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Efeitos da Laserterapia de Baixa Potência na Reabilitação de Atletas com Lesão Muscular de Isquiotibiais: Um Ensaio Controlado Randomizado

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Dissertação submetida ao Programa de Pós-Graduação em Ciências da Reabilitação da Universidade Federal de Ciências da Saúde de Porto Alegre como requisito para a obtenção do grau de Mestre.

Orientador: Dr. Bruno Manfredini Baroni

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RESUMO

Estudos em modelos animais demonstraram efeitos positivos da Laser terapia de baixa potência (LBP) na cicatrização de tecidos após lesões musculares. No entanto, não existem ensaios clínicos randomizados que analisem o papel da LBP durante a reabilitação de lesões por estiramento de isquiotibiais (LEI's) em humanos. Os objetivos do presente estudo foi avaliar os efeitos da LBP na reabilitação funcional após LEI em atletas amadores. Atletas do sexo masculino (18-40 anos de idade) que sofreram LEI foram randomizados em grupo LBP ou grupo placebo. Todos os pacientes realizaram o mesmo programa de reabilitação baseado em evidências até que preenchessem os critérios específicos para retornar ao esporte. Eles foram tratados com LBP (comprimento de onda: 850 nm; dose de energia: 90 Joules) ou placebo imediatamente após cada sessão de reabilitação. O desfecho primário foi o tempo para retornar ao esporte. Os desfechos secundários foram o número de sessões de reabilitação, flexibilidade e força dos isquiotibiais. A flexibilidade e a força foram medidas através de testes clínicos usando um aplicativo para smartphone e um dinamômetro manual, respectivamente. Vinte e quatro atletas iniciaram a reabilitação e 22 (11 por grupo) completaram o cronograma do estudo. Os participantes dos grupos LBP e placebo apresentaram idade, massa corporal, estatura, características da lesão e níveis basais de flexibilidade e força de isquiotibiais semelhantes. Os dois grupos aumentaram a flexibilidade e a força de forma similar ao longo do programa de reabilitação. O tempo de retorno ao esporte foi o mesmo para atletas tratados com LBP (23 ± 9 dias) e placebo (24 ± 13 dias). Concluímos que a LBP, conforme utilizada neste estudo, não otimizou a reabilitação funcional após LEI em atletas amadores tratados com um programa de exercícios baseados em evidências.

Palavras-chave: Terapia de fotobiomodulação; agentes físicos; posterior da coxa

ABSTRACT

Animal model studies have demonstrated positive effects of low-level laser therapy (LLLT) on tissue healing following muscle injuries. However, there are no randomized clinical trials analyzing the role of LLLT during rehabilitation of muscle strain injuries in humans. The aim of the current study was to evaluate the effects of LLLT on functional rehabilitation following hamstring strain injury (HSI) in amateur athletes. Male athletes (18-40 years old) who sustained HSI were randomized into either LLLT group or placebo group. All patients were engaged in the same evidence-based rehabilitation program until met specific criteria to return to sport. They were treated with LLLT (wavelength: 850 nm; energy dose: 90 Joules) or placebo immediately after each rehabilitation session. The primary outcome was time to return to sport. Secondary outcomes were the number of rehabilitation sessions, hamstring flexibility, and hamstring strength. Flexibility and strength were measured through clinical tests using smartphone app and handheld dynamometer, respectively. Twenty-four athletes began rehabilitation, and 22 (11 per group) completed the study schedule. Participants of LLLT and placebo groups had similar age, body size, injury characteristics, and baseline levels of hamstring flexibility and strength. The two groups increased flexibility and strength similarly along the rehabilitation program. Time to return to sport was the same for athletes treated with LLLT (23±9 days) and placebo (24±13 days). In conclusion, LLLT, as used in this study, did not optimize functional rehabilitation following HSI in amateur athletes treated with an evidence-based exercise program.

