

Non randomised trial of GRAVITY system therapy effectiveness in chronic, low intensity low back disc disease

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Abstract

Study aim: Chronic low back pain (CLBP) is a therapeutically challenging pain syndrome. Physical exercises are the most common therapy used in CLBP treatment. The aim of the study was to verify if GRAVITY system exercise can be effective in the therapy of chronic discogenic low back pain. The GRAVITY system exercise aims at strengthening full body muscles using the trainee's own body weight only.

Material and methods: The study was registered at ClinicalTrials.gov Identifier: NCT04765293. We used TREND statement. The study populations were 50 patients with CLBP. The study population (group I) consisted of 25 patients who had GRAVITY system exercise. The clinical control group were 25 patients who received standard treatment in an outpatient clinic of National Health Fund. Before the start of the training, the patients' had their muscle strength responsible for stabilizing the lumbar segment measured. We also measured patients' Oswestry Disability Index (ODI) prior to and after the therapy cycle. The therapy was conducted twice a week for 40 minutes over the period of 4 weeks. The clinical control group were 25 patients who received treatment from the National Health Fund and had only standardised physical therapy (laser, ultrasound, cryotherapy and magnetic therapy) sessions for two weeks.

Results. We found statistically significant reduction in pain and disability in the study population after the treatment, but muscle strength did not increase significantly.

Conclusions: 1. GRAVITY system exercise might efficient in pain and disability reduction. Muscle strength did not increase after therapy. 2. Pain and disability had positive correlation with female sex, decreased physical activity and sedentary work.

Key words: Disc disease – GRAVITY exercises – Chronic low back pain

Introduction

Lumbar spine disc disease affect approximately 75% of population [2, 5] and results in disabilities of various degrees [6]. The condition is self-limiting, yet in a proportion of the population it may lead to chronic pain, which is a therapeutic challenge [4]. One of the treatment methods, besides other modalities i.e. pharmacotherapy, manual therapy, McKenzie method, is strengthening the muscles responsible for core stabilization of the spine [20]. Physical exercise is the most common form of therapy in chronic pain, and according to systematic reviews exercise strengthening the trunk muscles are most effective [8].

Core stability is described as a corset supporting the spine, composed of the following muscles: abdominal muscles from the front, erector spinae muscles from the back, the diaphragm from the top and the pelvic floor muscles from the bottom [9]. Abdominal muscles have

particular role in the stabilization of the lumbar region of the spine [2]. Simultaneous tensing of the above mentioned muscles allows for maintaining the intra-abdominal pressure, and consequently for maintaining normal posture, for safe sports training and for maintaining stable centre of pressure [12]. Decreased core stability may lead to hypermobility in intervertebral joints [16]. Chronic back pain is often accompanied by weakened trunk muscles [8]. Spine stabilization training is composed of numerous exercises, and isolating the work of individual muscles would be difficult. The training may involve exercises with equipment, or exercises preparing for functional training [10]. Meta-analyses have found that even though exercise can have significant effect on low back pain, there is no evidence that some exercise types are more effective than others [17]. For this reason we decided to test the effect of GRAVITY® system on patients with low back chronic pain as it was not evaluated in available literature before.

The aim of the study was to examine the effect of GRAVITY® system therapy on chronic disc-related pain in lumbar spine. We made a hypothesis that patients who regularly perform core strengthening exercises based on Gravity system will decrease pain and disability, and increase muscle strength in higher extent comparing to control group, that receive passive physical therapy.

Material and methods

We conducted the study after obtaining the Consent of the Senate Ethics Commission of the Józef Pilsudski University of Physical Education in Warsaw no 01-21/2020. The study was registered at ClinicalTrials.gov Identifier: NCT04765293; date of first registration (19/02/2021). To transparent reporting of the study, with sufficient detail and clarity we used Transparent Reporting of Evaluations with Non-randomized Designs (TREND) statement.

All patients ($n = 60$) voluntarily, prospectively registered for the two types of treatments. From all patients recruited initially failed to meet eligibility criteria: 0 patients in study, and 1 in the control group. Refused to participate in the study: 5 patients in study group, and 4 in the control group (Fig. 1).

Finally the study involved 50 patients with low back chronic pain. The study population (group I) consisted of 25 patients who had Gravity system exercise. The control group were 25 patients who received standard treatment in an outpatient clinic of National Health Fund. The physiotherapy staff involved in treatment of both groups was blinded regarding the study aim and assessment procedure. Patients voluntarily registered for the treatments sessions.

