

Manual Therapy vs. Kinesiotherapy for People with Lumbar Discopathy: A Pilot Randomized Trial

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Abstract: Lumbar discopathy is a painful pathology, which needs conservative treatment to relieve symptoms. The aim of this study was to compare the effect of Kaltenborn-Evjenth Orthopedic Manual Therapy (KEOMT) and Kinesiotherapy (KIN) on quality of life, and pain in patients with lumbar discopathy. The study was designed as a pilot randomized controlled trial with concealed allocation, assessor blinding, and intention-to-treat analysis. Eighty participants, 40-70 years old suffering from lumbar discopathy were randomized to an experimental (KEOMT) and a control (KIN) groups. Both groups completed 10 treatments for 5 weeks. All evaluations were performed at baseline (Week 0), and after the treatment (Week 5) for: quality of life (Short Form-36 questionnaire – SF-36), and pain (visual analog scale – VAS). After the intervention the statistical significant between group differences favoring the KEOMT were found in the SF-36 with regard to physical function ($p = 0.027$), role physical ($p = 0.004$), bodily pain ($p = 0.027$), general health ($p = 0.018$), vitality ($p = 0.019$), social functioning ($p = 0.034$), role emotional ($p = 0.028$), mental health ($p = 0.015$), and on VAS ($p = 0.014$). It was concluded that patients achieve better health benefits caused by KEOMT.

Keywords: Kaltenborn-Evjenth Orthopedic Manual Therapy, Kinesiotherapy, Lumbar Discopathy

1. Introduction

Every kind of discopathy is associated with pain. The quality of life with pain is poor, and there's a high risk of a chronic illness' development [1-3]. Numerous modalities of therapeutic interventions are available for lumbar discopathy treatment: physical therapy, drugs, behavior therapy, and neural blockade. In cases resistant to conservative treatment, surgical treatment is used [4-9]. Manual therapy is another option, although its effectiveness remains controversial. A systematic review from Cochrane Database concludes, that addition of manual therapy offers no benefits [10], but a few randomized controlled trials demonstrate positive effects of manual therapy in pain and physical disfunctions [11, 12, 13].

Despite this fact, a systematic review shows a lack of compare the effectiveness of manual therapy versus classical kinesiotherapy in the same randomized study. So, the lack of this kind of research has become the main reason for carrying out the present study. Consequently, we conducted a pilot randomized

trial to compare the effects of manual therapy and kinesiotherapy on the quality of life and pain in patients with lumbar discopathy. In our study we chose Kaltenborn-Evjenth Orthopedic Manual Therapy (KEOMT) and classical kinesiotherapy (KIN), because Physiotherapy Outpatient Department of the Regional Hospital in Sandomierz specializes in this type of therapies. The physiotherapist with a postgraduate degree in KEOMT as well as in KIN, and 10 years' experience performs the interventions, which increase the possibility of obtaining the maximum health benefits by the patients. We hope the treatment protocol and the results of our study will become a contribution to improving the therapeutic effects and the health benefits in patients suffering from lumbar discopathy.

2. Method

2.1. Design

It was a pilot randomized trial with concealed allocation, assessor blinding, and intention-to-treat analysis. The study

was conducted according to the Declaration of Helsinki, the guidelines for Good Clinical Practice, and the Consolidated Standards of Reporting Trials (CONSORT) Statement guidelines [14]. The study protocol was approved by the Holycross College Ethics Committee. Any changes during the randomized trial were reported to the Holycross College Ethics Committee. Participants were recruited from the Physiotherapy Outpatient Department of the Regional Hospital in Sandomierz, Poland. All the patients gave their written informed consent to participate in the study.

2.2. Inclusion/Exclusion Criteria

The inclusion criteria were: (a) patients, 40-70 years old diagnosed with Magnetic Resonance Imaging (MRI) scan on the lumbar disc disease; (b) lumbar discopathy defined as ≥ 1 year duration; (c) pain associated with disc disease (failure of the intervertebral disc, herniated of disc); (d) pain radiating to the extremities associated with compression and nerve roots irritation; (e) ability to perform physical exercises; (f) not currently receiving any physical therapy treatments for the lumbar discopathy condition.

The exclusion criteria were: (a) osteoporosis; (b) uncontrolled hypertension or cardiovascular, pulmonary diseases; (c) skin changes; (d) inability to comprehend and complete study assessments or comply with study instructions; (e) inflammation (ankylosing spondylitis, rheumatoid arthritis); (f) spine injuries

(subluxation in intervertebral joints, spinal compression fractures, vertebral transverse process fractures); (g) congenital and acquired disorders of spine statics (scoliosis, spondylosis, spondylolisthesis, sacralization of L₅, lumbalization of S₁, spina bifida); (h) previous back surgery.