Keywords: Photobiomodulation therapy; physical agents; posterior thigh

LISTA DE FIGURAS

Revisão de Literatura:

Artigo:

LISTA DE TABELAS

Artigo:

LISTA DE ABREVIATURAS E SIGLAS

Introdução e revisão de literatura:

LEI - Lesão de estiramento de isquiotibiais

LBP - Laserterapia de baixa potência

TRE – Treino de resistência excêntrica

DMIE – Dano muscular induzido por exercício

DMIT – Dor muscular de início tardio

LASER – *light amplification by stimulated emission of radiation*

AINE – Anti-inflamatório não esteróide

ERO – Espécies reativas de oxigênio

Artigo:

HSI – Hamstring Strain Injury

LLLT – Low-level Laser Therapy

PSLR – Passive Straight Leg Raise

KET – Knee Extension Test

MHFAKE – Maximal Hip Flexion Active Knee Extension

ROM – Range of Motion

HHD – Handheld Dynamometer

ES – Effect Size

EIMD – Exercise-induced muscle damage

CK – Creatine Kinase

SUMÁRIO

1. INTRODUÇÃO

O tecido muscular é comumente lesionado no esporte[109]. Lesões musculares são as lesões de não contato mais comuns em esportes que envolvem movimentos de alta velocidade[27]. Elas compreendem de 10% a 55% de todas as lesões no esporte[37,44,58,60]. Pelo fato de as lesões musculares estarem relacionadas a esportes que tem a corrida como uma das funções principais, os músculos mais comumente afetados são aqueles com uma participação maior nessa função. Noventa e dois por cento de todas as lesões musculares de membros inferiores afetam isquiotibiais, adutores, quadríceps ou panturrilha (gastrocnêmicos e sóleo), sendo a musculatura isquiotibial a mais comumente envolvida[38]. Um estudo recente[39] com acompanhamento das principais ligas europeias por 16 anos identificou as lesões mais comuns no futebol. Os autores demonstraram que a lesão por estiramento de isquiotibiais (LEI) foi a lesão mais comum (13,8%) dentre todas as lesões descritas no estudo. Além disso, a LEI afastou os atletas da prática esportiva por uma média de 18 dias, o que é considerado um tempo moderado. O afastamento de um atleta gera prejuízos financeiros pro clube envolvido[46,117] e afeta negativamente o desempenho do atleta[107]. Portanto, a investigação de estratégias com o potencial de acelerar o tempo de recuperação das LEI's se faz necessária.

A laserterapia de baixa potência (LBP) é um recurso terapêutico que tem sido amplamente investigado nos últimos anos[4,64] por seu potencial de contribuir para o processo de regeneração tecidual[111]. Postula-se que a absorção da energia luminosa por parte de cromóforos específicos na mitocôndria tem a capacidade de desencadear os processos celulares responsáveis pelos efeitos terapêuticos nos tecidos tratados com a LBP[111]. Estudos em modelos animais demonstraram que a LBP contribui significativamente para a recuperação de lesões musculares[6]. A LBP tem o potencial de modular o processo inflamatório[93] e o estresse oxidativo[15], estimular a angiogênese[103] e melhorar a distribuição de colágeno[7] após a lesão muscular. Em humanos, a LBP tem sido amplamente utilizada para atenuar os sintomas de dano muscular induzido pelo exercício (DMIE)[64]. O DMIE é caracterizado por danos à estrutura miofibrilar causada por uma sobrecarga imposta ao músculo de forma cíclica e controlada[88]. Os sintomas de DMIE são perda de força e potência muscular, diminuição da flexibilidade, presença de dor muscular de início tardio (DMIT) e edema[88]. Embora hajam diferenças entre DMIE e lesão muscular, especialmente no que tange ao tempo de recuperação[73], a fase aguda do processo inflamatório no DMIE e na lesão muscular é indistinguível[108]. Além disso, logo após a lesão muscular os sintomas são similares àqueles observados no DMIE[48]. Portanto, considerando que investigações anteriores mostraram que a LBP tem a capacidade de melhorar os sintomas do DMIE[8,16,65,72,86], é plausível considerar que efeitos semelhantes podem ser observados em lesões musculares.

