A tailored exercise program versus general exercise for a subgroup of patients with low back pain and movement control impairment: A randomised controlled trial with one-year follow-up

Citation for published version (APA):

Saner, J., Kool, J., Sieben, J. M., Luomajoki, H., Bastiaenen, C. H. G., & de Bie, R. A. (2015). A tailored exercise program versus general exercise for a subgroup of patients with low back pain and movement control impairment: A randomised controlled trial with one-year follow-up. *Manual Therapy*, 20(5), 672-679. <https://doi.org/10.1016/j.math.2015.02.005>

Document status and date:

Published: 01/10/2015

DOI:

[10.1016/j.math.2015.02.005](https://doi.org/10.1016/j.math.2015.02.005)

Document Version:

Publisher's PDF, also known as Version of record

Document license:

Taverne

Please check the document version of this publication:

- A submitted manuscript is the version of the article upon submission and before peer-review. There can be important differences between the submitted version and the official published version of record. People interested in the research are advised to contact the author for the final version of the publication, or visit the DOI to the publisher's website.
- The final author version and the galley proof are versions of the publication after peer review.
- The final published version features the final layout of the paper including the volume, issue and page numbers.

[Link to publication](#)

General rights

Copyright and moral rights for the publications made accessible in the public portal are retained by the authors and/or other copyright owners and it is a condition of accessing publications that users recognise and abide by the legal requirements associated with these rights.

- Users may download and print one copy of any publication from the public portal for the purpose of private study or research.
- You may not further distribute the material or use it for any profit-making activity or commercial gain
- You may freely distribute the URL identifying the publication in the public portal.

If the publication is distributed under the terms of Article 25fa of the Dutch Copyright Act, indicated by the "Taverne" license above, please follow below link for the End User Agreement:

www.umlib.nl/taverne-license

Take down policy

If you believe that this document breaches copyright please contact us at:

repository@maastrichtuniversity.nl

providing details and we will investigate your claim.

Download date: 26 Apr. 2023

Original article

A tailored exercise program versus general exercise for a subgroup of patients with low back pain and movement control impairment: A randomised controlled trial with one-year follow-up

Jeannette Saner ^{a, b, *}, Jan Kool ^{a, 1}, Judith M. Sieben ^{b, c}, Hannu Luomajoki ^a, Carolien H.G. Bastiaenen ^{b, d}, Rob A. de Bie ^{b, d}

^a Zurich University of Applied Sciences ZHAW, School of Health Professions, Institute of Physiotherapy, Technikumstrasse 71, Postfach 8401, Winterthur, Switzerland

^b CAPHRI School for Public Health and Primary Care, PO Box 616, 6200 MD Maastricht, The Netherlands

^c Maastricht University, Dept. of Anatomy & Embryology, PO Box 616, 6200 MD Maastricht, The Netherlands

^d Maastricht University, Dept. of Epidemiology, PO Box 616, 6200 MD Maastricht, The Netherlands

ARTICLE INFO

Article history:

Received 6 September 2014

Received in revised form

26 January 2015

Accepted 17 February 2015

Keywords:

Randomised controlled trial
Movement control impairment
Exercise
Low back pain
Clinical trial
Disability

ABSTRACT

Background: Exercise is an effective treatment for patients with sub-acute and chronic non-specific low back pain (NSLBP). Previous studies have shown that a subgroup of patients with NSLBP and movement control impairment (MCI) can be diagnosed with substantial reliability. However, which type of exercises are most beneficial to this subgroup is still unknown.

Objectives: The effectiveness of a specific exercise treatment to improve movement control was tested in this study.

Methods: Using a multicentre randomised controlled trial (RCT), we compared exercises that targeted MCI (MC) with a general exercise (GE) treatment. After randomisation, patients in both groups ($n(\text{MC}) = 52$; $n(\text{GE}) = 54$) were treated in eight private physiotherapy practices and five hospital outpatient physiotherapy centres. Follow-up measurements were taken at post-treatment, six months and 12 months. The primary outcome measurement was the Patient Specific Function Scale (PSFS).

Results: PSFS showed no difference between groups after treatment, or at six months and 12 months. Secondary outcome analysis for pain and disability, measured with the Graded Chronic Pain scale and the Roland Morris Disability Questionnaire respectively, showed that a small improvement post-treatment levelled off over the long term. Both groups improved significantly ($p < 0.001$) over the course of one year.

Conclusion: This study found no additional benefit of specific exercises targeting MCI.

© 2015 Elsevier Ltd. All rights reserved.

1. Introduction

Sixty to eighty percent of the adult population suffers from low back pain (LBP) at some point during life (Airaksinen et al., 2006). A

previous episode of back pain is highly predictive of future episodes (Stanton et al., 2008; Kolb et al., 2011). In most cases, according to guidelines, a specific diagnosis is not possible and the complaints are labelled as non-specific low back pain (NSLBP) (Waddell, 1987; Airaksinen et al., 2006).

Evidence shows that exercise in general is an effective treatment for patients with sub-acute or chronic NSLBP (Hayden et al., 2005). Due to the great heterogeneity of this patient group, clinicians and researchers have tried to identify subgroups of NSLBP that respond positively to and benefit most from a specific exercise treatment (Foster et al., 2011; Karayannis et al., 2012). One potential subgroup are patients with movement control impairment (MCI), as classified by O'Sullivan (O'Sullivan, 2005). Patients with MCI present with mechanically induced pain in static postures together with visible

* Corresponding author. ZHAW Departement Gesundheit, Institut für Physiotherapie, Technikumstrasse 71, PO Box, 8401 Winterthur, Switzerland. Tel./fax: +41 58 934 63 70.