2.3. Randomization

Ninety-five participants with with lumbar discopathy were screened for inclusion by an independent physician who was not involved into the study between 11 April 2016 and 20 May 2016. Fifteen participants were excluded for various reasons (see Figure 1). Finally, eighty participants were randomized and allocated with a 1:1 ratio to KEOMT group or KIN group using a simple randomization scheme generated by software (www.randomization.com). The baseline characteristics of participants are shown in Table 1 and in the first two columns of data in Table 2. The investigator responsible for randomly assigning participants to the treatment groups did not know in advance which treatment one would receive (concealed allocation) and did not participate in administering the intervention or measuring the outcomes. The participants and the therapists administering the intervention were not blinded. The investigators responsible for the outcome assessment were blinded to the groups allocation and were not involved into the study.

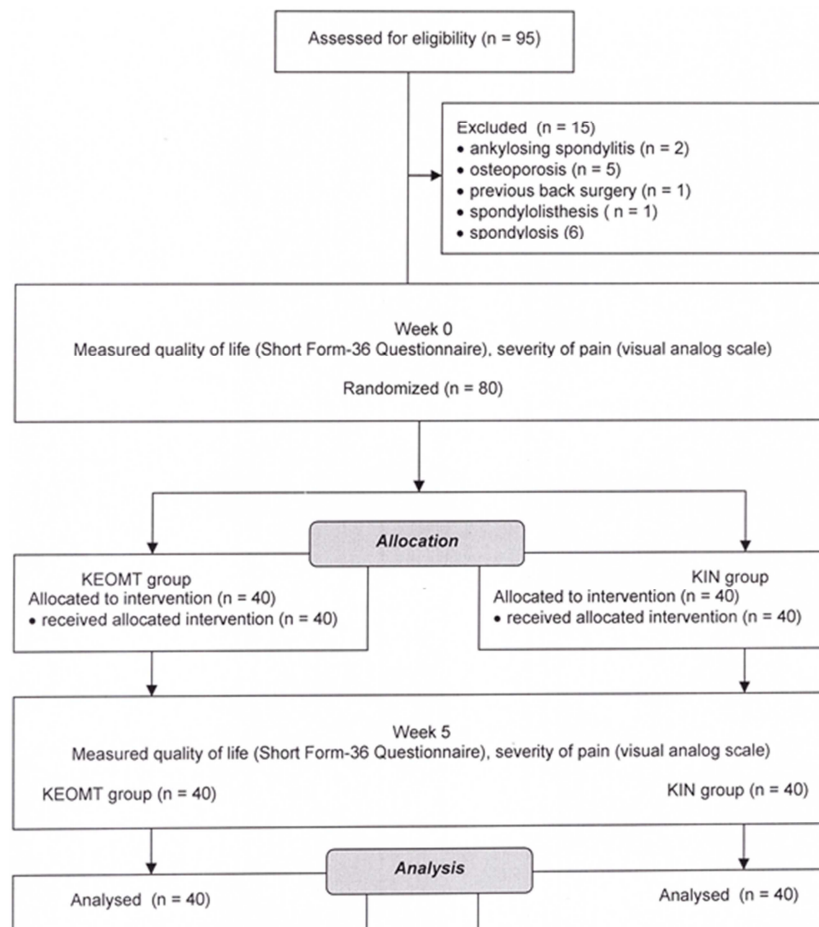


Figure 1. Recruitment and flow of participants through the trial.

Table 1. Characteristics of the participants.

Characteristic	Group Exp (n = 40)	Group Con (n = 40)
Females/males, (n)	30/10	32/8
Age (yr), mean (SD)	56.0 (6.0)	57.0 (5.5)
Height (m), mean (SD)	1.76 (0.06)	1.77 (0.05)
Mass (kg), mean (SD)	76.7 (6.5)	77.0 (6.0)
BMI (kg/m ²), mean (SD)	24.66 (0.78)	24.42 (0.83)
Level of education		
Primary school graduates, (n)	18	15
Secondary school graduates, (n)	12	16
University graduates, (n)	10	9
Duration of complaints (yr), mean (SD)	8.5 (1.7)	8.0 (1.5)

Exp = Kaltenborn-Evjenth Orthopedic Manual Therapy, KEOMT; Con = Kinesiotherapy, KIN.