The 25 study population patients (14 women and 11 men) were aged 23 to 65 years. They were compared to the 25 control patients (15 women and 10 men) aged 30 to 82 years. Table 1 presents their biometric data.

In the study population, 21 patients (84%) had sedentary work, and 11 patients (44%) additionally did some kind of sport. In the clinical control group 18 subjects (72%) had sedentary work, and 12 subjects (48%) confirmed engaging in additional physical activity.

The criteria for subject inclusion in the study population were: patients with chronic regional spinal pain (longer than 3 months), diagnosed with lumbar spinal disc disease confirmed with medical examination and anamnesis by a physiotherapist/ neurosurgeon; current MRI scan, patients without history of spinal surgery, without earlier physiotherapy, regular participation in therapy twice a week for 4 weeks.

The exclusion criteria were: patient with spinal dysfunctions other than disc disease, history of spinal surgery, physiotherapy attendance before the start of the study.

The clinical control group were patients who were also diagnosed with chronic spinal pain related to disc disease, who received daily physical therapy treatment at a National Health Fund clinic. GRAVITY therapy group had therapy less frequent – twice a week for 4 weeks for 40 minutes that made $2 \times 40 \text{ min} \times 4 \text{ weeks} = 320 \text{ minutes}$. Control group had standard, two weeks ambulant every day physical therapy sessions, 5 times a week 30 min, that is 10 sessions $30 \text{ min} \times 10 = 300 \text{ min}$. So the total amount of treatment was comparable. All participants in both groups completed the study.

We used the Oswestry Disability Index (ODI) to determine the disability level of patient with low back pain [13], and VAS scale (0-10) to measure pain intensity.

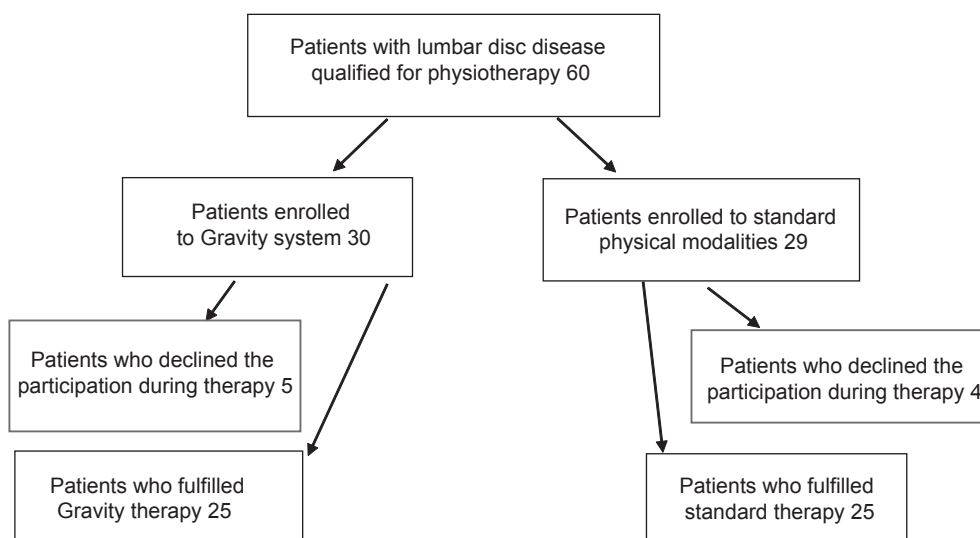


Figure 1. Flow of participants through each stage of the study

Table 1. Biometric data of study population and control group

Group		Age [years]	Height [m]	Body mass [kg]	BMI
Gravity	Mean	42.92	1.74	73.12	24.05
	SD	11.23	0.10	12.51	3.46
	Median	41.00	1.75	71.00	22.84
	Minimum	23.00	1.60	55.00	19.59
	Maximum	65.00	2.01	104.00	30.49
Control	Mean	60.52	1.69	78.12	27.22
	SD	14.70	0.09	11.48	3.12
	Median	63.00	1.68	78.00	27.17
	Minimum	30.00	1.50	50.00	21.64
	Maximum	82.00	1.85	102.00	34.67
Mann-Whitney	U	110.50	233.50	216.00	152.50
	Z	-3.92	-1.54	-1.87	-3.11
	p	<0.001	0.13	0.06	0.002
	Effect size	0.31	0.05	0.07	0.19

The next stage of examination was the lumbopelvic complex stability test by Sahrmann [15]. The test comprised of several activities which had to be performed without lifting the lumbar region. The more difficult activity a patient was able to perform, the higher was assessed their muscle strength.