E-mail addresses: jeannette.saner@zhaw.ch (J. Saner), jan.kool@kliniken-valens.ch (J. Kool), j.sieben@maastrichtuniversity.nl (J.M. Sieben), hannu.luomajoki@zhaw.ch (H. Luomajoki), chg.bastiaenen@maastrichtuniversity.nl (C.H.G. Bastiaenen), ra.debie@maastrichtuniversity.nl (R.A. de Bie).

¹ Present address: Research Department, Rehabilitation Centre Valens, 7317 Valens, Switzerland.

movement abnormalities, such as decreased or increased movement of parts of the lumbar spine, or discrepancies in the proportion of hip, leg and spine movements. It is assumed that these movement abnormalities are influenced by current pain, previous pain episodes and the belief that pain provoked by movement is harmful (O'Sullivan, 2005). The classification of MCI is based on the observation of aberrant movements accompanied by postural pain (O'Sullivan, 2005). A further sub-classification of MCI identifies the specific movement direction in which control is reduced (Dankaerts et al., 2006; Dankaerts and O'Sullivan, 2011). The sub-classification categories are flexion, active extension, passive extension, lateral shift or multidirectional MCI (O'Sullivan, 2005). Many MCI test procedures have been developed in recent years, (Sahrmann, 2002; O'Sullivan, 2005; Carlsson and Rasmussen-Barr, 2013). In order to define MCI subgroups more clearly, several tests have been evaluated by Luomajoki with a set of 6 MCI tests showing substantial intra-rater and inter-rater reliability (Luomajoki et al., 2007). MCI tests were shown to effectively distinguish healthy persons from patients with LBP (Luomajoki et al., 2008, 2010).

On the assumption that MCI patients would show better outcomes from treatment targeted at the individual MCI sub-classification, specific exercises were developed that aimed at relearning normal movement patterns (Luomajoki et al., 2010). These exercises were performed with increasing levels of difficulty (Luomajoki, 2010). Patients performed initial, easy, low load exercises, e.g. the positioning of the spine in a neutral position, and progressed to increased load and more complex functional requirements. Finally, unconscious application of the learnt movement patterns in daily activities was trained. These MCI subgroup specific exercises were targeted at the functional movement problems of the individual patient. However, it remains unclear as to whether individually-tailored treatment leads to superior outcomes.

To date, the proposed mechanisms and treatment of local stabilising muscles, such as multifidi and transversus abdominis, have received considerable attention in spinal control research. Two recent meta-analyses measuring pain and disability outcomes compared specific motor control exercises with other forms of exercises but obtained different results. Both papers showed favourable outcomes on both pain and disability for motor control over other forms of exercise in the short and intermediate term. They also agreed that no long term benefit on pain was seen. However, there was disagreement regarding the long term effect on disability (Bystrom et al., 2013; Smith et al., 2014). An RCT assessing the effectiveness of exercises and behavioural treatment for MCI, as proposed by O'Sullivan, showed some evidence of improved disability and pain when compared with manual therapy and exercise (Vibe Fersum et al., 2013). However, the latter study is regarded of moderate quality due to the substantial loss of patients in follow-up and to a lack of intention to treat analysis. Furthermore, the question remains unanswered as to which was responsible for the difference: the exercises or the behavioural approach.

To clarify, which exercise approach is superior for patients in the MCI subgroups, movement control (MC) exercises were compared with general exercises (GE) in this current study. A clearly described general exercise programme was selected for the control group to allow for a realistic treatment option. A previous study, in which patients were not assessed for subgroups, had found a better short term effect on disability in patients with LBP with this exercise regime than lumbar stabilising exercise plus general exercise (Koumantakis et al., 2005).

We studied the effects of specific movement control exercises versus general exercise in a multicentre RCT. This article reports on

the results at the six-month and 12 months follow-up and demonstrates the effect on disability and pain of specifically-tailored, active exercise treatment compared with general exercise treatment in patients with NSLBP and MCI.

2. Methods and material

2.1. Trial design

A parallel-group RCT with follow-ups at six months and 12 months was performed in five hospital outpatient departments and eight private practices in Switzerland. Patients were recruited from referring hospitals and resident physicians, as well as through advertising amongst the staff and students of the Zurich University of Applied Sciences, Winterthur, Switzerland (ZHAW). The trial was registered (ISRCTN80064281) and ethical approval obtained from the Swiss Ethics Committee KEK-ZH-NR: 2010-0034/5. The protocol has been previously published (Saner et al., 2011).

2.2. Participants

Patients presenting with sub-acute or chronic low back pain (persisting for longer than six weeks and no radiating symptoms below the knee) were recruited. Age had to be 18–75 years. Eligible patients also had to present with: predefined MCI complaints (pain provocation in static positions) (Dankaerts and O'Sullivan, 2011), together with a score of two or more positive results out of the six MCI tests (Luomajoki et al., 2007). Disability levels had to be at least five points on the Roland Morris Disability Questionnaire (RMDQ) (Roland and Morris, 1983; Wiesinger et al., 1999; Pengel et al., 2004).

