has been identified as one of the promising recent developments in back pain research (Koes et al, 2006). Evidence has emerged that treatment-based on classification is superior to non-specific treatment (Fritz et al, 2003; Long et al, 2004; Brennan et al, 2006, Browder et al, 2007). Long et al (2004) demonstrated that directional preference exercises (DP) were more effective than the use of general exercises in reducing pain and restoring function in the short-term ( $P < 0.001$ ). The trial sample involved acute to chronic patients and those with local spine pain through to those with sciatica. Fritz et al (2003) demonstrated that treatment based on classification was more effective than treatment according to contemporary back pain guidelines ( $P = < 0.029$ ). Brennan et al (2006) demonstrated no significant difference between three groups receiving DP exercises, stabilisation exercises and manipulation, but significant differences if patients received the treatment that matched their classification group ( $P = 0.013$ ). Most of these trials have recruited acute and sub-acute LBP patients, although 50% of the population in one trial was defined as chronic (Long et al, 2004) and centralisation has been

identified in about 50% of the CLBP population (Aina et al, 2004). However, the role of DP exercises in the management of a CLBP population has not been specifically explored before.

One of the more commonly used methods of sub-grouping patients is the McKenzie Method (McKenzie and May, 2003). This method is based on the patient's pain response to certain movements and postures during assessment, which are used to identify a patient's directional preference. DP is defined as the movement or posture that decreases or centralises pain that emanates from the spine and/or increases range of movement (McKenzie and May, 2003). The separate, but associated, phenomenon of centralisation refers to the abolition of distal pain in response to repeated movements or sustained postures, and also refers to the abolition of any remaining spinal pain. Both centralisation and DP are common clinical occurrences (Aina et al, 2004; Long et al, 2004), and are detected with reasonably good levels of reliability amongst those with training in the method (Kilpikoski et al, 2002; Razmjou et al, 2000; Fritz et al, 2000). Mechanical syndromes in the McKenzie system are derangement, dysfunction and postural syndromes, with the biggest proportion of spinal patients being classified with derangement (May, 2006). DP and centralisation occur only in the substantial derangement group (McKenzie and May, 2003). The prevalence of derangement syndrome in low back pain patients has been reported to be between 75% and 80% (Hefford, 2008).

An alternative way of constructing sub-groups of the LBP population is the development of clinical prediction rules (CPR) for a positive response to a particular intervention, based on signs and symptoms. For instance, CPR have been developed for those who respond positively to non-specific spinal manipulation and those who respond positively to stabilisation exercises (May and Rosedale, 2008). The CPR for stabilisation exercises has been derived in one population (Hicks et al, 2005) and validated in another (Brennan et al, 2006). The criteria were as follows:

- Age < 40 years
- Average straight leg raise > 91°
- Any 'aberrant movements' present: instability catch, painful arc of movement, thigh climbing, or reversal of lumbopelvic rhythm
- Positive prone instability test.

With three or more positive tests, the sensitivity, specificity, and positive likelihood ratio of a positive response to stabilisation exercises was 56%, 86%, and 4.0, and with two or more tests, it was 83%, 56%, and 1.9 respectively (Hicks et al, 2005). After pre-trial testing of these clinical prediction rules, in which two criteria were commonly found but three rarely, we adopted an inclusion criteria of two out of four.

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Thus, the aim of this research was to compare the effectiveness of DP and stabilisation exercises in the management of CLBP. Criteria for recruiting patients were the existence of DP and two out of four of the clinical prediction rule criteria for stabilisation exercises. Our null hypothesis was based on the statement: There will be no difference in pain and functional outcomes in patients with CLBP between those who receive exercises matching their directional preference and those who receive a stabilisation exercise programme. Thus the alternative hypothesis was: Patients with CLBP receiving exercises matching their directional preference will have significantly reduced pain and improved functional outcomes in comparison with patients receiving a stabilisation exercise programme.

