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Osteopathic Manual Treatment vs Kaltenborn–Evjenth Orthopedic Manual Therapy for Chronic Low Back Pain: A Proposal for a Protocol for Randomized Trials

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ABSTRACT

Introduction: Numerous modalities of conservative therapeutic interventions are available to achieve the best health benefits in people with Low Back Pain (LBP), e.g., kinesiotherapy, physical therapy, behavior therapy. People with LBP continue to experience pain and disability despite receiving the best evidence based therapy. Osteopathic Manual Therapy (OMT) and Kaltenborn–Evjenth Orthopedic Manual Therapy (KEOMT) are the other options, although their effectiveness remains controversial. The aim of this study is a proposal for a protocol for randomized trials to compare the effectiveness of OMT vs. KEOMT on pain and disability in people suffering from LBP.

Methods and analysis: It's a randomized study with two-arms parallel, designed with concealed allocation, the assessor's blinding with intention to-treat analysis. It will include 34 people a group with severe disability ranged from 41 to 60% in Oswestry Disability Index (ODI). There will be two groups: a treatment group (OMT) and a comparison group (KEOMT). All the patients in both groups will receive 2 treatments a week for 5 weeks. Each session in both groups will not exceed 30 minutes. During each session OMT and KEOMT techniques will be repeated 3 times. A baseline assessment will be performed pre and post intervention, two days later. The following parameters will be assessed during the evaluations: Numeric Pain Rating Scale – NPRS, ODI.

Ethics and dissemination: The trial was approved by the Scientific Research Ethics Committee of University of Warmia and Mazury, Olsztyn, Poland. Registration approval number: 9/2018.

Trial registration: The study protocol was prospectively registered in the Chinese Clinical Trial Registry on December 28, 2019 (registration ID: ChiCTR1900028580).

Strengths and Limitations of this Study

- The participants' random allocation to the experimental and the control groups.
- The same experienced physiotherapist, blind to the outcome measures, provides the interventions.
- The same assistant, blind to the group allocation, administers the outcomes.
- The same number of the interventions, the compared contact time with the physiotherapist providing the interventions.
- A short follow-up period and/or a rather small sample size.

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INTRODUCTION

Low Back Pain (LBP), is one of the most common health problems in modern and developed societies. It is known that almost 80% of the population is affected by this dysfunction, and that half of them underwent at least one kind of painful incident a year. This problem affects people between 45 and 60 years of age, professionally active [1,2]. If LBP persists for 3 months it is considered as chronic and may cause physical and psychological limits, and a major economic burden causes absence from work [3-5]. Numerous modalities of conservative therapeutic interventions are available to achieve the best health benefits in people suffering from LBP, e.g., kinesiotherapy, physical therapy, behavior therapy [6-10]. People with LBP continue to experience pain and disability despite receiving the best evidence based therapy, and a further research is needed to improve the treatment. Osteopathic Manual Therapy (OMT) and Kaltenborn-Evjenth Orthopedic Manual Therapy (KEOMT) are another option, but its effectiveness remains controversial. Although practice guidelines recommend considering OMT for chronic LBP, a systematic review found in the Cochrane Database concluded that it offered no benefits [11]. Nevertheless, a few Randomized Controlled Trials (RCTs) demonstrated clinically relevant LBP improvement in patients treated with OMT [12-15].

OMT and KEOMT differ from each other. For example, in OMT, visceral manipulative treatment, myofascial release treatment or indirect techniques – strain and counterstrain techniques are used, which are not included in the KEOMT. Despite this fact, a systematic review shows that nobody has ever compared the effectiveness of OMT vs. KEOMT in the same randomized study. So, the lack of this kind of a research is the main reason for carrying out the present study based on a proposal for a protocol for randomized trials. The research team will consequently conduct a randomized study to compare the effects of OMT and KEOMT on Numeric Pain Rating Scale (NPRS) and Oswestry Disability Index (ODI) in people suffering from chronic LBP.