Excluded were patients (1) with LBP due to known or suspected specific causes with recent surgery on the spine (<6 weeks); (2) with spondylodesis; (3) with comorbid health conditions, which limited exercise training. (4) To focus on patients with pain responding to movement, we also excluded patients complaining of constant pain and/or pain below the knee. (5) To avoid confounding by psychosocial factors, patients with a score of more than 130 on the Örebro Musculoskeletal Pain Screening Questionnaire (ÖMPSQ) (Linton and Boersma, 2003) and/or (6) more than 3 months of sick leave due to LBP were also excluded. German language had to be sufficient to understand study information, instructions and questionnaires. For further details see flow chart Fig. 1.

2.3. Randomisation and blinding

Following signing informed consent, patients attended baseline assessment, which was conducted by an independent, experienced and specially-trained physiotherapist. Eligible patients were randomly allocated to one of two groups. The computer-generated randomisation schedule was produced before trial start, using block-randomisation with a block size of four. Group allocation was communicated to the therapist by means of telephone contact from an independent research assistant at the ZHAW. Outcome assessors and data analysts were blinded to the allocation and were not involved in treatment throughout the trial. Blinding of patients and physiotherapists to the allocation was not possible, but patients were kept naïve to the specific research goal. Physiotherapists of the MC group received all baseline information concerning the MCI sub-classification and instruction on the six physical tests, in order to plan and apply a specific treatment. All other physiotherapists involved remained masked for initial assessments and trial results.

Fig. 1. Flowchart of participants through the trial. Non-response rate is only valid for the equivalent follow up.

2.4. Interventions

Patients in both groups received individual treatment sessions of 30 min, preferably twice per week, over a period of nine to 12 weeks. Progression of the treatment, in accordance with the treatment protocol, was determined by the physiotherapist. Ten minutes of each session was allowed for other physiotherapy applications, where necessary. The length and type of additional interventions were recorded and monitored. All patients received instructions for a minimum of three home exercises and were encouraged to practise them at least twice a week for up to one year after treatment. Patients were contacted by telephone after six months and encouraged to maintain the training.

Movement control (MC) treatment consisted of active exercises addressing the pain-provoking postures and control of the impaired movement(s). These were assessed and classified at baseline, as proposed by O'Sullivan and Luomajoki (O'Sullivan, 2005; Dankaerts, O'Sullivan, 2006) (Luomajoki et al., 2010). As initial exercises, patients learnt to perform controlled movements with low load in supported positions. Later they progressed to open chain positions, to exercises involving controlled movements with increased load and to specific functional tasks. Strength and endurance training was allowed once movement control was achieved. Following the rationale that the MC test battery is representative of functional MCI, the focus of the treatment was on functional restoration of the impaired movement(s). Exercises aimed specifically at local lumbar stabilising muscles (Hides et al., 2001), or treatment according to behavioural classification as recently proposed by O'Sullivan (O'Sullivan, 2012), were not included in the MCI treatment protocol. For example, patient A,

when asked to bend forward without moving the lower part of the spine, was not able to stabilise the lumbar spine: this MCI was classified as flexion impairment, and the corresponding test is called "waiter's bow". In treatment, the patient learns to control the lumbar spine stepwise: initially performing exercises with hip movements only in well-supported body positions (such as lying and sitting) and gradually progressing to exercises in standing. Load, frequency and velocity can gradually be increased once the movement is retrained. The ultimate goal is that patient A should be able to move freely and automatically in complex functional situations according to his personal needs in daily life.

General exercise (GE) treatment aimed to improve the muscular strength of the lumbar and pelvic region and legs. In a standardised programme, as described in a study manual, all relevant muscle groups (abdominals, erector spinae, gluteals, quadriceps and hamstrings) were addressed in each treatment (Koumantakis et al., 2005). Start load and progression were assessed individually and followed a submaximal training protocol, according to the guidelines of the American College of Sports Medicine (Whaley, 2006).

The main contrast between the two programmes was the tailored-exercise training targeting functional improvement of MCI in the experimental group, as opposed to the non-specific general strength training performed by the control group.

All therapists showed a positive attitude towards their treatment group and had used the treatments in their daily practice. Therapists in the MC group were either trained to OMT (Orthopaedic Manual Therapy) standard or were novice physiotherapists working under the supervision of a highly-qualified OMT clinician of the ZHAW. All physiotherapists attended at least 4 h of specific

training on the protocol of their respective treatment. Additionally, they received a manual of conduct and exercise procedures. The therapists reported the trained exercises, number and description of home exercises and other interventions for each patient in a written log.

2.5. Baseline descriptors

Demographic and psychosocial characteristics of age, sex, height, weight, sports activities, workload, work status, sickness absence, medication, duration of LBP-related symptoms and Örebro musculoskeletal pain questionnaire (ÖMPQ) were recorded at baseline.

2.6. Outcome measures

Measurements of outcome were taken at baseline, post-treatment, after six months and 12 months. Outcome measures pre- and post-treatment were obtained by a research assistant onsite. Research assistants at the study centre collected primary outcome measures at six months and 12 months by telephone. On this occasion, they communicated the questionnaire on secondary outcomes, which were delivered and returned by postal mail.

Primary outcome was patient-specific LBP-related activity limitation measured with the Patient Specific Functional Scale (PSFS), the latter having shown excellent reliability for mechanical and chronic LBP (Stratford P, 1995; Hall et al., 2011; Horn et al., 2012) and concurrent validity with Roland–Morris Disability Questionnaire (RMDQ). PSFS was selected because it showed good responsiveness in patients with moderate LBP complaints and reflected patients' individual relevant limitations (Pengel et al., 2004; Hall et al., 2010).