All the patients were examined twice: before starting the therapy cycle (twice a week for 40 minutes for 4 weeks) and after the therapy. They were informed about the aim of the study, the study course and the possible risks. The participation in the study was voluntary and anonymous. The patients signed informed consent to participate in the study. The next step was the lumbopelvic complex stability test. Patients took it in lying position. The therapist placed their hand under the patient's lumbar region, with the patient's spinous processes resting on second to fifth metacarpal heads. Then, the therapist instructed the patient on the type of movement the patient was supposed to perform. The patient's task was to perform the task without lifting the lumbar region off the therapists' fingers. If the task was performed correctly, the next level task ensued. If the patient lifted their lumbar region, it meant that they did not have enough muscle strength for that level. The test was to be performed without pain, and if the patient felt pain, the test was discontinued and the patient was assigned muscle strength from the level without pain syndromes. Each correctly performed task translated into a given level of muscle strength.

Level 0.3 – lying on the back with the limbs flexed at the hips and knees. The patient drew the knee to the chest, then returned to the starting position. Level 0.4 – lying on

the back, the patient held flexed leg with their arms at their chest, and then drew the other leg. Level 0.5 – the same exercise as in position 0.4, yet without stabilizing the leg with the arms. Level 1a – one leg flexed at the hip and the knee, the other leg was lying extended and then it was raised upwards, extended. Then, the patient swapped legs and repeated the task. Level 1b – patient position as in 1a, yet the extended leg was brought up to the flexed leg. Then the patient swapped legs and repeated the exercise. Level 2 – one leg was flexed at 90° at the hip and at the knee, the other leg was extended. The patient extended the flexed leg, sliding the heel on the ground. After the knee was fully extended, the leg returned to the starting position. Then the patient swapped legs. Level 3 – the patient flexed first one leg and then the other leg to 90°, and then extended first one leg and then the other leg and slid them out on the ground. After the knee was fully extended, the limb returned to the starting position. Level 4 – both legs were extended on the ground, then the patient flexed both limbs sliding their heel on the ground, and then lifted them, flexing the leg at the hip to 90° and returned to starting position. Level 5 – starting position as in level 4, the patient flexed legs at the hip and the knee and drew them to the chest, then the patient extended both legs simultaneously at the hip and the knee, thus returning to the starting position.

Therapy

GRAVITY system exercise is conducted on a machine. The tasks were non-weight bearing, and the only external load was the body mass of the trainee. The degree of

unloading (the level of exercise) was chosen depending on the patient's body mass, their current health and the difficulty of the exercise. The machine allowed for exercising any chosen muscle group at chosen setting of the bench, platform and ropes. GRAVITY system exercise aimed at general posture improvement and at strengthening the desired movement path, along with strengthening the deep spinal and abdominal muscles.

The training sessions started with manometer exercise – the manometer was placed under the lumbar region of the spine. As the patient exhaled and tensed their abdominal muscles, manometer membrane was pumped to 40 mmHg. This provided non-invasive biofeedback, making the patients aware if their deep smooth muscles maintained the desired tension [18]. The patients were to conduct all exercises (knee bends on a sloping bench, lower limb abduction, upper and lower body exercise) while simultaneously maintaining abdominal muscles tension on the level of 40 mmHg.

Then, the patients conducted their training designed accordingly to their individual needs. The most common exercise set was the following: moving their arms from behind the head in the lying on the back position (2×12 repetitions), abductions to 90° in the lying position (3 sets of 10 repetitions for both the right and the left side), adduction of both arms in the sitting position facing the machine (2×12), pulling the bench (2×12) (fig. 2), abdominal oblique muscle tension (2×10) (fig. 3), rotating the trunk in sitting position (2×10 on the right and on the left sides), plank (2×30 s), knees to chest (2×10), heels-up

on the platform (3×15 left leg, right leg, both feet), steps forward (2×10 right leg and left leg). While exercising, the patients were to maintain the right body posture actively by tensing their abdominal muscles. Each exercise could be performed in several variations, such as: both limbs working out simultaneously, or single limb workout, or increasing the level through making the exercise easier or more difficult to perform. At the end of each training session patients stretched individual muscle groups (e.g. posterior thigh muscles, quadriceps femoris muscle, and triceps surae muscle) or they used rollers. Informed consent for publication of identifying images in an online open-access publication were obtained.

In the clinical control group, the patients had physical therapy such as: laser therapy, cryotherapy, magnetotherapy, TENS and interference currents. They had therapy every day for the period of two weeks.

Both groups had different blinded clinicians supervising therapy. Another specialist (ZK) collected and analysed the treatment results.

