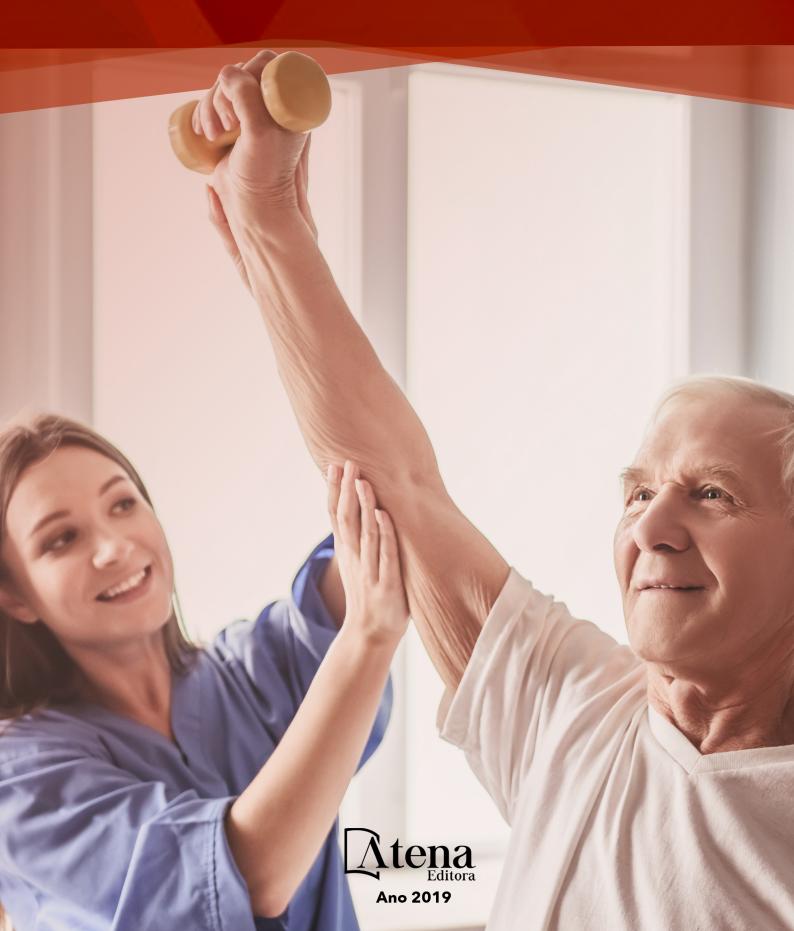
Fundamentos e Práticas da Fisioterapia 6

Bárbara Martins Soares Larissa Louise Campanholi (Organizadoras)



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Fundamentos e Práticas da Fisioterapia 6

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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 11
A EFICÁCIA DA TERAPIA MANUAL NO TRATAMENTO DA CERVICALGIA UM RELATO DE CASO
Ana Paula Moreira Furtado
Sayuri Jucá Gonçalves
Amanda Portela do Prado
Glaucineide Pereira da Silva
Karla Sabrina Leite Moreira
Vivian Bertoldo dos Santos
Sabrina Kelly Matos de Freitas Alisson Gomes Fernandes
Maria Juliana Dourado Teófilo
Edla Romão Façanha
Patrícia Dandara dos Santos Sousa
Pedro Pinheiro de Queiroz Neto
Patricia da Silva Taddeo
Marcia Maria Gonçalves Felinto Chaves
Paulo Fernando Machado Paredes
Josenilda Malveira Cavalcanti
DOI 10.22533/at.ed.5341907031
CAPÍTULO 27
A FISIOTERAPIA APÓS A MASTECTOMIA AUMENTA A AMPLITUDE DE MOVIMENTO, REDUZ A INCAPACIDADE E DOR
Fernanda Bispo de Oliveira
Cássia Giulliane Costa Santos
Jader de Farias Neto
Walderi Monteiro da Silva Júnior
Mariana Tirolli Rett
DOI 10.22533/at.ed.5341907032
CAPÍTULO 317
A FISIOTERAPIA AQUÁTICA E OS BENEFÍCIOS CAUSADOS EM PACIENTES COM FIBROMIALGIA
Antonia Gecileuda Nascimento Freitas
Maria Augusta Amorim Franco de Sá
Marina Carvalho Magalhães Araújo
Marylia Araújo Milanêz
Samara Soares Rosa
Waldeck Pessoa da Cruz Filho
DOI 10.22533/at.ed.5341907033