Secondary outcome variables were pain over the last three months (measured with the subscales "Characteristic Pain Intensity" of the Graded Chronic Pain Scale (GCPS) (Turk & Melzack, 2011) (v. 2.0)) and disability (measured with the subscales "Disability Score" of the GCPS and the Roland–Morris Disability Questionnaire (RMDQ) (Roland and Morris, 1983)). Total GCPS scores for pain ranged from 0 to 30 and for disability from 0 to 40. Reliability and validity of GCPS and RMDQ were high for the English and the German versions (Wiesinger et al., 1999; Roland and Fairbank, 2000; Klasen et al., 2004). More details about outcome measurements are described in the study protocol (Saner et al., 2011).

2.7. Adherence and satisfaction

Adherence to treatment by patients and therapists was monitored using log books and a comprehensive questionnaire, both during and after treatment. Patient satisfaction was assessed with a numeric rating scale from 0 (extremely dissatisfied) to 10 (completely satisfied) after six months and one year.

2.8. Data analysis

Descriptive statistics of demographic and clinical measures were performed. Analyses followed the intention-to-treat principle. For the primary outcome, only the first activity mentioned in the PSFS was used for analysis, i.e. the first open-ended response item, since correlation between the averages of the three activities versus the first activity was very high at 0.9. Univariate analysis of variance (ANOVA) for the primary outcome and subsequent analysis of covariance (ANCOVA) analysed the potential influence of the identified covariates of baseline differences and pain duration.

Missing data for this analysis were replaced by the group mean value (Hollis and Campbell, 1999).

For primary and secondary outcome, we fitted a linear mixed model (LMM) to the data with time, treatment group and the interaction time: treatment group as fixed effects, subject was included as random intercept (Son et al., 2012). Random intercept models are equivalent to repeated measures ANOVA and take into account the correlation between repeated measurements. In contrast to classical repeated measures ANOVA, they can deal naturally with missing observations. All missing values were handled in the model as missing at random. In a first step, the parameters of the model were estimated; in a second step, specific contrasts were estimated.

For the intervention, we described differences of adherence between both groups regarding frequency of home exercises and patient satisfaction. For work status descriptive data over one year were provided.

Analyses were conducted using IBM SPSS Statistics 20. Two-sided significance was set at $p \leq 0.05$.

3. Results

3.1. Participants

Between August 2010 and February 2012 a total of 201 patients were evaluated for eligibility. As described in the flow chart (Fig. 1), 48 patients did not meet the primary inclusion criteria. A further 47 patients were excluded from randomisation after baseline assessment. The main reasons for exclusion were minimal disability (<5 RMDQ) or no movement control impairment (<2 MCI tests positive). After signing informed consent, 106 patients were randomised (MC = 52, GE = 54). The final number of participants equates to the sample size calculation (power 0.9; 2-sided α 0.05; 10% drop out) (Saner et al., 2011). Follow-up data collection ended in March 2013.

Table 1 shows that most baseline characteristics were similar in both groups. There were more men than women, participants were relatively active in sports, only 11% were absent from work or on restricted work because of their LBP. Participants with LBP for longer than one year comprised 80%. Patients in the MC group had experienced a longer mean duration of pain than those in the GE group.

For unknown reasons, three patients in the MC and two in the GE group withdrew from the study during treatment. One patient withdrew for other unrelated medical reasons. Baseline characteristics did not differ between assessed and non-assessed patients during follow-up, except for the duration of pain (MC/GE; 9.0/15.7 years). The attrition rate of six % was within the anticipated 10%.

3.2. Primary outcome

Table 2 and Fig. 2 show outcomes for LMM of treatment effects of PSFS at all follow-ups. Both groups improved significantly over time ($p < 0.001$). The time and group interaction effect for the PSFS was not significant ($p > 0.05$). A slight post-treatment trend in favour of the MC group (mean -0.4 ; -1.4 to 0.6 , 95%CI) levelled off at 6 months. Baseline differences and information from the literature identified pain duration as potentially having an influence on outcomes (Dunn and Croft, 2006; Hill et al., 2008; Von Korf and Dunn, 2008). However, the results were not changed to a level of significance and these variables were not taken into account for further analysis (LMM) (Ryoo, 2011).

The minimal clinical important change was reported >0.9 on PSFS for mechanical pain (Stratford et al., 1995) and >1.9 for chronic pain (Maughan and Lewis, 2010). 95 patients (89.9%) reached the

Table 1
Baseline demographic data and baseline results of questionnaires.

		Movement control n = 52	General exercise n = 54	Total group n = 106
Age (y)	mean (SD)	42.8 (13.8)	40.5 (14.7)	41.6 (1.4)
Gender	female, n	16	24	40
Height (cm)	mean (SD)	173.0 (8.5)	173.9 (8.0)	173.6 (8.3)
Weight (kg)	mean (SD)	75.5 (11.7)	74.7 (11.9)	75.4 (12.1)
Physical workload	low, n	23 (44.2%)	21 (38.9%)	44 (41.5%)
	medium, n	22 (42.3%)	26 (48.1%)	48 (45.3%)
	heavy, n	5 (9.6%)	6 (11.1%)	11 (10.4%)
	missing, n	2 (3.8%)	1 (1.9%)	3 (2.8%)
Sport participation	no	19 (36.5%)	16 (30.8%)	35 (33.0%)
	1–2x week	21 (42.0%)	23 (43.1%)	44 (41.5%)
	>2x week	10 (20.0%)	13 (25.0%)	23 (21.7%)
	missing	2 (3.8%)	2 (3.8%)	4 (3.8%)
Work status, n	sick leave	1 (1.9%)	5 (9.3%)	6 (5.7%)
	part-time leave	3 (5.8%)	3 (5.6%)	6 (5.7%)
	full-time	39 (75.0%)	38 (70.4%)	77 (72.6%)
	no paid job	5 (9.6%)	8 (14.8%)	13 (12.3%)
	missing	4 (7.7%)	0	4 (3.8%)
Pain Duration ^a (y)	mean (SD)	11.6 (12.8)	8.4 (8.9)	10.0 (11.0)
	<1 year, n	4	8	12 (11.3%)
	1–5 years, n	17	15	32 (30.2%)
	>5 years, n	26	27	53 (50.0%)
	Missing, n	5	4	9 (8.5%)
ÖMPQ	mean (SD)	78.3 (24.3)	81.5 (20.4)	79.9 (22.3)