2.4. Intervention

The whole treatment was performed at the Physiotherapy Outpatient Department of the Regional Hospital in Sandomierz, Poland. The same physiotherapist with a postgraduate degree in manual therapy and physiotherapy and 10 years' experience provided all the interventions in both groups, and remained blind to the primary and the secondary outcome measures throughout the trial.

The following interventions were performed:

1. Kaltenborn-Evjenth Orthopedic Manual Therapy was received by all the participants in KEOMT group (40 participants, 10 treatments, twice per week, for 5 weeks). KEOMT included: lumbar segmental traction in a supine position and in a side-lying position, lumbar segmental mobilization (flexion, extension, gliding therapy grade III) in a side-lying position, soft tissue mobilization. Each of the techniques was repeated 30 times (three sets, with 10 repetitions). Each session didn't exceed 30 minutes.
2. Classical kinesiotherapy received all the participants in the KIN group (40 participants, 10 treatments, twice per week, for 5 weeks). KIN program included: exercises for strengthening the abdominal, trunk extensor, as well as for gluteal muscles, and exercises for stretching the hamstring, psoas, and paraspinal muscles. The participants performed three sets of exercises, with 10 repetitions of each exercise per set. Each session didn't exceed 45 minutes.

2.5. Outcome Measures

An assessor blind to the assignment of the patients performed all evaluations at baseline (Week 0), after 5 weeks (Week 5). The following parameters were assessed during all the evaluations:

Primary outcome:

- The quality of life – the Short Form-36 questionnaire (SF-36) include 36 questions, is a grouped into eight different domains of health: physical functioning, role limitation due to physical problems, bodily pain, general health perception, vitality, social function, role limitation due to emotional problems, and mental health. The score ranged from 0 to 100 points: 100 – the best life quality, 0 – the worst one [15, 16]. The

participants marked each of the domains after usual daily activities. The each domain results in points were recorded for statistical analysis.

Secondary outcome:

- Pain – measured with the patient indicating his/her current level of pain by marking a point on a 10-cm visual analog scale (VAS), for which 0 represents the pain absence and 10 represents the unbearable pain. The results in centimeters were recorded for statistical analysis.

2.6. Data Analysis

The sample size was determined a priori by a statistical power calculation based on anticipated group differences in SF-36 scores at week 5. For this calculation the minimal clinically important difference between groups (KEOMT vs. KIN) was defined as 10 points, the standard deviation (SD) was estimated to be 30 points. Assuming significance level of 5% and a test power of 80%, we calculated that we needed minimum 35 participants in each group. The data were analyzed with descriptive as mean, standard deviation (SD) of the two groups, mean (SD) within-groups differences, 95% confidence interval (95% CI) of mean between-groups differences, and inferential techniques. A mean of between-groups differences (95% CI) was calculated for each of the outcomes based on the change scores (ie, week 5 minus week 0 scores). The Shapiro-Wilk test identified the non-normal distribution of all the data. To compare the differences of the therapy effects between the experimental (MT-C) and the control (KIN-C) groups, the Mann-Whitney U test was used. To describe the differences in related treatments, the effect size between-groups differences was calculated using Cohen's *d*, and classified as small ($d \geq 0.20$ and < 0.50), medium ($d \geq 0.50$ and < 0.80) and large ($d \geq 0.80$) [17]. The comparison of the proportion of clinically important difference at Week 5 (improved percentage $\geq 30\%$ for quality of life and pain intensity) between KEOMT and KIN treatments was tested by Chi-square value for a 2x2 contingency table as well as relative risk with 95% CI. The level of statistical significance was set at two-tailed *p* value of 0.05. The analysis were performed by a blinded and independent statistician according to a pre-specified statistical analysis plan on an intention-to-treat basis.

3. Results

3.1. Compliance with the Study Protocol

During the treatments the patients did not receive any other physical methods. No participants received the wrong intervention. No adverse events were observed during the treatment. All the participants were analyzed in the group to which they had been randomly allocated.

3.2. Effect of Intervention

After the intervention the improvement for the quality of life was identified in both groups. We found the significant between-groups differences on the SF-36 scores. The greatest between-groups differences were identified for the physical role, the emotional role domains, by a mean of 17 points, and by a mean of 15 points (95% CI 5 to 30; 95% CI -1 to 30)

respectively, in favor for the KEOMT group, and the smallest ones were observed for the general health and vitality domains, by a mean of 8 points (95% CI 1 to 15) in favor for the KEOMT group. Regarding the other domains the between-groups differences on SF-36 were also in favor for the KEOMT group. The effect size and 95% CI for the quality of life domains that were statistically significantly different between groups with Mann-Whitney U test are shown in Table 2. After the intervention (Week 5) we identified the reduce of pain severity in both groups. We found the significant between-groups differences on the VAS. The KEOMT group had lower score of pain severity on the VAS, by a mean of 1 centimeter (95% CI -1 to 0). The effect size and 95% CI for the parameters that were statistically significantly different between groups with Mann-Whitney U test were shown in Table 2.