### METHODS

#### Patients and settings

Seventy-five consecutive patients of either gender between 18 and 65 age years old with CLBP, duration three months or more, were screened by Rehabilitation Service Physicians and referred to physiotherapy, in the Central Military Hospital in Prague, the Czech Republic. Patients were mostly referred into this service by primary care physicians from Prague and its environs. Patients were included with a primary complaint of LBP (pain in the lumbar and/or buttock area) with or without referral into the lower limb, and if they were willing to participate. Red flags indicative of serious spinal pathology (Waddell, 2004), signs and symptoms of major nerve root compromise (with at least two of these signs: dermatomal sensory loss, myotomal muscle weakness, reduced lower limb reflexes), pregnancy, history of spinal surgery, previous experience of either intervention, or Roland Morris Disability score less than four or greater than 20 were the exclusion criteria. Consecutive patients who met these inclusion / exclusion criteria underwent a baseline evaluation to determine the presence of DP (McKenzie and May, 2003) and at least two out of the four stabilisation clinical prediction rule criteria (Hicks et al, 2005). Out of the 75 patients recruited, 62 met these final criteria, and all patients signed an informed-consent form before participating in the study.

#### Clinical Procedures and Randomization

All 75 consecutive patients were examined by a physiotherapist trained at the highest level of the MDT. The patients were assessed for directional preference, involving repeated movements, up to four to five sets of 10 of each movement, in standing, lying and in sagittal and frontal planes. The full assessment is described in detail and familiar to the assessing therapists (McKenzie and May, 2003). Our determination of directional preference was based on the following responses:

- Abolition of distal pain in response to repeated movement or sustained postures (centralisation) that remains improved after the test movements.

- Decrease in spinal or distal pain in response to repeated movement or sustained postures that remains improved after the test movements.

After that, the patients were assessed for the criteria developed for the stabilisation clinical prediction rule (Hicks et al, 2005). All of them had at least two out of the four stabilisation clinical prediction rule criteria.

In addition to the initial physiotherapy appointment, a routine assessment was carried out and standard outcome measures were completed. The Numeric Pain Rating Scale (NPRS) for back pain and for leg pain (Childs et al, 2005; Farrar et al, 2000, 2001; Jensen et al, 1999), the Roland-Morris Disability Questionnaire (RMDQ) (Pengel et al, 2004; Stratford et al, 1994); these same outcome measures were re-assessed at four weeks and six and 12 months as well as the Global Perceived Effect Score (Beurskens and de Vet, 1996).

A randomisation schedule using a computer-generated table was developed to assign patients to the treatment groups. A member of the team not involved in data collection generated consecutively numbered opaque envelopes containing each participation's allocation. Patients drawing an envelope containing Group 1 were randomised to receive directional preference exercises and patients receiving the envelope containing Group 2 were randomised to receive the stabilisation exercise programme.

#### Interventions

Patients randomised to Group 1 were taught directional preference exercises by four therapists with training in McKenzie's Mechanical Diagnosis and Therapy, courses A to D and the Credentialing exam. The group used a sheet with instructions on how to perform exercises regularly at home or at work. These patients received advice in line with their DP, which is to perform exercises and movements appropriate to their DP regularly, and temporarily to refrain from movements and especially sustained postures in the opposite direction.

Patients randomised to Group 2 were treated by one of four therapists with training in providing core stability exercise programmes that are popular in the Czech Republic. Two sorts of programmes are commonly used, both involving central nervous system stimulation by therapists and activation of deep stability muscle groups. One used progressive proprioceptive neuromuscular facilitation (PNF); with techniques and exercise patterns commonly used (Voss et al, 1985; Adler et al, 2003). The method aims to stimulate global muscle control with the use of guided patterns of movement. The other method also uses manual stimulation on clearly defined points on the body by therapists to stimulate central nervous system coordination and deep muscle reflex activity (Vojta, 1995). This type of therapy was termed Reflex Locomotion, which was ini-



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tially designed to enhance the motor development of children. However, the motor responses were also said to generate global patterns of muscle activation in adults. The approach uses progressive levels of gravity-loaded positions to increase stimulation of core trunk muscles and is combined with Pilates training. Thus, these techniques share many similarities with stabilisation programmes commonly used in other countries, i.e. the belief that coordination is more important than gross strengthening, core trunk muscles are the focus, and loading is done in a progressive manner. The group was also issued a sheet with instructions on how to perform the exercises regularly at home.

Therapists were instructed to treat according to the study protocol only, and not include additional interventions. A maximum of six sessions were available for both groups, but if therapist and patient were happy with progress, it was possible for patients to be discharged before this.

**Data Analysis**

We calculated sample sizes for both primary outcomes and selected the larger sample size. We calculated that a sample size of 30 participants in each group gave 90% power to detect a mean 2.0 (SD 2) difference in NPRS between the groups with an alpha level of 0.05, and allowed 27% over-recruitment. For the RMDQ, using an alpha level of 0.05 and power at 90% with an anticipated change of 4.9 (SD 5.0) gave a sample size of 23 per group; so 30 per group included 23% over-recruitment.