Abbreviations: y = year; SD = standard deviation; ÖMPQ: Oerebrö musculoskeletal pain questionnaire.

^a Overall duration of LBP.

first (MC/GE; 90.4%/88.9%) and 81 (76.4%) the second value (MC/GE; 75.0%/77.8%).

3.3. Secondary outcomes

Table 2 and Fig. 2 show the results of GCPS and RMDQ. Pain differences were non-significant at all follow-ups. The between-group difference for the RMDQ in favour of the MCI group, which was significant post-treatment, was no longer significant after six and 12 months.

As in the primary outcome, all secondary outcomes improved significantly over time in both groups. Again, the main effect over time was shown between pre- and post-treatment and improvements were maintained for up to one year.

All but one patient, who were initially on full or partial sick leave because of their back pain, improved their work status. One patient in the GE group remained on partial sick leave.

3.4. Treatment descriptives

Patients received a mean of 8–9 treatment sessions (range MC 4–18; GE 5–25) in both groups. Patients completing treatment reported a mean number of recommended exercises of MC/GE 3.9/5.0, respectively. One year after randomisation, approximately 46% of the patients in both groups (MC/GE; n = 20/22) reported that they still did their exercises in accordance with the recommended twice per week or daily. Patient satisfaction with treatment was comparable between groups. At the six months and twelve months follow-ups 70% and 80% of the patients in both groups rated satisfaction with treatment as high to very high (8 or more on a 0–10 scale) (Kool et al., 2007).

Patients in both groups started with a mean number of impaired movement control tests of 3.9, the MC group improved to a mean of

Table 2

Outcomes of linear mixed model (LMM) for primary and for secondary results of each group. Treatment effects measured post-treatment, 6 months and 12 months.

Primary outcome				
	Movement control n = 52	General exercise n = 54	Estimated mean difference (95%CI)	p
Patient Specific Functional Scale (PSFS)				
Overall time × group interaction effect: F = 0.2 p = 0.89				
Baseline	4.3	4		
Post-treatment	7.3	6.6	−0.4 (−1.4 to 0.6)	0.48
6 months	7.6	7.0	−0.2 (−1.3 to 0.7)	0.62
12 months	7.9	7.5	−0.08 (−1.1 to 0.9)	0.88
Secondary outcome				
Graded Chronic Pain Scale – Characteristic Pain Intensity in last 3 months (GCPS sub-score pain)				
Overall time × group interaction effect: F = 0.6 p = 0.6				
Baseline	14.5	16.5		
Post-treatment	10.1	13.0	0.8 (−1.4 to 3.1)	0.47
6 months	8.7	10.0	−0.7 (−3.0 to 1.8)	0.55
12 months	7.6	9.2	−0.5 (−2.8 to 1.8)	0.69
Roland Morris Disability Questionnaire (RMDQ)				
Overall time × group interaction effect: F = 1.6 p = 0.19				
Baseline	9.1	8.2		
Post-treatment	4.5	5.3	1.6 (0.1 to 3.1)	0.04*
6 months	4.3	4.5	1.0 (−0.5 to 2.5)	0.19
12 months	4.0	4.3	1.6 (−0.4 to 2.6)	0.13
Graded Chronic Pain Scale – Disability in last 3 months (GCPS sub-score disability)				
Overall time × group interaction effect: F = 0.05 p = 0.9				
Baseline	11.5	13.3		
Post-treatment	7.0	8.7	−0.2 (−6.1 to 5.8)	0.9
6 months	5.3	6.2	−1.1 (−7.1 to 5.0)	0.7
12 months	7.3	9.0	−0.2 (−6.2 to 5.8)	0.9
Graded Chronic Pain Scale (GCPS total score)				
Overall time × group interaction effect: F = 0.6 p = 0.6				
Baseline	25.9	29.5		
Post-treatment	17.5	21.8	0.4 (−4.2 to 5.1)	0.8
6 months	14.2	16.6	−1.5 (−6.3 to 3.3)	0.5
12 months	12.4	14.4	−2.4 (−7.1 to 2.3)	0.3

○ For PSFS self-score activity mentioned first from 0 (unable to perform) to 10 (able to perform without difficulties).

○ RMDQ score on 24 items on a 0 (able to perform without difficulties) to 1 (perform with difficulties) scale.

○ GCPS characteristic pain intensity on three items (actual pain, worst pain, usual pain).

○ GCPS disability score on four items (days kept from activities, inference with daily, social and work activities) both on a 0 (for no pain) to 10 (for pain as bad as could be) scale.