In our study OMT and KEOMT will be applied because the Physiotherapy Center of the Motion System in Krzeszowice, Poland, specializes in this type of therapy and the physiotherapist employed there has a postgraduate degree in manual therapy and 15 year's experience. He is the person, who performs the interventions. This fact increases the possibility of obtaining the maximum health benefits by the patients.

We hope, that the treatment protocol and the results of our study will become a contribution to improve therapeutic effects and health benefits in patients suffering from chronic LBP. Moreover, the results may be addressed not only to doctors, physiotherapists, but, particularly to the patients with chronic LBP in order to choose the most appropriate types of treatment based on their preferences and convenience.

METHODS AND ANALYSIS

To report this study protocol we followed the Standard Protocol Items: Recommendations for Interventional Trials (SPIRIT) [16] and the Template for Intervention Description and Replication checklist (TIDieR) [17]. The randomized trial developed using this protocol, will be reported according to the Consolidated Standards of Reporting Trials (CONSORT) [18] statement for randomized trials of non-pharmacologic treatments. The trial is registered on 28/12/2019 on the Chinese Clinical Trial Registry (ChiCTR1900028580) platform.

STUDY DESIGN

It will be a randomized controlled study which will consist of a two-arms parallel designed with concealed allocation, the assessor's blinding with intention to-treat analysis. A baseline assessment (A1) will be performed before the 5-weeks interventional period and post-intervention, two days after the last session of the treatment (A2). An assessor blind to the assignment of the patients will perform all the evaluations. Each patient will be assessed in the same period of the day in a physiotherapy research laboratory by the same assessor. All the participants will be advised not to practice any other type of regular physical exercises during the study protocol. A verbal and written explanation of the objectives and methodology of the study will be provided to all the participants, and their willing to participate will be signing a written consent form, approved by the local ethics committee. The following parameters will be assessed during the evaluations: NPRS, ODI. A detailed timeline of the trial is presented in table 1.

Patients and public involvement

Neither patients nor local public will be involved in the plan and design of this study.

Participants

The participants will be recruited from the local community with the help of advertisements in newspapers and electronic newsletters, from January 7th 2020 to February 7th 2020 at the Physiotherapy Center of the Motion System in Krzeszowice, Poland. The treatment will start on February 15th 2020 and finish on April 15th 2020. Unfortunately Covid 19 pandemic broke this study.

The 40-60 years old patients will be included to the research if they report having LBP during most of the days during the past three months; if they have a severe disability ranged from 41 to 60% in ODI [19]; if they agree to be treated with OMT or KEOMT; if they are permanently employed and motivated to continue their professional activity.

The patients will be excluded if they report "red flags" suggesting serious underlying conditions as the cause

Table 1: Timeline of the study phases.

		Enrolment	Baseline Assessment	Intervention	Post-intervention assessment
Study phase		-1 week -24 to -8days	(A1) Day 0	Week 1 to Week 5 2x/week	(A2) week 5 2 days after last session
Enrolment	Eligibility screening	X			
	Informed consent	X			
Interventions	Allocation			X	
	OMT			X	
	KEOMT			X	
Assessments	NPRS		X		X
	ODI		X		X

OMT: Osteopathic Manual Therapy; KEOMT: Kaltenborn-Evjenth Orthopedic Manual Therapy;
NPRS: Numeric Pain Rating Scale; ODI: Oswestry Disability Index

of LBP [20]. If they confess such cases as: cancer; an unexplained weight loss; immune suppression; a urinary infection; an intravenous drugs taking; a prolonged using of corticosteroids; a spinal fracture or a significant trauma; a urinary retention or an overflow incontinence; a loss of anal sphincter tone or fecal incontinence; a saddle anesthesia; a global or progressive motor weakness in the lower extremities.