CAPÍTULO 424
A INTERVENÇÃO DA ACUPUNTURA NO TRATAMENTO DE LOMBALGIA
Sayuri Jucá Gonçalves Ana Paula Moreira Furtado Amanda Portela do Prado Glaucineide Pereira da Silva Karla Sabrina Leite Moreira Vivian Bertoldo dos Santos Sabrina Kelly Matos de Freitas Alisson Gomes Fernandes Maria Juliana Dourado Teófilo Edla Romão Façanha Patrícia Dandara dos Santos Sousa Pedro Pinheiro de Queiroz Neto Josenilda Malveira Cavalcanti Patricia da Silva Taddeo Marcia Maria Gonçalves Felinto Chaves Paulo Fernando Machado Paredes
DOI 10.22533/at.ed.5341907034
CAPÍTULO 5
Alessandra Riniere Araújo Sousa Carla Valéria Silva Oliveira Maria Augusta Amorim Franco de Sá
DOI 10.22533/at.ed.5341907035
CAPÍTULO 637
ANÁLISE DO NÍVEL DA DOR CAUSADA PELO ESTRESSE EM PRESBÍTEROS (CRIAÇÃO DE UM PROTOCOLO DE TERAPIA MANUAL) Nathalia de Barros Peixoto Giane Dantas de Macedo Freitas DOI 10.22533/at.ed.5341907036
CAPÍTULO 754
ASSOCIAÇÃO DA ANSIEDADE COM A SÍNDROME DA FIBROMIALGIA EM PACIENTES ATENDIDOS NO SETOR DE FISIOTERAPIA AQUÁTICA DA CLÍNICAS INTEGRADAS GUAIRACÁ – ESTUDO TRANSVERSAL
Jaqueline Antoneli Rech Elizandra Aparecida Caldas da Cruz Camila Kich Claudia Bernardes Maganhini Simone Mader Dall'Agnol Franciele Aparecida Amaral DOI 10.22533/at.ed.5341907037

CAPÍTULO 863
DIFERENÇA CLÍNICA ENTRE DRY NEEDLING E ACUPUNTURA NOS DIFERENTES TRATAMENTOS FISIOTERAPÊUTICOS
Clara Beatriz Torres Maciel
Luana Feitosa Calado Maytta Rochelly Lopes da Silva
Náthaly Thays Silva Farias
João Paulo Maciel Cavalcanti de Albuquerque
DOI 10.22533/at.ed.5341907038
CAPÍTULO 970
EFEITO DA BANDAGEM ELÁSTICA TERAPÊUTICA NAS ALGIAS LOMBARES: REVISÃO SISTEMÁTICA
Míriam Alves Silva
Gabriel Mauriz de Moura Rocha Ionara Pontes da Silva
Carolyne Carvalho Caxias
Margarete Lopes Riotinto
DOI 10.22533/at.ed.5341907039
CAPÍTULO 1083
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
Diogo Correa Maldonado
Luiz Augusto Miziara Ribeiro Diogo Bernardo Cavalcanti de Arruda
Giuliano Roberto Gonçalves
Adriano Rodrigues Oliveira
DOI 10.22533/at.ed.53419070310
CAPÍTULO 1195
EFICÁCIA DA MANIPULAÇÃO ARTICULAR NO TRATAMENTO DA CERVICALGIA: UMA REVISÃO SISTEMÁTICA
Ana Carolina de Oliveira Brito Santos
Roberta Lima Monte Santo
Gabriela Silva Barros Henrique de Jesus Dias
Cláudia Jeane Claudino de Pontes Miranda
DOI 10.22533/at.ed.53419070311

