Fundamentos e Práticas da Fisioterapia 6

Bárbara Martins Soares
Larissa Louise Campanholi
(Organizadoras)

Atena Editora
Ano 2019

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2019 *by Atena Editora*

Editora Chefe: Profª Drª Antonella Carvalho de Oliveira
Diagramação e Edição de Arte: Geraldo Alves e Natália Sandrini
Revisão: Os autores

Dados Internacionais de Catalogação na Publicação (CIP)
(eDOC BRASIL, Belo Horizonte/MG)

F981 Fundamentos e práticas da fisioterapia 6 [recurso eletrônico] / Organizadoras Bárbara Martins Soares, Larissa Louise Campanholi. – Ponta Grossa (PR): Atena Editora, 2019. – (Fundamentos e Práticas da Fisioterapia; v. 6)

Formato: PDF
Requisitos de sistema: Adobe Acrobat Reader
Modo de acesso: World Wide Web
Inclui bibliografia
ISBN 978-85-7247-153-4
DOI 10.22533/at.ed.534190703

1. Fisioterapia. I. Soares, Bárbara Martins. II. Campanholi, Larissa Louise.

CDD 615.82

Elaborado por Maurício Amormino Júnior – CRB6/2422

APRESENTAÇÃO

A fisioterapia é uma ciência relativamente nova, pois foi reconhecida no Brasil como profissão no dia 13 de outubro de 1969. De lá para cá, muitos profissionais tem se destacado na publicação de estudos científicos, o que gera mais conhecimento para um tratamento eficaz. Atualmente a fisioterapia tem tido repercussões significativas, sendo citada frequentemente nas mídias, demonstrando sua importância e relevância. Há diversas especialidades reconhecidas pelo Conselho Federal de Fisioterapia e Terapia Ocupacional (COFFITO): Fisioterapia em Acupuntura, Aquática, Cardiovascular, Dermatofuncional, Esportiva, em Gerontologia, do Trabalho, Neurofuncional, em Oncologia, Respiratória, Traumato-Ortopédica, em Osteopatia, em Quiropraxia, em Saúde da Mulher, em Terapia Intensiva. O fisioterapeuta trabalha tanto na prevenção quanto no tratamento de doenças e lesões, empregando diversas técnicas como por exemplo, a cinesioterapia e a terapia manual, que tem como objetivo manter, restaurar ou desenvolver a capacidade física e funcional do paciente. O bom profissional deve realizar conduta fisioterapêutica baseada em evidências científicas, ou seja, analisar o resultado dos estudos e aplicar em sua prática clínica. Neste volume 6, apresentamos a você artigos científicos relacionados à educação em fisioterapia em acupuntura, aquática, em oncologia, traumato-ortopédica e em osteopatia.

Boa leitura.

Larissa Louise Campanholi e Bárbara Martins Soares Cruz.

SUMÁRIO

CAPÍTULO 10

EFFECTS OF THE COMBINATION OF LOW-LEVEL LASER THERAPY AND SHORTWAVE DIATHERMY FOR THE TREATMENT OF NONSPECIFIC LOW BACK PAIN - A RANDOMIZED, DOUBLE-BLIND, SHAM-CONTROLLED PILOT STUDY

Leandro Henrique Grecco
Faculdade São Leopoldo Mandic, Instituto de Pesquisas São Leopoldo Mandic-Anatomia Humana.
Campinas – São Paulo

Diogo Correa Maldonado
Universidade Nove de Julho/ Universidade Federal de São Paulo – Dept. Morfologia Humana e Genética.
São Paulo – São Paulo

Luiz Augusto Miziara Ribeiro
Universidade Nove de Julho, Diretoria da saúde/ Fisioterapia.
São Paulo – São Paulo

Diogo Bernardo Cavalcanti de Arruda
Hospital Municipal de Barueri, Dept. Neurocirurgia
Barueri – São Paulo