The patients will be also excluded if they report: a recent low back surgery; a receipt of worker's compensation benefits or an ongoing litigation involving back problems; medical conditions that might impede OMT or KEOMT protocol implementation; corticosteroid taking during the past month; taking a manual therapy during the past three months or more than three times during the past year. The patients will be excluded if females are pregnant or plan a pregnancy during the course of the trial; if any of the following signs of lumbar radiculopathy are observed during the clinical screening: ankle dorsiflexion weakness; great toe extensor weakness; impaired ankle reflexes; loss of light touch sensation in the medial, dorsal, and lateral aspects of the foot; shooting posterior leg pain or foot pain upon ipsilateral or contralateral straight leg raising [20].

Randomization

The participants will be randomized and allocated with a 1:1 ratio into either a treatment group (OMT) or a comparison group (KEOMT) using a simple randomization scheme generated by software (www.randomization.com). Individual, sequentially numbered index cards with the random assignments will be prepared. The index cards will be folded and placed in sealed opaque envelopes. The physician, a member of the research team, who is blinded to the baseline examination findings will open the envelopes to attribute the interventions according to the group assignments.

Interventions

The whole treatment will be performed at the Physiotherapy Center of the Motion System in Krzeszowice, Poland. The same physiotherapist, with a postgraduate degree in manual therapy and 15 years of experience will provide all the treatments in both groups, he will also be blinded to the outcome measures. All the patients in the treatment group (OMT; $n = 34$) and the comparison group (KEOMT; $n = 34$) will receive 2 treatments weekly for 5 weeks. Each session in both groups will not exceed 30 minutes. During each session OMT techniques as well as KEOMT ones will be repeated 3 times.

The OMT protocol will be limited to the following OMT techniques: [1,21] direct techniques - High-Velocity/Low-Amplitude (HVLA); indirect techniques - Strain and Counterstrain Techniques (SCS), Myofascial Release Treatment (MFR); Visceral Manipulative Treatment (VIS).

HVLA: The position for lumbar spine manipulation is very similar to that used during sacroiliac joint techniques. The patient is placed in this lateral recumbent position, and therapist tries to isolate the area to be manipulated by hooking the spinous process of the lumbar vertebra. The joint is then stressed to its end range of motion with the forearm placed over the ischial tuberosity. At this point, a high-velocity, low-amplitude impulse can be applied. An alternate technique is to place the hypothenar eminence on the paraspinal tissues and again stress the joint to its end range of motion. A high-velocity, low-amplitude impulse is applied again.

SCS: The patient is in prone position, the operator is on the opposite side. The operator takes the patient's leg above the knee, he extends and lifts it in the upper lumbar direction; side bend outside - the operator moves the

patient's leg towards the operator; rotation – the same move in the direction opposite the operator.

MFR: The patient is in prone position. The therapist stands at his side. The therapist's left hand crosses and maintains a pressure downward and caudal on the sacral promontory. The therapist's right hand straddles the lumbar spinous processes and the pressure is applied downward and cephalac.

VIS: The patient lies on his back; lower extremities are bent at the knee joints. Upper extremities are along the trunk. The therapist stands on the left of the patient at the level of his pelvis and puts the base of his palm under the hypothetical line where the duo denojejunal flexure comes together with the ileocecal fold. In the exhalation phase he applies pressure in a horizontal direction. During the inhalation phase, he slightly reduces the pressure while the therapist repeats this action simultaneously with the respiratory cycle, performing something like "pumping" of the strained tissues.

The KEOMT includes lumbar segmental traction and lumbar segmental mobilization (ie, flexion, and gliding therapy grade 3) [22].

Lumbar segmental traction

The patient is in the right lateral recumbent position with his knees flexed above the level of the abdomen. The physician's fingers hook over the proximal transverse processes or in the soft tissues of the proximal paravertebral area. The physician's fingers pull the surface in the opposite directions while counter pressure is applied by the physician's thigh or thighs against the patient's knees.

Lumbar segmental flexion mobilization

The patient is lying on his side on a bed, the patient's hip joint and knee joints are bent. While facing the patient, the therapist places his right hand (fixed hand) on the lumbar vertebrae of the patient and fixes his fingers on the transverse process or spinous process of the vertebra. The therapist's left hand (moving hand) is placed on the sacral vertebrae of the patient and his fingers are placed on the transverse process or spinous process of the vertebra. The therapist's chest is put into tight contact with the two knee joints of the patient to move the patient's pelvis in a caudal-ventral direction.