Table 2. Mean (SD) of groups, mean (SD) difference within groups, and mean (95% CI) difference between groups for SF-36 (in points) and VAS (in centimeters) outcomes.

Outcome	Groups				Difference within groups		Difference between groups		
	Week 0		Week 5		Week 5 minus Week 0		Week 5 minus Week 0		Effect size (Cohen d)
	Exp (n = 40)	Con (n = 40)	Exp (n = 40)	Con (n = 40)	Exp	Con	Exp minus Con	p value	
<i>SF-36</i>									
PF	38(12)	42(2)	65(25)	55(21)	27(32)	13(27)	10(-1 to 19)	0.027*	0.47
RP	32(10)	30(8)	62(30)	45(26)	30(26)	15(23)	17(5 to 30)	0.004*	0.61
BP	36(16)	38(17)	70(19)	60(19)	34(31)	23(33)	10(1 to 17)	0.027*	0.34
GH	43(14)	42(15)	69(17)	61(16)	30(27)	19(29)	8(1 to 15)	0.018*	0.39
V	46(15)	45(15)	71(17)	64(15)	26(27)	17(27)	8(1 to 15)	0.019*	0.33
SF	41(12)	44(13)	70(24)	60(21)	29(29)	16(30)	10(0 to 20)	0.034*	0.44
RE	24(9)	24(9)	58(37)	43(32)	34(32)	19(27)	15(-1 to 30)	0.028*	0.51
MH	49(10)	46(9)	71(20)	60(18)	21(21)	13(19)	11(2 to 19)	0.015*	0.40
VAS	6(1)	6(2)	3(1)	4(2)	-3(1)	-2(1)	-1(-1 to 0)	0.014*	1.00

Exp = Kaltenborn-Evjenth Orthopedic Manual Therapy, KEOMT; Con = Kinesiotherapy, KIN; VAS = visual analog scale; SF-36 = Short Form-36 questionnaire, when PF = physical function, RP = role physical, BP = bodily pain, GH = general health, V = vitality, SF = social functioning, RE = role emotional, MH = mental health.
*Statistically significant p < 0.05.

After the treatment (Week 5) the participants in the KEOMT group had greater success rate than those in the KIN group on SF-36. The outcomes ranged from 93% for KEOMT versus 53% for KIN in role physical (RR = 6.33, 95% CI 2.03 to 19.72), and to 70% versus 47% in mental health (RR = 1.75, 95% CI 1.00 to 3.06) respectively. What is more, after the treatment (Week 5) the success rate (VAS outcome) of KEOMT was 85% versus 43% for KIN (RR = 3.83, 95% CI 1.75 to 8.40). The relative risk and 95% CI for all the parameters that were statistically significantly

different between groups with Chi-square test were shown in Table 3.

So, there are the relationships between a kind of treatment and health benefits among the people suffering from lumbar discopathy. Moreover, the outcomes were monitored by telephone interviews 1 month after the final session of the treatment. Nobody from the participants reported either the deterioration of their health benefit effects or any adverse events.

Table 3. Number of participants (%) after treatment (Week 5) for each outcome in each group and Chi square, relative risk (95% CI) between groups for SF-36 and VAS outcomes.

Outcome	Groups				Chi-square test	p value	Relative risk (95% CI)
	Exp (n = 40)	Con (n = 40)	Exp (n = 40)	Con (n = 40)			
	improved ≥ 30% n (%)		improved < 30% n (%)				
<i>SF-36</i>							
PF	34(85)	23(57)	6(15)	17(43)	7.384	0.013*	2.83(1.25 to 6.44)
RP	37(93)	21(53)	3(7)	19(47)	16.050	< 0.000*	6.33(2.03 to 19.72)
BP	30(75)	18(45)	10(25)	22(55)	7.500	0.006*	2.20(1.20 to 4.03)