Giuliano Roberto Gonçalves
Centro Universitário UniMetrocamp, Dept. Anatomia Humana
Campinas – São Paulo

Adriano Rodrigues Oliveira
Universidade Nove de Julho, Diretoria da saúde/ Fisioterapia.
São Paulo – São Paulo

ABSTRACT: The aim of the present study was to evaluate the effect of combined therapy (physical exercise, LASER and shortwave diathermy) on nonspecific low back pain. METHODS: A prospective, randomized, sham-controlled, double-blind pilot study was conducted involving 40 individuals divided into four groups: exercise group (exercise + sham laser + sham shortwave diathermy); LLLT group (exercise + active laser + sham shortwave diathermy); diathermy group (exercise + sham laser + active shortwave diathermy); and combination group (exercise + active laser + active shortwave diathermy). The visual analog scale (VAS) and Roland-Morris Disability Questionnaire (RMDQ) were used for the evaluation of the primary outcome. RESULT: Significant differences ($p < 0.05$) were found in all groups in comparison to baseline, but no statistically significant differences were found among the groups. Analyzing the protocols separately, the VAS score was reduced by more than 38% at the post-intervention evaluation and 53% at the follow-up evaluation, with an extremely strong effect size ($p < 0.05$). The RMDQ score was reduced by more than 77% at the post-intervention evaluation and 79% at the follow-up evaluation. CONCLUSION: Thermal and phototherapeutic resources are effective for the treatment of chronic low back pain. However, no statistically significant differences were found between the different groups (exercise alone, exercise + LLLT, exercise + shortwave diathermy and exercise + LLLT + shortwave diathermy). Further controlled studies with larger samples and a longer follow-up time are

needed to determine the usefulness of combining physical resources for the treatment of chronic nonspecific low back pain.
KEYWORDS: Nonspecific low back pain; Laser; Shortwave diathermy; Physical exercise

1 I INTRODUCTION

Chronic nonspecific low back pain is a public health problem with epidemic proportions worldwide (BALAGUÉ et al, 2016). The identification and elimination of risk factors, pharmacological treatment, psychological treatment and physical therapy are the foundations of recovery from this problem (PATRICK et al, 2014). Different non-pharmacological strategies have been discussed in the literature for effective, long-lasting treatment of low back pain, including thermal and phototherapeutic resources (CHOU & HUFFMAN, 2007).

Studies have demonstrated that low level laser therapy (LLLT) and shortwave diathermy can alleviate pain symptoms in 70 to 80% of patients (GLAZOV et al, 2013; AHMED et al, 2009). According to the American Physical Therapy Association, thermal or phototherapeutic resources alone are not enough in most cases and should be administered in combination with other interventions, such as a supervised exercise program to strengthen muscles and enhance one's flexibility (ALEXANDRIA, 2014).

There is a gap in knowledge regarding combined therapies. Much information is based on clinical practice, but without the support of scientific evidence. Thus, aim of the present study was to evaluate the effect of combined therapy (physical exercise, LLLT and shortwave diathermy) on nonspecific low back pain. The hypothesis is that combined therapy achieves better results in comparison to therapy without the use of thermal and/or phototherapeutic agents.

2 I METHODS

Study design and ethical considerations

A prospective, randomized, sham-controlled, double-blind, pilot study was conducted (Figure 1) in compliance with the ethical standards of the Declaration of Helsinki and received approval from the Human Research Ethics Committee of the University *Nove de Julho* (São Paulo, SP, Brazil) under process number 9379/2012.