All the participants will be advised not to practice any other type of regular physical exercises during the study protocol that could compete with the OMT or KOMT protocol.

Outcome measurements

An assessor blind to the assignment of the patients will perform all the evaluations at baseline (Week 0), and two

days post-treatment (Week 5). The following parameters will be assessed during the evaluations

Primary outcome: Numeric Pain Rating Scale – NPRS is an 11-points scale that characterizes a participant's pain with 0 for 'no pain' and 10 for 'the most severe pain'. The participants will make three pain ratings corresponding to their current feeling, the best and the worst pain experienced over the past 24 hours. The average of the 3 ratings will be used to represent the patient's level of pain over the previous 24 hours.

Secondary outcome: Oswestry Disability Index – ODI indicates the level of disability which is caused by lumbar spine pain. During the examination the patients will answer the questions about: pain intensity, personal care, lifting of objects, walking, sitting, standing, sleeping, sexual life, social life, travelling. The answers let classify the limitations in the functioning of the patients. The answers will be classified from 0 to 5 points. The general result of the disability level will be performed in a points scale from 0 to 50 or in a percentage scale from 0 to 100. The lower the score the better the patient's functional status is. The patients will point each answer after their daily activities over the previous 24 hours. The results in points will be recorded for the statistical analysis. The authorized Polish version of the ODI will be used [23].

DATA ANALYSIS

The data collected through digital forms will be directly structured in an electronic database, supported by a cloud-based management system that preserves integrity and security of the participants' data. A priori sample size will be determined giving the anticipated Cohen's d effect size of 0.7, the probability level of 5%, and the desired statistical test power level of 80%. Taking into account the expecting dropout rate of 10%, we need to enroll 34 patients per group [24]. The data will be 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) will be calculated for each of the outcomes based on the change scores (i.e., week 5 minus week 0 scores). The Shapiro-Wilk test will identify the normal or non-normal distribution of all the data. Regarding the different between-groups baseline characteristics, they will be analyzed with parametric or non-parametric tests as well as to compare the differences of the therapies effects post-intervention between the groups. To describe the differences in related treatments, the Effect Size (ES) between-groups differences will be calculated using Cohen's d, and classified as small ($d > 0.20$ and < 0.50), medium ($d > 0.50$ and < 0.80) and large ($d > 0.80$) [25]. The level of statistical significance will be set at two-tailed p value of 0.05. The analysis will be performed by a blinded independent statistician according to the pre-

specified statistical analysis plan on an intention-to-treat basis. Statistica version 12 (StatSoft, Poland) will be used for the statistical analysis.

ETHICS AND DISSEMINATION

All the participants will provide the written informed consent following verbal and written explanations of the study protocol and the opportunity to ask questions. The participants are free to withdraw from the trial at any time without prejudice to future treatment. The results will be presented at scientific meetings and published in peer-reviewed journals. All the publications and presentations related to the study will be authorized and reviewed by the study investigators.

TRIAL STATUS

The trial is currently recruiting and is expected to be completed (including follow-up testing) by April 2020. Unfortunately Covid 19 pandemic broke this study.

AUTHORS CONTRIBUTION

PL, WK, GM, JN, and JB designed the study protocol. PL wrote the first draft of it and together with GM, JN, JB, JP, BP, DW, JN revised and produced the final version of the protocol. All the authors have read and approved the final version of the protocol. P.L. takes responsibility for the integrity of the work as a whole.

ETHICS APPROVAL

The trial was approved by the Scientific Research Ethics Committee of University of Warmia and Mazury, Olsztyn, Poland. Registration approval number: 9/2018. The trial will be conducted according to the Helsinki Statement. The study protocol was prospectively registered in the Chinese Clinical Trial Registry on December 28, 2019 (registration ID: ChiCTR1900028580).

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