A evidência atual é promissora no que diz respeito ao papel do LBP nas lesões musculares, tanto que, recentemente, uma diretriz[21] recomendou o uso do LBP durante o tratamento de lesões musculares de membros inferiores em atletas. No entanto, até a presente data, não há ensaios controlados randomizados para suportar a recomendação do LBP na reabilitação de lesão muscular em humanos. Assim, o objetivo geral do presente estudo foi avaliar os efeitos do LBP na recuperação funcional da LEI em atletas amadores.

A presente dissertação, portanto, foi motivada pela necessidade de descobrir se a LBP tem a capacidade de acelerar a recuperação funcional de atletas que sofreram LEI. A busca pela resposta nos impeliu a desenvolver um ensaio controlado randomizado durante o período do mestrado. O conteúdo da presente dissertação será apresentado em duas partes. A primeira parte abrange uma revisão de literatura descrevendo a LEI e as minúcias sobre a reabilitação dessa lesão, além de aspectos inerentes a LBP e as evidências desta modalidade terapêutica na recuperação de lesão muscular (em animais) e DMIE (em humanos). A segunda parte é apresentada em formato de artigo científico e descreve por completo o estudo original desenvolvido nessa temática.

2. REVISÃO DE LITERATURA

2.1. Lesões de isquiotibiais no esporte

Isquiotibiais é o nome atribuído ao grupo muscular localizado na região posterior da coxa que origina-se no ísquio e insere-se na tíbia, formado pelos músculos bíceps femoral, semitendinoso e semimebranoso[116] (Figura 1). Juntos, esses três músculos têm a função de estender o quadril e flexionar o joelho[79,80]. Além disso, os isquiotibiais são fundamentais na desaceleração do membro inferior na fase de balanço terminal e apoio inicial durante a corrida[51].