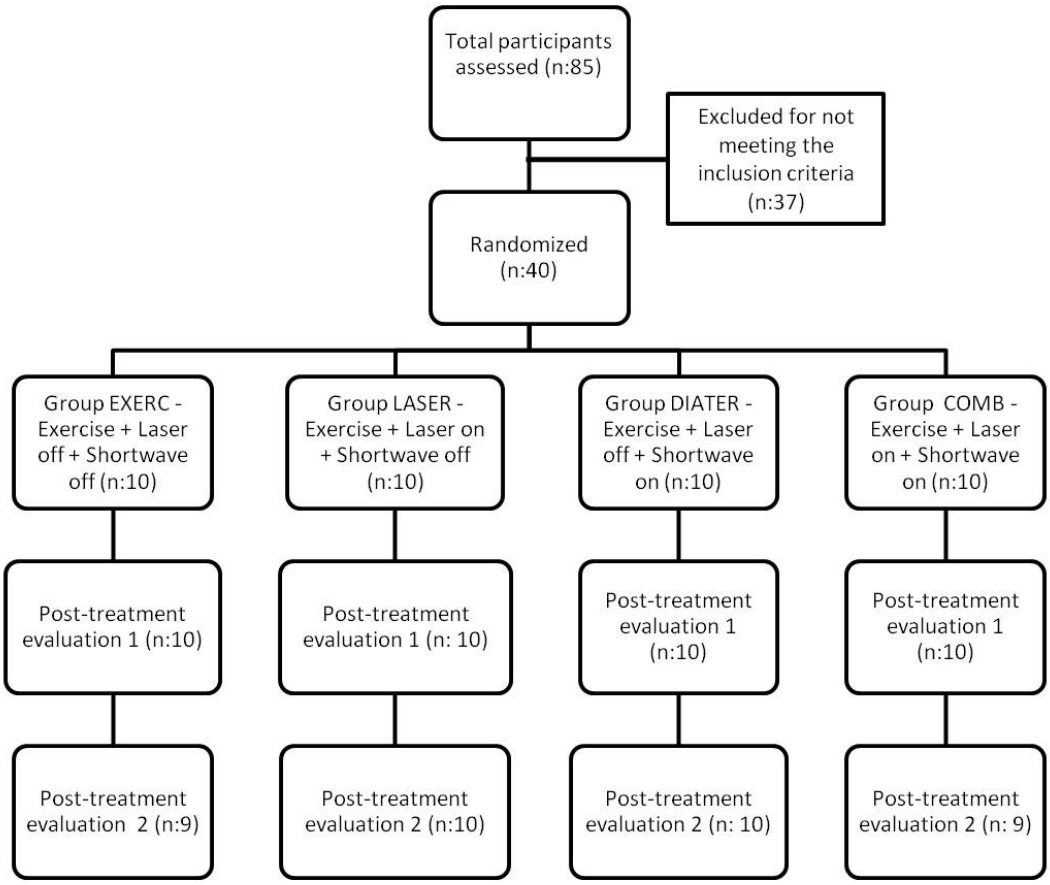

Figure 1: Flowchart of sample selection, interventions and evaluations

Participants

Individuals were recruited from the Physical Therapy Clinics of University Nove de Julho (units: Vila Maria and Memorial, both in the city of São Paulo, Brazil). Potentially eligible participants were interviewed and submitted to a screening procedure by two physiotherapists. Eligible volunteers who agreed to participate received clarifications regarding the objectives and procedures and signed a statement of informed consent in compliance with Resolution 196/96 of the Brazilian National Board of Health. This study was conducted between April 2012 and December 2016.

The inclusion criteria were chronic nonspecific low back pain for more than 8 weeks, age ≥ 20 years, score ≥ 4 on the visual analog scale (VAS), score ≥ 4 on the Roland-Morris Disability Questionnaire (RMDQ), no previous history of physical therapy, no cognitive impairment that could interfere with the performance of tasks and a signed statement of informed consent. The exclusion criteria were clinical signs of radiculopathy, lumbar stenosis, fibromyalgia, spondylolisthesis, a history of spine or abdomen surgery (arthrodesis or metallic implants), pregnancy, diagnosis of cancer, intra-uterine device, acute low back pain, acute lower limb pain, recent history of violent trauma and lack of cooperation or cognitive capacity regarding the execution of the clinical procedures.