Outcome	Groups				Chi-square test	p value	Relative risk (95% CI)
	Exp (n = 40) improved ≥ 30% n (%)	Con (n = 40)	Exp (n = 40) improved < 30% n (%)	Con (n = 40)			
GH	35(88)	26(65)	5(12)	14(35)	5.591	0.035*	2.80(1.11 to 7.04)
V	33(83)	24(60)	7(17)	16(40)	4.942	0.026*	2.28(1.05 to 4.95)
SF	30(75)	19(47)	10(25)	21(53)	6.372	0.016*	2.10(1.14 to 3.87)
RE	29(73)	20(50)	11(27)	20(50)	4.266	0.039*	1.82(1.00 to 3.28)
MH	28(70)	19(47)	12(30)	21(53)	4.178	0.041*	1.75(1.00 to 3.06)
VAS	34(85)	17(43)	6(15)	23(57)	15.632	< 0.000*	3.83(1.75 to 8.40)

Exp = Kaltenborn-Evjenth Orthopedic Manual Therapy, KEOMT; Con = Kinesiotherapy, KIN; VAS: visual analog scale, SF-36 = Short Form-36 questionnaire, when PF = physical function, RP = role physical, BP = bodily pain, GH = general health, V = vitality, SF = social functioning, RE = role emotional, MH = mental health.
 *Statistically significant p < 0.05.

4. Discussion

The purpose of the present study was to compare the effects of KEOMT and KIN on SF-36 and VAS in patients suffering from lumbar discopathy. Manual therapy has been frequently used to reduce low back pain and to increase the range of joint motions. Choi et al [18] suggested that manual therapy using joint mobilization techniques and flexion-distraction techniques is considered to be an effective intervention for addressing low back pain and disc heights in patients with chronic low back pain.

Park and Wang [19] in their case study suggested that joint mobilization using KEOMT and PNF had a positive effect on the pain of patients with chronic low back pain and a lumbar transitional vertebra. Ko et al [20] reported that chronic low back pain of the patients in a thoracic joint mobilization group showed greater pain reduction than in an exercise group. López et al [21] reported that joint postero-anterior mobilization had effected the pain of chronic low back patients. The methods of the studies are very different from those of the present one.

We applied KEOMT-C in the experimental group and KIN in the control group. Manual therapy techniques, joint mobilization techniques can affect the neurophysiological and mechanical aspects of pain, or muscle spasm, and they are effectively used in treating joints with hypomobility, those that gradually show mobility restrictions, and those that are functionally fixed. Manual therapy alleviates disc problems and removes the pressure imposed on the discs by creating zero gravity or negative pressure conditions inside the spinal canal so that nutritive substances and oxygen are supplied to the discs. It reduces pressure inside the intervertebral discs by softly extending certain parts of the discs through the decompression of lesion sites.

On the other hand, kinesiotherapy accelerates repair and substitution processes in the musculoskeletal system, and prevents the development of detrimental substitute motor patterns. It also prevents the progress of changes in bones, joints, muscles and ligaments. Kinesiotherapy involving movement is to break the vicious circle of pain by reducing reflex increase in paraspinal muscle tension. Exercising also serves to improve stability of the lumbar spine by increasing intraabdominal pressure and restoring muscle balance, which

prevents the recurrence of symptoms [22, 23].

Despite on, the participants with lumbar discopathy who were treated with KEOMT had statistically significant better score of quality of life, lower score of pain severity in the short-term compared with the patients who were treated with KIN. The therapeutic effects persisted unchanged for 1 month post-treatment.

It is unlikely that the differences of the results between groups can be explained in terms of a spontaneous remission or through natural resolution, because one of a requirement of the study was to have been in a chronic stable condition.

So, the main physiological benefit of KEOMT over KIN can probably explain that the mobilization procedure stretches the joint capsule, gently mobilizes any restriction to normal movement within the limits of patient’s tolerance and likely reduces the muscles’ spasm of the spine.

This study had several strengths, including that it was analyzed using the intention-to-treat principle and that the participants were assigned randomly to the KEOMT (experimental) or to the KIN (control) groups. The interventions were provided by the same experienced physiotherapist, blind to the outcome measures. The participants received the same number of interventions, had comparable contact time with the physiotherapist providing the interventions.

The major limitation was the short follow-up period. A future study of long term effects is needed to confirm this finding. The second limitation is a small sample size. A future study with a larger sample size is needed to confirm our results.

5. Conclusion

KEOMT is more effective than KIN in improving quality of life, and pain in patients suffering from lumbar discopathy. All of these results may be valuable for doctors, physiotherapists and patients with lumbar discopathy in choosing the most appropriate types of treatment based on the patients’ preference and convenience.

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