Patients from both groups did not received any other simultaneous treatments (e.g., pharmacological or psychological).

Statistical analysis

Statistical analysis of the collected data was conducted with the SPSS 26 statistical package. We analysed qualitative and quantitative data. Quantitative data was presented in the form of descriptive statistics using such measurements as: arithmetic mean, standard deviation and median.



Figure 2. Pulling exercise



Figure 3. Abdominal oblique strengthening exercises

We used the Mann-Whitney U-test to assess the differences between two qualitative groups. The non-parametric test was chosen as there was lack of normal distribution. Normal distribution was verified with the Shapiro-Wilk test. Kendall's Tau-B rank correlation coefficient was used to compare the quantitative data. In both tests, minimal statistical significance was set at $p < 0.05$.

The effect sizes and post-hoc test power estimation have been established using G*Power 3.1.9.6. package.

Results

In both groups, the following parameters were assessed: pain, ODI disability, and muscle strength according to the Sahrman test scale [15]. Table 2 presents the results before and after therapy in Gravity and control group.

Before therapies groups were not different regarding pain, disability and muscle strength. After therapy we found significant difference in pain decrease (Table 2).

We compared the differences after therapy between the Gravity and the control group. We found statistically significant differences in pain, disability and muscle strength in Gravity group and in disability in control group (Table 3).

We analysed correlations within Gravity and control groups between pain, disability and muscle strength and anthropometric parameters. In the study population we found correlations between muscle strength and age (negative) and height (positive) (Table 4).

In control group (Table 5) we found correlation between height and muscle disability (negative) and ODI after therapy (negative). There were correlations between BMI and muscle strength negative) before and after therapy.

Table 2. Results in the Gravity and control group before and after therapy

Group		Pain VAS before therapy	ODI before	Muscle strength before	Pain VAS after therapy	ODI after	Muscle strength after
Gravity	Mean	2.64	36.96	0.26	1.4	25.72	0.376
	SD	1.15	13.50	0.16	1.00	12.48	0.17
	Median	3	34	0.3	2	26	0.3
Control	Mean	2.44	32.24	0.264	2.2	28.4	0.272
	SD	1.29	12.48	0.23	1.16	11.45	0.24
	Median	2	32	0.3	2	28	0.3
Mann-Whitney	U	280	254	309.5	192	226.5	270.5
	Z	-0.66	-1.14	-0.06	-2.43	-1.76	-0.82
	P	0.51	0.26	0.95	0.02	0.08	0.41
	Effect size	0.01	0.03	0.00	0.12	0.06	0.01

Table 3. Comparison of results between study parameter before and after therapy

Group		Pain change	ODI change	Muscle strength change
Gravity	Z	-3.684	-4.384	-2.958
	Asymp. Sig. (2-tailed)	<0.001	<0.001	0.003
	Effect size	0.7368	0.8768	0.5916
	Power	0.968	0.993	0.877
Control	Z	-1.684	-4.145	-1.414
	Asymp. Sig. (2-tailed)	0.092	<0.001	0.157
	Effect size	0.3368	0.829	0.2828
	Power		0.989	

Table 4. Kendall Tau-B correlations in Gravity group

		Pain before	ODI before	Muscle strength before	Pain after	ODI after	Muscle strength after
Age	Correlation coefficient	−0.012	0.195	−0.089	0.266	0.277	−0.484
	Sig. (2-tailed)	0.941	0.181	0.583	0.093	0.057	0.003
Height	Correlation coefficient	0.121	−0.007	−0.077	0.032	−0.003	0.004
	Sig. (2-tailed)	0.941	0.181	0.583	0.093	0.057	0.003
Body mass	Correlation coefficient	0.123	0.154	−0.17	0.145	0.209	−0.181
	Sig. (2-tailed)	0.442	0.291	0.295	0.361	0.152	0.26
BMI	Correlation coefficient	0.016	0.108	−0.122	0.082	0.19	−0.142
	Sig. (2-tailed)	0.921	0.454	0.449	0.605	0.19	0.371

Table 5. Kendall Tau-B correlations in control group

		Pain before	ODI before	Muscle strength before	Pain after	ODI after	Muscle strength after
Age	Correlation coefficient	−0.286	0.069	−0.102	−0.251	0.082	−0.093
	Sig. (2-tailed)	0.071	0.638	0.521	0.111	0.573	0.556
Height	Correlation coefficient	−0.297	−0.385	0.094	−0.3	−0.342	0.097
	Sig. (2-tailed)	0.06	0.009	0.554	0.056	0.019	0.539
Body mass	Correlation coefficient	−0.016	−0.177	−0.254	−0.062	−0.184	−0.235
	Sig. (2-tailed)	0.921	0.23	0.114	0.694	0.213	0.14
BMI	Correlation coefficient	0.272	0.168	−0.51	0.188	0.133	−0.465
	Sig. (2-tailed)	0.084	0.25	0.001	0.23	0.361	0.003

Sex differences in studied parameters were also analysed. Only in control group ODI values were significantly differ (18.53 females vs 12.5 males, $z = -2.783$, $p = 0.005$).