The participants were randomly allocated to four groups: exercise group (exercise + sham laser + sham shortwave diathermy); LLLT group (exercise + active laser + sham shortwave diathermy); diathermy group (exercise + sham laser + active shortwave

diathermy); and combination group (exercise + active laser + active shortwave diathermy). A block randomization procedure (blocks of eight) was used, involving a set of numbered, sealed, opaque envelopes to ensure confidentiality. Each envelope contained a card stipulating to which group each individual would be allocated. The volunteers were blinded to the allocation and were informed of the possibility of receiving sham treatment regarding the thermal and phototherapeutic resources, but all would be submitted to the exercise protocol. The researchers involved in the application of the thermal and phototherapeutic resources were also blinded to the allocation of the participants throughout the development and analysis of the study.

Interventions

A chart was used for the socio-demographic data, results of the physical exam and tests applied during each evaluation (baseline, two days after completing the treatment [post-intervention]) and one month after completing the treatment [follow up]). The protocols consisted of three weekly sessions for five weeks (total: 15 sessions).

Exercise program

The exercise program was based on the guidelines of the American College of Physicians and the American Pain Society (CHOU & HUFFMAN, 2007) for the treatment of low back pain and the sessions were supervised by physiotherapists). The participants were instructed to report any complaints related to the exercises and not to participate in any other physical therapy program throughout the duration of the study. The protocol was as follows:

- Strengthening of abdominal and erector spinae muscles: three sets of 15 repetitions of each exercise with a two-minute rest period between sets;
- Proprioceptive neuromuscular facilitation: contraction and relaxation of the hamstrings for six seconds; stretching of the erector spinae, iliopsoas, hamstrings, triceps surae and femoral quadriceps with three sets of three repetitions performed for 30-seconds for each stretch and a one-minute rest period between stretches.

Laser therapy

A pulsating gallium-arsenide laser (Endophoton LLT-IR - KLD Biosistemas - Brazil) (wavelength: 904 nm; power: 47 W; exposure time automatically adjusted by the device; energy density: 4J) duly calibrated by the manufacturer was used for LLLT. Point application was employed in the regions of the lumbar joint facets and specific trigger points reported by the patient during palpation (mean: 12 ± 2 points). During sham stimulation, the same procedure was conducted with the device switched off.

Shortwave diathermy

The Diatermed II (CARCI - Brazil) was used for shortwave diathermy for 15 minutes, with coplanar application and the intensity adjusted between comfortable and tolerable heat. During sham stimulation, the same procedure was conducted with the device only switched on for the initial and final 30 seconds.

For these procedures, the participants were informed of the possibility of feeling or not feeling a sensation of heat and were asked to report any complaints related to the exercises and/or thermal and/or phototherapeutic agents as well as not to participate in any other physical therapy program throughout the duration of the study.

Outcome Measures

The primary outcome was low back pain severity measured using the VAS, which consists of a 10-cm straight line with “no pain” printed at one extremity and “unbearable pain” printed at the other extremity. The patient was instructed to mark a point on the line that represented the intensity of pain he/she was feeling at the time (LANGLEY & SHEPPEARD, 1985) The Roland-Morris Disability Questionnaire (RMDQ) was used to determine functional disability. The RMDQ is a self-administered questionnaire with 24 questions with dichotomous responses (yes or no). The final score is determined by the sum of “yes” responses and ranges from 0 to 24, with higher scores denoting greater disability (NUSBAUM et al, 2001)

Statistical analysis

The Kurtosis test was used to determine the adherence of the data to the Gaussian curve. The variables proved to be parametric and were expressed as mean and standard deviation values, with respective 95% confidence intervals. Repeated-measurements ANOVA was used for the inter-group comparisons to evaluate the effect of the interventions on the primary outcome. In the intra-group comparisons, repeated-measures ANOVA was used with pain intensity as the dependent variable and time as the main factor, followed by the Bonferroni post hoc correction. The level of significance was set at 5% ($p < 0.05$) and the test power was 80%. Intention-to-treat analysis was employed when a patient dropped out of the study, with the last results repeated through to the final evaluation. The SPSS program (version 21.0) was used for all statistical analyses.