All outcomes were collected by a member of the team not involved in data collection and treatment as well, and then they were mailed to a statistician who was not involved in the patient care process. Results were analysed using the computer programme SPSS / PSAW (version 19). Each patient was assigned a code to maintain anonymity and confidentiality. All data was assumed to be ordinal, so non-parametric tests will be used. Two-way repeated measure 2x2 ANOVA (group effects of two levels and time effect of two levels) was performed on the following outcome variables: RMDQ, PNRS for leg and back, and GPES. Based on this analysis, the following effects will be tested, namely: group by time interaction effect, time effect and group effect. If there is a statistically significant group by time interaction effect detected this indicates the group effect varies with time or vice versa. Further testing of simple effects was then performed to determine whether there is any group effect using Chi-square analysis. For all outcomes, significance was set at alpha=0.05 level.

**Results**

Sixty-two patients were recruited; their baseline details are in Table 1. The two groups were very similar at baseline. Fifty-three patients (85%) were followed up at

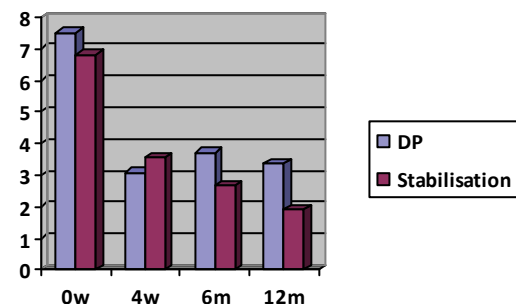
four weeks, 50 (81%) at six months, and 44 (71%) at 12 months.

**Table 1. Baseline description of patients**

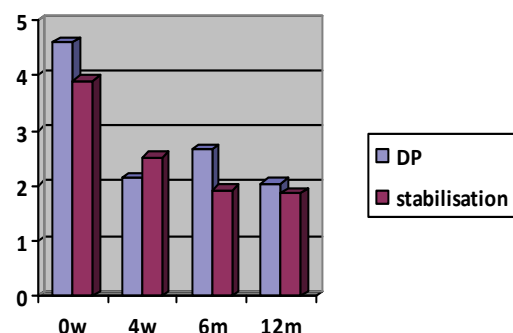
Variable	MDT (N=31)	Stabilisation (N=31)
Age - mean (SD)	43.7 (11.5)	44.8 (11.9)
Gender (female)	15 (48%)	17 (55%)
Working	26 (84%)	27 (87%)
Sick leave	2 (6%)	0
Sport active	16 (52%)	18 (58%)
Most common postural set sitting	26 (84%)	21 (68%)
Centralisation	19 (61%)	17 (55%)
RMDQ - mean (SD)	7.5 (2.8)	6.8 (3.0)
Low Back Pain - mean (SD)	4.6 (1.65)	3.9 (1.8)
Leg pain - mean (SD)	2.3 (2.0)	1.5 (1.95)

There was a significant effect over time in both groups in the GPES / LBP / leg pain and RMDQ ( $P < 0.0001$ ), but no significant difference between groups at any time point ( $P = 0.42 / 0.15 / 0.88 / 0.32$ ). As there was no difference no further testing was necessary, but the Chi-square tests again found no differences between the groups. Figures 1-3 illustrate the outcomes over time of the RMDQ, LBP and leg pain.

**Figure 1. The Roland-Morris Disability Questionnaire outcomes**

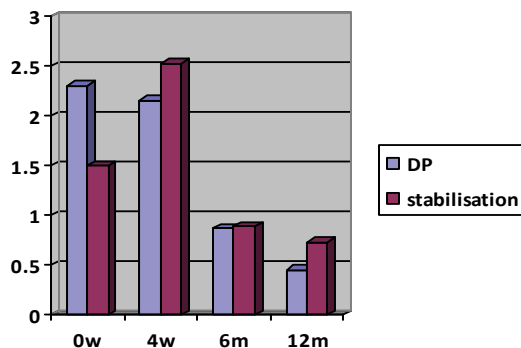


**Figure 2. Low back pain scores**



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Figure 3. Leg pain scores



### Discussion

There was a significant improvement in both groups over time. We could not confirm the alternative hypothesis, that patients with CLBP receiving exercises matching their directional preference would have significantly reduced pain and improved functional outcomes in comparison with patients receiving a stabilisation exercise programme, as there were no significant differences between the groups.