○ GCPS total score 0 to 70 adding sub-score for pain and disability.

Overall effect shows results over 12 months. Data are unadjusted mean for each time point. Estimated Mean difference (95%CI) contains results between each time period. Minus scores of mean difference in PSFS favour MC, in all secondary outcomes minus scores favour GE.

1.8 and the GE patients to 2.8 positive tests after treatment. The 10 min allocated to other physiotherapy applications was monitored in the log book and did not exceed the allowance for any patient.

A total of 28 physiotherapists performed the treatments. Therapists in both groups had mixed levels of experience. Due to the two different recruitment processes, therapists in private practice reported mean years of experience MC/GE; 12.9/9.8. Physiotherapists from the ZHAW (four therapists in each group) were novices and were treating 15 patients in each group.

4. Discussion

The findings of this study indicate no additional benefit on disability and pain to patients with NSLBP and MCI of movement control exercise versus general exercise. Both groups improved significantly on all outcomes over time.

Fig. 2. Long term results of primary and secondary outcomes. Patient Specific Functional Scale (PSFS) (0–10); Graded Chronic Pain Scale (GCPS) subscale for characteristic pain (0–30); Roland Morris Disability Scale (RMDQ) (0–24); GCPS subscale disability (0–40); measured at baseline (time1), post-treatment (time2), after 6 months (time3) and 12 months (time4).

4.1. Strengths of this study

This trial was prospectively registered, the protocol was published and every attempt was made in the design to minimise bias.

In general, patients were representative of people with mild to moderate pain and disability as a result of their long-lasting low back disorders. Patients with a high risk of psychosocial burden were excluded, in order to principally address the physical aspects of NSLBP.

For the interventions, we chose two exercise programmes, which had previously shown positive effects, with the aim of clarifying the choice of treatment for the physiotherapist. The pragmatic approach, with 28 physiotherapists in different clinical settings and therapists with different length of work experience, shows that the treatments are widely applicable.

The adherence to the intervention protocol was high for therapists and patients in both groups. A blinded research assistant, who obtained the third and fourth PSFS results by telephone, also encouraged participants to stay compliant with their home exercise programme. This might have supported the high adherence and follow-up rates (Evers et al., 2012).

4.2. Limitations of this study

The unexpected improvements in both groups may be influenced by the inclusion criteria of the study. Previous observational studies, analysing the natural history of LBP, have stated repeatedly that patients with previous episodes of back pain are likely to remain in a stable situation over years with no improvement over time (Von Korff, 1994; Tamcan et al., 2010). In our RCT, a selection bias towards a NSLBP population with low psychosocial influence

and high self-management competence may be present and must be considered when selecting either exercise programme for future treatment. Additionally, the inclusion criteria of MCI - 2 positive tests out of 6 – was designed to select patients who would have the best chance of improvement with specific exercises. Likewise, it was not possible to blind physiotherapists or patients due to the nature of the treatment; patients would have noticed during treatment whether they were performing a general exercise program or tailored, focused exercises that matched the tests they underwent at baseline. The therapists treating patients in the MCI group had an OMT degree, which is a two-year postgraduate specialisation in musculoskeletal physiotherapy. It was assumed that they were sufficiently specialised in treating MCI. However, O'Sullivan claims that it needs a further 100-h programme to learn to treat patients in this subgroup. Therefore, the equal results might be due to insufficient training. However, in our opinion, treatment of MCI is achievable by every physiotherapist, should be not too complex and form part of every physiotherapists toolbox.

4.3. Comparison with other studies

We are not aware of any results from other RCTs with the same inclusion criteria and this type of MC treatment. In a study of moderate methodological quality, a similar patient group, identified with the same classification system, found a significant benefit from behaviourally-orientated exercises when compared with spinal manipulation plus exercise (Vibe Fersum et al., 2013). Other than in our study, patients were additionally classified according to their behavioural pattern. The intervention of the experimental group followed a mixed approach of exercise and cognitive behavioural treatment. We are aware of changes to the assessment

and treatment approaches in more recent years (O'Sullivan, 2012). Nowadays, non-specific low back pain disorders should be considered within the multidimensional bio-psycho-social framework. Implementation of this approach is of major concern regarding the „beliefs“ of the therapists in terms of how they understand and deal with NSLBP.

4.4. The importance of exercise in NSLBP

The results of our study support previous findings that exercise in general, regardless of the type, is beneficial for patients with NSLBP. Alongside disability, pain, a major concern for patients, improved significantly and continuously. Clearly both treatments share general effective aspects of exercise. All patients receive attention to their complaints, they are introduced to exercise at their level of fitness, and the exercises are controlled regularly. As a result, they improve their physical activity levels, fitness and gain confidence in movement and adjustment of lifestyle.

Furthermore, the importance of general influences of the therapeutic relationship and the effects on pain beliefs, as explained in the common factors model, may be underestimated (Hall et al., 2010; Miciak et al., 2012). This assumption is supported by the high level of satisfaction with treatment in both groups. Although all these factors are likely to explain a substantial part of the improvement in both groups, the previously mentioned effect of some degree of selection bias towards a sample with an existing good prognosis, cannot be ruled out.

5. Conclusion

Contrary to our expectation, MC exercise and GE exercise appear equally effective in the patient subgroup included in this study. We can conclude that the contrast between both types of intervention did not bring additional value to the shared effects. Decisions for the application of either active treatment approach can currently not be taken on the basis of the results of this study. It is possible that the type of exercise treatment is less important than previously presumed; that the patient is guided to a consistent long-term exercise lifestyle is of most importance.