3 I RESULTS

Forty volunteers were included in the study, with 10 volunteers randomly allocated to the four study groups. One patient in the exercise group and one in the combination group did not return for the second evaluation. Thus, the VAS and RMDQ scores of the previous evaluation of these two individuals were repeated (intention-to-treat

analysis). Table 1 displays the socio-demographic, clinical and baseline characteristics of each group. No significant differences were found regarding the characteristics of the different groups.

	EXER (n:10)	LASER (n:10)	DIATER (n:10)	COMB (n:10)
Sex (n; (%))				
Female	6 (15.8)	4 (10.5)	6 (15.8)	6 (15.8)
Male	4 (10.5)	6 (15.8)	4 (10.5)	4 (10.5)
Age (years; (SD))	43.56 (11.4)	49.33 (15.28)	53.2 (20.05)	50.0 (21.05)
BMI (n; (SD))				
Normal weight	2 (5.2)	4 (10.5)	5 (13.2)	4 (10.5)
Overweight	7 (18.3)	6 (15.8)	1 (3.8)	3 (7.9)
Obesity	1 (3.8)	0	4 (10.5)	3 (7.9)
Physical activity (n; (%))	3 (7.9)	3 (7.9)	5 (13.2)	4 (10.5)
Pain				
VAS (cm; (SD))	6.9 (1.2)	7.8 (0.8)	6.8 (1.6)	7.2 (1.2)
Duration (days; (SD))	87.3 (20.7)	82.6 (23.7)	85.2 (30.1)	87.2 (34.4)
RMDQ (score; (SD))	13.5 (4.8)	14.5 (6.3)	15.8 (3.6)	14.6 (5.1)

Table 1: Baseline characteristics of the sample

SD: Standard Deviation; BMI: Body Mass Index; VAS: Visual Analogic Score; RMDQ: Roland Morris Disability Questionnaire.

Figure 2A displays the VAS scores. Significant differences were found in all groups in comparison to the baseline evaluation. These results persisted through to the follow-up evaluation (one month after the conclusion of the interventions). However, no significant differences were found among the different interventions. The same results were seen regarding the RMDQ scores (Figure 2B).