CAPÍTULO 12106
HOUVE VARIAÇÃO DE TEMPERATURA SECUNDÁRIA À APLICAÇÃO DE TÉCNICAS DE AGULHAMENTO PARA RECUPERAÇÃO DE FADIGA MUSCULAR AGUDA PERIFÉRICA? UM ESTUDO PILOTO
Gabriel Barreto Antonino
Ana Paula de Lima Ferreira Jéssica Leite Reis Barbosa
Débora Kristinni Vieira Barbosa
Eduardo José Nepomuceno Montenegro Alberto Galvão de Moura Filho
Horianna Cristina Silva de Mendonça
Kennedy Freitas Pereira Alves
François Talles Medeiros Rodrigues Maria das Graças Rodrigues de Araújo
DOI 10.22533/at.ed.53419070312
CAPÍTULO 13117
INFLUÊNCIA AGUDA DA MONOBRA OSTEOPÁTICA NO LIMIAR DE DOR DA COLUNA VERTEBRAL TORÁCICA
Fábio Firmino de Albuquerque Gurgel
Isabela Pinheiro Cavalcanti Lima Ellen Rafaela da Costa Silva
Thayane Suyane de Lima
Victória Maria Maia Oliveira Rebouças Moisés Costa do Couto
DOI 10.22533/at.ed.53419070313
CAPÍTULO 14
Rafael Limeira Cavalcanti
Yanka de Miranda Silva
Ivanna Fernandes dos Santos Karinna Sonálya Aires da Costa
Rodrigo Marcel Valentim da Silva
Patrícia Froes Meyer DOI 10.22533/at.ed.53419070314
CAPÍTULO 15
INFLUÊNCIA DA CINESIOTERAPIA LABORAL NA REDUÇÃO DA DOR OSTEOMUSCULAR EM DOCENTES
Ariany Franciely Fonseca Renó Gislene Guimarães Garcia Tomazini
DOI 10.22533/at.ed.53419070315
CAPÍTULO 16
PERCEPÇÃO DO LIMIAR DE DOR APÓS MANIPULAÇÃO OSTEOPÁTICA DA ARTICULAÇÃO ATLANTO-AXIAL
Fábio Firmino de Albuquerque Gurgel Isabela Pinheiro Cavalcanti Lima
Maria Irany Knackfuss
Thayane Suyane de Lima
Natyane Melo da Silva Gislainy Luciana Gomes Câmara
Moisés Costa do Couto
DOI 10.22533/at.ed.53419070316

CAPÍTULO 17
PREVALÊNCIA DAS ALTERAÇÕES OSTEOMUSCULARES EM TRABALHADORES DE UMA EMPRESA DE MATERIAL DE CONSTRUÇÃO
Henrique Toledo Silva Campos Victor Barbosa Nascimento
Camila Correia Dias
Denise de Souza Pereira Maria de Fátima Albuquerque Sousa
Luana Rosa Gomes Torres
Renata Cardoso Couto
Érika Rosângela Alves Prado DOI 10.22533/at.ed.53419070317
CAPÍTULO 18 174
REABILITAÇÃO VESTIBULAR EM IDOSOS: PREVENINDO AS QUEDAS OCASIONADAS PELA TONTURA
Leonora Oliveira Leite
Ana Karla Pereira Azevedo Alan Alves de Souza
Mateus Kaled Teles Albuquerque
Guilherme Douglas Braga de Sousa
Paulo Fernando Machado Paredes Patricia da Silva Taddeo
DOI 10.22533/at.ed.53419070318
CAPÍTULO 19
RECURSOS CINESIOTERAPÊUTICOS E MANUAIS APLICADOS EM PACIENTE COM OSTEOPOROSE LOMBAR E LOMBALGIA: UM RELATO DE CASO
Thayná da Silva Lima Thayane Gabriele Lopes Juvenal
Amanda Portela do Prado
Matheus Kiraly Neris Lopes
Guilherme Douglas Braga de Sousa
Mateus Kaled Teles Albuquerque Vera Lúcia Santos Almeida
Anakira Suiane Lopes de Almeida
Josenilda Malveira Cavalcanti
Rinna Rocha Lopes
DOI 10.22533/at.ed.53419070319
CAPÍTULO 20185
RECURSOS FISIOTERAPÊUTICOS NO MANEJO DA DOR ONCOLÓGICA EM PACIENTES COM CÂNCER DE MAMA: UMA REVISÃO INTEGRATIVA DE LITERATURA
Caroline Ferreira
Jonas Aléxis Skupien Simone Medianeira da Silva
DOI 10.22533/at.ed.53419070320
CAPÍTULO 21
RECURSOS TERAPÊUTICOS PARA O ALÍVIO DA DOR NAS DISFUNÇÕES
TEMPOROMANDIBULARES: UMA REVISÃO DE LITERATURA Josyanne da Silva Soares
oosyanno da onva odaros