Based on the results of this study, we can recommend exercise therapy for patients with NSLBP and MCI, either using movement control or general exercise. Future research on treatment for NSLBP may reconsider the concept of testing exercises for specific subgroups. If the theoretical model, clinical findings, patients likely to respond to the treatment (but with a prognosis that can be improved) and adequate treatment goals are found, the means to treat need to have sufficient contrast. The concept behind exercise may not be based so much on specific movements, but on activity per se, the dosage of exercise, the kind of information and general aspects of a physiotherapy treatment.

Acknowledgements

The authors would like to thank all patients who participated in this study.

We wish to thank physiotherapists and doctors in clinics and practices in Switzerland, which are: Bethesda Spital, Basel; Kantonsspital Winterthur, Winterthur; Klinik, Schulthess, Zurich; Medbase Physiotherapie, Winterthur; Physiotherapie Seen, Winterthur; Physiotherapie Bellaria, Zurich; Physiotherapie Erlenbach, Erlenbach; Physiotherapie Reinach, Reinach; Physiotherapie Würenlingen, Würenlingen; Provital Physiotherapie, Egg; Rheumaklinik, Universitätsspital Zurich, Zurich; Segeten Physiotherapie, Zurich; Uniklinik Balgrist, Zurich. We also wish to thank Christa Wachter for her help in the randomisation process, André Meichtry

for statistical advice and Karen Linwood–Williams for proof reading the manuscript.

The project was supported by the Swiss National Science Foundation (SNSF). (Project no. 127240).

References

- Airaksinen O, Brox J, Cedraschi C, Hildebrandt J, Klaber-Moffett J, Kovacs F, et al. Chapter 4. European guidelines for the management of chronic nonspecific low back pain. *Eur Spine J* 2006;15(Suppl 2):S192–300.
- Bystrom MG, Rasmussen-Barr E, Grooten WJ. Motor control exercises reduces pain and disability in chronic and recurrent low back pain: a meta-analysis. *Spine (Phila Pa 1976)* 2013;38:E350–8.
- Carlsson H, Rasmussen-Barr E. Clinical screening tests for assessing movement control in non-specific low-back pain. A systematic review of intra- and inter-observer reliability studies. *Man Ther* 2013;18:103–10.
- Dankaerts W, O'Sullivan P. The validity of O'Sullivan's classification system (CS) for a sub-group of NS-CLBP with motor control impairment (MCI): overview of a series of studies and review of the literature. *Man Ther* 2011;16:9–14.
- Dankaerts W, O'Sullivan PB, Straker LM, Burnett AF, Skouen JS. The inter-examiner reliability of a classification method for non-specific chronic low back pain patients with motor control impairment. *Man Ther* 2006;11:28–39.
- Dunn KM, Croft PR. The importance of symptom duration in determining prognosis. *Pain* 2006;121:126–32.
- Evers A, Klusmann V, Ziegelmann JP, Schwarzer R, Heuser I. Long-term adherence to a physical activity intervention: the role of telephone-assisted vs. self-administered coping plans and strategy use. *Psychol Health* 2012;27:784–97.
- Foster NE, Hill JC, Hay EM. Subgrouping patients with low back pain in primary care: are we getting any better at it? *Man Ther* 2011;16:3–8.
- Hall AM, Ferreira PH, Maher CG, Latimer J, Ferreira ML. The influence of the therapist-patient relationship on treatment outcome in physical rehabilitation: a systematic review. *Phys Ther* 2010;90:1099–110.
- Hall AM, Maher CG, Latimer J, Ferreira ML, Costa LO. The patient-specific functional scale is more responsive than the Roland Morris disability questionnaire when activity limitation is low. *Eur Spine J* 2011;20:79–86.
- Hayden JA, van Tulder MW, Malmivaara AV, Koes BW. Meta-analysis: exercise therapy for nonspecific low back pain. *Ann Intern Med* 2005;142:765–75.
- Hides JA, Jull GA, Richardson CA. Long-term effects of specific stabilizing exercises for first-episode low back pain. *Spine (Phila Pa 1976)* 2001;26:E243–8.
- Hill JC, Dunn KM, Lewis M, Mullis R, Main CJ, Foster NE, et al. A primary care back pain screening tool: identifying patient subgroups for initial treatment. *Arthritis Rheum* 2008;59:632–41.
- Hollis S, Campbell F. What is meant by intention to treat analysis? Survey of published randomised controlled trials. *BMJ* 1999;319:670–4.
- Horn KK, Jennings S, Richardson G, Vliet DV, Hefford C, Abbott JH. The patient-specific functional scale: psychometrics, clinimetrics, and application as a clinical outcome measure. *J Orthop Sports Phys Ther* 2012;42:30–42.
- Karayannis NV, Jull GA, Hodges PW. Physiotherapy movement based classification approaches to low back pain: comparison of subgroups through review and developer/expert survey. *BMC Musculoskelet Disord* 2012;13:24.
- Klasen BW, Hallner D, Schaub C, Willburger R, Hasenbring M. Validation and reliability of the German version of the Chronic Pain Grade questionnaire in primary care back pain patients. *Psychosoc Med* 2004;1. Doc07.
- Kolb E, Canjuga M, Bauer GF, Laubli T. Course of back pain across 5 years: a retrospective cohort study in the general population of Switzerland. *Spine (Phila Pa 1976)* 2011;36:E268–73.
- Kool J, Bachmann S, Oesch P, Knuesel O, Ambergen T, de Bie R, et al. Function-centered rehabilitation increases work days in patients with nonacute nonspecific low back pain: 1-year results from a randomized controlled trial. *Arch Phys Med Rehabil* 2007;88:1089–94.
- Koumantakis GA, Watson PJ, Oldham JA. Trunk muscle stabilization training plus general exercise versus general exercise only: randomized controlled trial of patients with recurrent low back pain. *Phys Ther* 2005;85:209–25.
- Linton SJ, Boersma K. Early identification of patients at risk of developing a persistent back problem: the predictive validity of the Orebro Musculoskeletal Pain Questionnaire. *Clin J Pain* 2003;19:80–6.
- Luomajoki H. Movement control impairment as a sub-group of non-specific low back pain: evaluation of movement control test battery as a practical tool in the diagnosis of movement control impairment and treatment of this dysfunction. Kuopio, Finland: University of Eastern Finland; 2010.
- Luomajoki H, Kool J, de Bruin ED, Airaksinen O. Reliability of movement control tests in the lumbar spine. *BMC Musculoskelet Disord* 2007;8:90.
- Luomajoki H, Kool J, de Bruin ED, Airaksinen O. Movement control tests of the low back: evaluation of the difference between patients with low back pain and healthy controls. *BMC Musculoskelet Disord* 2008;9:170.
- Luomajoki H, Kool J, de Bruin ED, Airaksinen O. Improvement in low back movement control, decreased pain and disability, resulting from specific exercise intervention. *Sports Med Arthrosc Rehabil Ther Technol* 2010;2:11.
- Maughan EF, Lewis JS. Outcome measures in chronic low back pain. *Eur Spine J* 2010;19:1484–94.
- Miciak M, Gross DP, Joyce A. A review of the psychotherapeutic 'common factors' model and its application in physical therapy: the need to consider