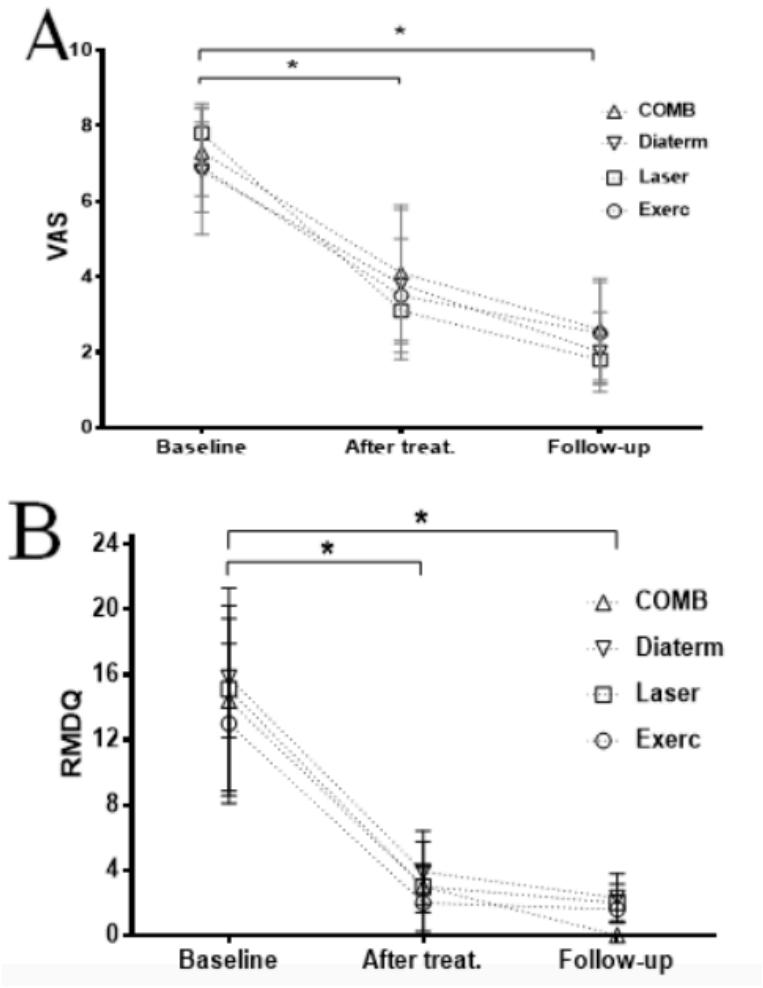

Figure 2: A) Mean pain levels (as assessed by visual analogue scale) at baseline, after treatment and follow-up in the 4 groups of treatments. B) Disability level of individuals (as assessed by Roland-Morris Disability Questionnaire) at baseline, after treatment and follow-up in the 4 groups of treatments. The results represent the mean ± SD. 10 subjects per group. *Significantly different from mean values of baseline ($p<0.05$).

As an additional analysis, the interventions were analyzed separately (without combinations) for the three evaluation times (Table 2). The clinical effects revealed a significant interaction effect (time and condition) for both the VAS and RMDQ. In comparison to baseline, all groups demonstrated a greater than 38% reduction in pain (VAS) immediately after treatment and a 53.31% reduction at the follow-up evaluation. The best VAS results were found in the laser group (59.84% post-intervention reduction and 76.8% reduction at follow up), which also demonstrated the largest effect sizes (6.02 and 7.69, respectively). Moreover, a more than 77% reduction in the RMDQ was found after treatment and a more the 79% reduction was found at follow up. The diathermy group demonstrated the largest effect sizes (3.26 and 3.69, respectively) regarding the RMDQ score.

4 I DISCUSSION

The present findings demonstrate the importance of physical therapy in the rehabilitation process of individuals with nonspecific low back pain and indicate the

efficacy of physical resources employed in an isolated manner as well as in combination. Although no statistically significant differences were found among the different treatment groups, the effect sizes of the reduction in pain and RMDQ score were extremely strong in all groups and all interventions likely have considerable clinical importance. Moreover, the effects persisted through to the one-month follow up, demonstrating the effectiveness of kinesiotherapy in the treatment of such patients.

A large number of systematic reviews of the literature have indicated that the treatment of low back pain is difficult and many established interventions have limited effectiveness (DEYO et al, 2015; PATTI et al, 2015; HIDALGO et al, 2014; GUZMÁN et al, 2001). Studies have been conducted to find effective therapies aimed at reducing complaints related to chronic low back pain and its consequences (DA LUZ et al, 2013; PATTI et al, 2015, PETIT et al, 2014). Physical agents and kinesiotherapy can minimize the perception of pain symptoms, are inexpensive and have few or no side effects, as demonstrated by the present findings, since the use of an additional physical resource combined with an exercise program led to greater effect sizes (ALEXANDRIA, 2014) The effect size regarding the VAS score was greater in the laser group, whereas the effect size regarding the RMDQ score was greater in the diathermy group.