However, there were some major limitations to the data collection and analysis that challenge this conclusion. Unfortunately, there was contamination of the therapy, which came to light towards the end of data collection. Most of the patients in the stabilisation group underwent end-range extension movement and mobilisation in multiple directions as well as stabilisation exercises, which was against the study protocol. Some patients were free from problems after the assessment, as they responded rapidly to repeated movements, but still underwent therapy in the stabilisation exercise group although they had no symptoms. Only one patient was treated with PNF, so this group did not really exist, and the therapy lasted three months, which was against the study protocol. Therefore, the non-significant results should not prompt generalisations, because treatment in the stabilisation group was not confined to stabilisation therapy. Furthermore, at one year, those lost to follow-up constituted 29% of the original sample.

Stabilisation therapy, now commonly referred to as motor control exercises, were developed based on the results of laboratory studies demonstrating that individuals with low back pain have impaired control of the deep (e.g. transversus abdominis and multifidus) and superficial trunk muscles responsible for maintaining the stability of the spine. Motor control exercises utilize principles of motor learning to regain control of the trunk muscles, posture, and movement pattern, ultimately leading to a reduction in the levels of pain and disability. However, there are no high-quality studies confirming that motor control exercises are superior to

other active approaches in the management of low back pain (Macedo et al, 2012). One study directly compared the effectiveness of motor control exercises and graded activity showed no significant differences between groups in relation to pain or disability at 6, 12 and 18 month follow-ups (Critchley et al, 2007). Directional preference and stabilisation exercises have previously demonstrated similar outcomes (Miller et al, 2005).

Although there was no significant difference in pain and functional outcomes in patients with CLBP receiving exercises matching their directional preference and patients receiving a stabilisation exercise programme in this study, we can see good results in both groups at one year follow-up. Respectively, patients with CLBP reported 96% improvement by exercise matching their directional preference and 78% for the stabilisation exercise programme. Almost all patients had a higher expectation of improvement in function when they agreed to be included in this study and most of them were able to follow an active coping strategy in both groups.

We found that in the directional preference (DP) group, we had a more rapid recovery than in the stabilisation exercise group, in spite of the treatment contamination in the stabilisation group. And we also identified that DP therapy was slightly more effective than the contaminated stabilization group at short-term (four weeks), than in 6 and 12 months follow-ups. Similar results have recently been found in a systematic review of directional preference exercises (Surkitt et al, 2012).

We found about 96% of chronic LBP patients in the DP group reported an improvement or significant improvement after discharge and one year follow up. Of 75 patients recruited, 62 had DP at baseline (83%). This is much higher than previous reports of centralisation in chronic low back pain (Aina et al, 2004), but similar to previous reports of DP in a mixed duration LBP population (Long et al, 2004).

This study may provide a lesson for research in the Czech Republic: that a randomised trial with patients with multifactorial etiology of LBP is possible, but it must be performed with people who are willing and able to work according to the pre-established study protocols. It should be noted all MDT therapists were abiding the protocol without any problem.

Another issue arising from the study is the value of the prone instability test, which is one of the stabilisation clinical prediction rule criteria. Out of 23 with a positive test at baseline, 10 were treated with directional preference exercises, and required full extension movement to fully recover. This would appear to challenge expectations around so-called instability in the spine, which theoretically might worsen because of end-range exercises.

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There was no significant difference in pain and functional outcomes in patients with CLBP receiving exercises matching their directional preference and patients receiving a stabilisation exercise programme. However, there was contamination of the stabilisation group. In addition, these patients underwent end-range extension movement and mobilisation in multiple directions. The directional preference (DP) group had a more rapid recovery than the stabilisation group. At one year follow up, there was about 96% improvement or significant improvement in DP group and 78% in the contaminated stabilisation group. It is also crucial to note all patients were highly motivated to improve their CLBP by the exercise. This is the first randomised trial on the effectiveness of management of CLBP done in the Czech Republic. Further high quality research on CLBP or LBP sub-groups is required.

**Acknowledgments**

I would like to thank my co-author Stephen May for his assistance, advice, data analysis and never-ending patience to answer all questions on research. A special thanksgiving belongs to all the team from the Central Military Hospital working on the study.

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