- general effects in physical therapy practice. *Scand J Caring Sci* 2012;26:394–403.
- O'Sullivan P. Diagnosis and classification of chronic low back pain disorders: maladaptive movement and motor control impairments as underlying mechanism. *Man Ther* 2005;10:242–55.
- O'Sullivan P. It's time for change with the management of non-specific chronic low back pain. *Br J Sports Med* 2012;46:224–7.
- Pengel LH, Refshauge KM, Maher CG. Responsiveness of pain, disability, and physical impairment outcomes in patients with low back pain. *Spine (Phila Pa 1976)* 2004;29:879–83.
- Roland M, Fairbank J. The Roland-Morris Disability Questionnaire and the Oswestry Disability Questionnaire. *Spine (Phila Pa 1976)* 2000;25:3115–24.
- Roland M, Morris R. A study of the natural history of back pain. Part I: development of a reliable and sensitive measure of disability in low-back pain. *Spine* 1983;8:141–4.
- Ryoo JH. Model selection with the linear mixed model for longitudinal data. *Multivar Behav Res* 2011;46:598–624.
- Sahrmann SA. *Diagnosis and treatment of movement impairment syndromes*. St.Louis: Mosby; 2002.
- Saner J, Kool J, de Bie RA, Sieben JM, Luomajoki H. Movement control exercise versus general exercise to reduce disability in patients with low back pain and movement control impairment. A randomised controlled trial. *BMC Musculoskelet Disord* 2011;12:207.
- Smith BE, Littlewood C, May S. An update of stabilisation exercises for low back pain: a systematic review with meta-analysis. *BMC Musculoskelet Disord* 2014;15:416.
- Son H, Friedmann E, Thomas SA. Application of pattern mixture models to address missing data in longitudinal data analysis using SPSS. *Nurs Res* 2012;61:195–203.
- Stanton TR, Henschke N, Maher CG, Refshauge KM, Latimer J, McAuley JH. After an episode of acute low back pain, recurrence is unpredictable and not as common as previously thought. *Spine (Phila Pa 1976)* 2008;33:2923–8.
- Stratford PGC, Westaway M, Binkley J. Assessing disability and change on individual patients: a report of a patient specific measure. *Physiother Can* 1995;47:258–63.
- Tamcan O, Mannion AF, Eisenring C, Horisberger B, Elfering A, Muller U. The course of chronic and recurrent low back pain in the general population. *Pain* 2010;150:451–7.
- Turk DC, Melzack R. *Handbook of pain assessment*. The Guildford Press; 2011.
- Vibe Fersum K, O'Sullivan P, Skouen JS, Smith A, Kvale A. Efficacy of classification-based cognitive functional therapy in patients with non-specific chronic low back pain: a randomized controlled trial. *Eur J Pain* 2013;17:916–28.
- Von Korff M. Studying the natural history of back pain. *Spine (Phila Pa 1976)* 1994;19:2041S–6S.
- Von Korff M, Dunn KM. Chronic pain reconsidered. *Pain* 2008;138:267–76.
- Waddell G. 1987 Volvo award in clinical sciences. A new clinical model for the treatment of low-back pain. *Spine (Phila Pa 1976)* 1987;12:632–44.
- Whaley MH. In: *Medicine ACoS*, editor. *ACSM's guidelines for exercise testing and prescription*. Lippincott Williams & Wilkins; 2006.
- Wiesinger GF, Nuhr M, Quittan M, Ebenbichler G, Wolf G, Fialka-Moser V. Cross-cultural adaptation of the Roland-Morris questionnaire for German-speaking patients with low back pain. *Spine (Phila Pa 1976)* 1999;24:1099–103.