DOI 10.22533/at.ed.53419070321

CAPÍTULO 22
TERAPIA MANUAL E CINESIOTERAPIA APLICADAS EM PACIENTE COM GONARTROSE: UM RELATO DE CASO Klivia Marcelino Pordeus Costa Karina Kelly Silva Jeronimo Elvira Maria Magalhães Martins Nayanne Ferreira de Sousa Josenilda Malveira Cavalcante Rinna Rocha Lopes DOI 10.22533/at.ed.53419070322
CAPÍTULO 23
TRATAMENTO DOS SINTOMAS DA CHIKUNGUNYA COM AURICULOACUPUNTURA: ESTUDO PILOTO
Fernando Leonel da Silva Jaqueline Leite Batista Iaponan Macedo Marins Filho Lígia Tomaz de Aquino Dayvson Diogo de Santana Silva José Luiz Gomes da Silva DOI 10.22533/at.ed.53419070323
CAPÍTULO 24219
ESTIMULAÇÃO ELÉTRICA NEUROMUSCULAR EM PACIENTES ADMITIDOS EM UNIDADE DE TERAPIA INTENSIVA: UMA REVISÃO SISTEMÁTICA Antonia Gecileuda Nascimento Freitas Altevir Alencar Filho Eric da Silva Maria Augusta Amorim Franco de Sá Saulo Araújo de Carvalho Waldeck Pessoa da Cruz Filho DOI 10.22533/at.ed.53419070324
SOBRE AS ORGANIZADORAS231

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

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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

randomized, sham-controlled, prospective, 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.

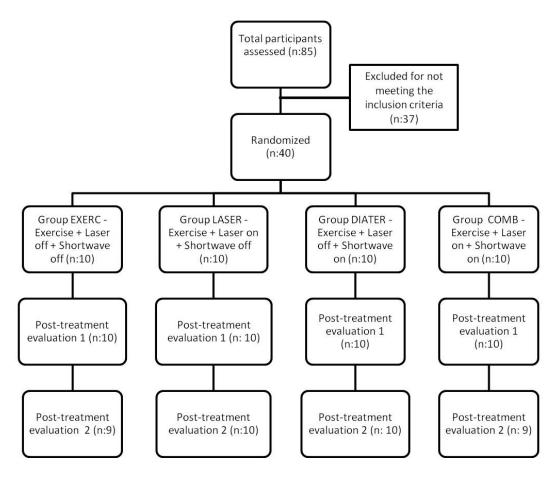


Figure 1: Flowchart of sample selection, interventions and evaluations

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 \geq 20 years, score \geq 4 on the visual analog scale (VAS), score \geq 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 | 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.

	EVED (mad 0)	LAGED (==40)	DIATED (m.d.0)	00145 (40)	
	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).

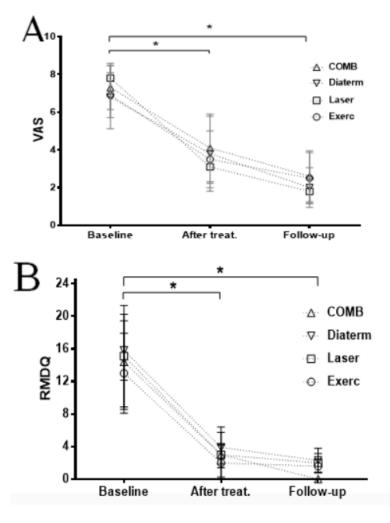


Figure 2: A) Mean pain levels (as assessed by visual analogue scale) at baseline, after treatment and follow-up in the 4 groups of treatments. B) Disability level of individuals (as assessed by Roland-Morris Disability Questionnaire) at baseline, after treatment and follow-up in the 4 groups of treatments. The results represent the mean \pm 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		
	В	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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