Table 2: Individual treatments on low back pain

TREATMENT	MEAN (SD)			PERCENTAGE OF MEAN CHANGE (SD)		MEAN DIFFERENCE (95% CI) OF PERCENTAGE CHANGE		EFFECT SIZE		P	
	B	A	M	B to A	B to M	B to A	B to M	B to A	B to M	B to A	B to M
VAS											
EXERC	6.9 (1.20)	3.5 (1.51)	2.5 (1.35)	-50.13 (15.34)	-63.72 (18.32)	-3.40 (-5.48 to -1.31)	-4.40 (-6.48 to -2.31)	2.84	3.66	< 0.0001	< 0.0001
LASER	7.8 (0.78)	3.1 (0.87)	1.8 (0.63)	-59.84 (11.48)	-76.98 (8.43)	-4.70 (-6.78 to -2.61)	-6.00 (-8.08 to -3.91)	6.02	7.69	< 0.0001	< 0.0001
DIATER	6.8 (1.68)	3.8 (1.98)	2.2 (1.03)	-46.66 (17.09)	-67.87 (11.45)	-3.00 (-5.08 to -0.91)	-4.80 (-6.88 to -2.71)	1.78	2.73	< 0.0001	< 0.0001
COMB	7.3 (1.15)	4.5 (2.06)	3.4 (1.42)	-38.15 (29.99)	-53.31 (18.40)	-3.20 (-5.28 to -1.11)	-4.70 (-6.78 to -2.61)	2.43	3.39	< 0.0001	< 0.0001
RMDQ											
EXERC	13 (4.90)	2 (2.31)	1.6 (0.84)	-84.94 (14.23)	-85.15 (12.17)	-11.00 (-16.20 to -5.80)	-11.40 (-16.60 to -6.50)	2.24	2.32	< 0.0001	< 0.0001
LASER	15.1 (6.23)	3.1 (2.64)	2.1 (1.29)	-83.71 (12.61)	-79.75 (18.31)	-12.10 (-17.30 to -6.90)	-14.70 (-18.40 to -8.31)	1.94	2.08	< 0.0001	< 0.0001
DIATER	15.8 (3.65)	3.9 (2.51)	2.3 (1.49)	-77.28 (12.97)	-84.69 (9.66)	-11.90 (-17.10 to -6.70)	-13.50 (-18.70 to -8.30)	3.26	3.69	< 0.0001	< 0.0001
COMB	14.4 (5.83)	3 (1.15)	0.8 (1.14)	-78.40 (3.52)	-93.58 (9.21)	-11.40 (-16.60 to -6.30)	-14.40 (-19.60 to -9.32)	1.95	2.31	< 0.0001	< 0.0001

B: Baseline; A: After treatment; M: 1 Month after treatment; SD: Standard deviation; CI: Confidence Interval; VAS: Visual Analogic Score; RMDQ: Roland Morris Disability Questionnaire.

There is no consensus on the best resources to apply for alleviating low back

pain. Shortwave diathermy is a deep heat modality that has a significant effect in relieving pain, as shown by the present results (AKYOL et al (2010); ROBERTSON et al, 2005). The diathermy group demonstrated a 46.6% reduction in the VAS score after the intervention and a 67.8% reduction at follow-up as well as strong effect sizes (1.78 and 2.73, respectively). Moreover, the diathermy group demonstrated the largest effect size regarding the RMQD score. Nonetheless, no significant differences were found in comparison to the other treatment protocols investigated. These findings are in agreement with data described by AHMED et al. (2009), who state that shortwave diathermy is effective in the treatment of chronic low back pain. The authors divided 97 individuals into two groups. One group received non-steroidal anti-inflammatory drugs, exercises, instructions regarding activities of daily living and shortwave diathermy and the second group received the same treatment, but without shortwave diathermy. After six weeks, significant improvements were found in both groups in comparison to baseline, along with a significant difference between groups (AHMED et al, 2009) GIBSON et al. (1985) found a 59% improvement in individuals treated with shortwave diathermy in comparison with a control group. Despite these encouraging results and the widespread clinical use of shortwave diathermy, few studies are found in the literature on thus use of this method for the treatment of low back pain.