Discussion

The study found that GRAVITY system exercise was an efficient form of therapy for chronic low back pain. We found statistically significant differences in measured pain and disability before and after a month of treatment. We did not find statistically significant differences in measured

abdominal muscle strength in the study population. We think that GRAVITY did not change muscle strength due to too short observation period and too small amount of exercise in the week. Further study should focus on this issue.

In the clinical control group we did not find significant differences in pain intensity and disability and in the core stability test. There were correlations in the clinical control group between pain intensity and disability, and between physical activity and disability. Additional physical activity affected subjective disability, while pain experienced in everyday activities significantly affected subjective disability.

Similar results were reported by other authors. In their study, Bento et al. analysed correlations between sex and pain intensity. Their study found that women reported low back pain as much more intensive than men. The same study analysed the impact of age on reported pain. It found that older men reported pain more frequently. This was related to the process of ageing and to related changes in posture [3]. The study by Jonsdottir et al. found correlations between reported pain and sex and between pain and age, too. In this study, pain was more often reported by women, and as many as 88% of patients aged 65 years and older reported low back pain [7].

Verbrugghe et al. studied isometric tensions of muscles of the back and of the abdomen, and searched for correlation with low back pain. They did not find any statistically significant differences. They also studied whether the subjective feeling of disability and other psychological factors had impact on intensity of reported pain, and also no correlation was found here [21]. In the study by Shariat et al. physical exercise was found to have positive impact on low back pain in office workers: in one group, patients had physical exercise only, and in the second group, the patients had both exercise and psychotherapy. In the group with two kinds of therapy conducted simultaneously patients' quality of life improved significantly [14].

Ramos et al. studied the impact of lumbar region multifidus muscles and the transverse abdominal muscle on low back pain. Their study found that patients who report pain have weakened multifidus muscles and insufficient tension of the transverse abdominal muscles in comparison to clinical controls. Patient perception of pain impacted their physical activity, consequently leading to muscle weakening [11].

In their meta-analysis, Searle et al found that exercise had considerable impact on treatment of low back pain. They found significant differences when comparing types of exercise – power, coordination and stabilization exercise proved to be most effective. However, the types of exercise considered in the analysis had different duration and intensity, and therefore it was not determined which therapy model was most advisable with this type of health issue. Power-resistance exercise for full body brought greatest improvement. It was proven that none single muscle was the key to stability in the lumbar region, and that physiotherapeutic programmes should be designed on the basis of this finding [12].

Amorim et al found in their study that free time physical activity decreased the frequency of experiencing low back pain. They also found that patients with recurring low back pain took up physical activity significantly less often, as they were anxious the pain might come back [1]. Suh et al found correlation between pain reduction and stabilizing exercise and walking. Their patients were divided into 4 groups with 4 different types of exercise: stretching

exercise, stabilizing exercise, walking, and walking combined with stabilizing exercise. Results in the last group were statistically significant, moreover, after 6 weeks of exercise the function of spinal muscles improved [19].

The value of the study. Our study found that GRAVITY system exercise was an efficient form of therapy for low back pain in disc disease. It is feasible option in terms of practitioner involvement and costs of treatment

Limitations of the study. Organizational issues related to the COVID-19 pandemics made it difficult for us to choose age-matched study groups.

Conclusions

1. GRAVITY system exercise might be efficient in pain and disability reduction. Muscle strength did not increase after therapy.
2. Pain and disability had positive correlation with decreased physical activity and sedentary work.
3. Implications of the findings for future practice include longer observation period to monitor if muscle strength will increase with time and selection of optimal procedures for treatment that simultaneously decrease pain, improve disability and muscle strength.

Conflict of interest: Authors state no conflict of interest.

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Received 01.09.2021

Accepted 28.02.2022

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Acknowledgments

This work was supported by the Ministry of Science and Higher Education in the year 2021 under Research Group no 4 at Jozef Pilsudski University of Physical Education in Warsaw "Physical activity and sports for people with special needs".