LLLT is another physiotherapy modality used in clinical practice for the treatment of low back pain. Studies have indicated the participation of peripheral opioid receptors as an anti-nociceptive mechanism of action (HAGIWARA, et al, 2009) In the present study, LLLT led to a 59.84% reduction in the VAS score after treatment and a 76.98% reduction at follow up, with strong effect sizes (6.02 and 7.69, respectively) as well as reductions in the RMQD scores. These findings are in agreement with data described by VALLONE et al. (2014), who demonstrated the effectiveness of laser combined with physical exercise in a three-week protocol, with reductions in pain in both groups (active and sham LLLT). The authors suggest that this therapy should be considered a valid treatment option in rehabilitation programs for patients with chronic, nonspecific low back pain. The present findings also point to the same functional benefits of LLLT.

In a study analyzing the adequate intensity of laser therapy, GLAZOV et al. (2015) found no significant differences between the active and sham groups. The authors randomly allocated 144 patients with low back pain into three groups: sham (0 J), low intensity (0.2 J) and high intensity (0.8 J). Reductions in pain occurred in all groups. The authors suggest a set of factors that may have contributed to this finding, such as i) the placebo effect, ii) the “regression toward the mean” phenomenon, iii) natural history and iv) the Hawthorne effect (effect of simply participating in an experiment). However, it was not clear whether the participants underwent other forms of treatment, as the authors mentioned that the co-intervention of exercise, a greater number of treatment sessions and a higher mean baseline pain level could be the reason for this effect.

The justifications given by the aforementioned authors may explain the findings of the present study. However, this study was designed based on the consensus in the

literature regarding the use of kinesiotherapy for the treatment of low back pain (CHOU & HUFFMAN, 2007) Regardless of the means employed (light or heat), clinically important reductions occurred in both pain and the RMQD score. There is evidence demonstrating the benefits of kinesiotherapy to reduce pain and reestablish adequate motor function.

In a systematic review of the literature and meta-analysis, SEARLE et al. (2015) analyzed 39 studies to determine the role of physical exercise in the treatment of low back pain. The authors found significant differences between treated groups and control groups. Moreover, the authors performed an exploratory analysis of subgroups and found significant effects for strengthening, resistance, coordination and stabilization exercises. In contrast, cardiopulmonary exercises were not found to be effective in the treatment of low back pain.

Some authors suggest that the combination of pharmacological (BARON et al, 2014) and non-pharmacological (CHAN et al, 2015) methods for the control of pain provides a better analgesic effect than the use of such methods in an isolated fashion. However, the current literature is scarce with regard to the combination of physical resources for the treatment of chronic low back pain. In the present study, no significant differences were found in the comparison of the combination of physical resources to a single resource or kinesiotherapy alone, but all protocols led to significant improvements in comparison to baseline. This pilot study fills an important gap in the literature regarding the combination of physical resources for the treatment of musculoskeletal disorders.

The present study has limitations that should be addressed. The lack of controlled studies involving the combination of these resources and the equipment parameters employed hinders correlations with the present findings. Quality of life and sleep quality questionnaires should have been administered, since the patients reported improvements in these aspects by the end of the study. The sample size could be considered another limitation. Considering the results obtained in the COMB group (mean (SD: 3.4 (1.42)) and EXEC group (mean (SD): 2.5 (1.35)), 30 individuals would be required in each group for a uni-directional alpha and 80% test power.

5 I CONCLUSION

The combination of physical resources did not influence the improvement in low back pain. All four protocols led to improvements after treatment. Physical therapy combined with laser therapy demonstrated the greatest clinical effect, although no statistically significant differences were found in relation to the other treatment protocols. Further controlled studies should be conducted with larger samples, greater variability in the equipment parameters and a longer follow-up time to demonstrate the effects of the combination of thermal and phototherapeutic agents in the treatment of chronic, nonspecific low back pain.

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ISBN 978-85-7247-153-4