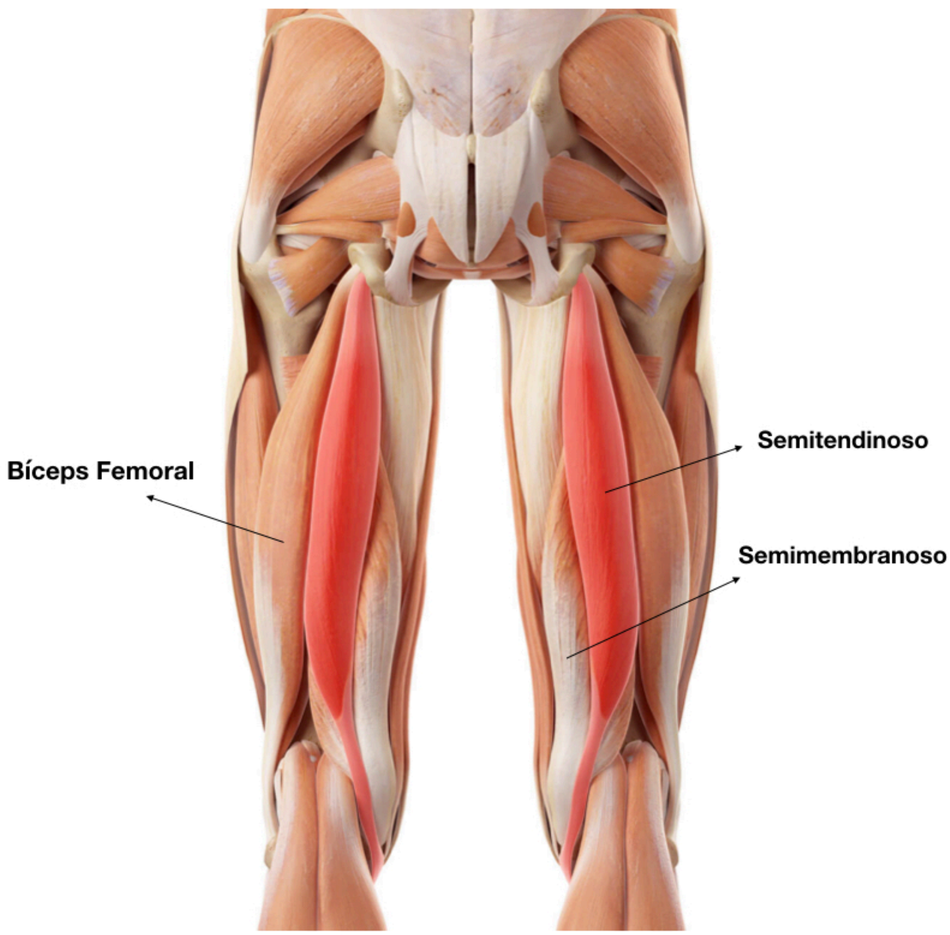

Figura 1 Ilustração dos três músculos que compõem um grupo denominado "isquiotibiais".

Embora a LEI ocorra durante movimentos diversos como o chute e a troca de direção, a corrida é o mecanismo mais comum[32,84]. A ocorrência de LEI está geralmente relacionada à fase de balanço terminal[32] e apoio inicial da corrida[84]. Portanto, atletas de esportes que têm uma alta demanda de tiros (*sprints*) são mais propensos à LEI. As LEI's afetam comumente corredores velocistas[69], atletas de rugby[26], basquetebol[23], futebol[37] e futebol americano[42]. Dançarinos de ballet também possuem uma alta susceptibilidade a LEI devido ao alongamento extremo ao qual os isquiotibiais são submetidos constantemente[11,102]. Além de possuir mecanismos diferentes, as LEI's possuem padrões de localização diferentes[11], o que interfere diretamente no protocolo de reabilitação (ver secção 2.2). A LEI que acontece durante a corrida em alta velocidade envolve mais comumente o bíceps femoral, ao passo que a LEI devido a alongamentos máximos da musculatura envolve normalmente o semimembranoso[10].

Lesões envolvendo a musculatura isquiotibial são responsáveis por cerca de 12% a 16% de todas as lesões no futebol[38,45]. Além disso, cerca de 30% de todas as lesões musculares são de isquiotibiais[54,83]. É indiscutível que a LEI representa um problema importante no meio esportivo. No futebol profissional, as lesões musculares são responsáveis por 18% do tempo de afastamento da prática esportiva[59], o que consequentemente diminui o desempenho da equipe[107] e gera prejuízos financeiros ao clube esportivo envolvido[46,117]. Além disso, uma vez presente, a LEI configura-se como o principal fator de risco para uma nova lesão[26], que normalmente demanda um período maior de recuperação[39].

2.2. Reabilitação de lesões de isquiotibiais

Embora o conhecimento sobre fatores de risco e métodos de prevenção esteja sendo aprimorado na última década, as LEI's ainda são muito frequentes[38,40], o que denota a importância de se investir no desenvolvimento de estratégias terapêuticas seguras e eficientes. Via de regra, o tempo de reabilitação de uma LEI irá variar de acordo com o tipo de lesão[14]. Lesões que envolvam o tendão proximal costumam afastar o atleta por um período de tempo maior[14]. Lesões distais, por sua vez, normalmente envolvem o bíceps femoral e tendem a ter um processo de reabilitação mais acelerado[14]. A maioria das lesões (54%) é considerada de gravidade moderada, com o atleta perdendo em média 17 dias de prática[40]. No entanto, 15% das lesões são graves, o que geralmente requer um período maior de reabilitação (> 28 dias)[40]. Além disso, em muitos casos, os atletas retornam ao esporte com déficits de força[107], o que pode ser um dos motivos da alta taxa de recidivas, principalmente quando a lesão acomete o bíceps femoral (18,4%)[47]. Para diminuir ao máximo a chance de uma recidiva, é importante que alguns fatores sejam levados em consideração durante a reabilitação.

Uma prerrogativa importante durante a reabilitação da LEI é a mobilização precoce[19]. A mobilização precoce parece ter vantagens sobre tratamentos mais conservadores em alguns distúrbios musculoesqueléticos[9,19,62]. Bayer et al.[19] relataram que atletas que iniciaram a reabilitação 2 dias após a lesão muscular em vez de esperar 9 dias retornaram ao esporte 3 semanas mais cedo. Os mecanismos responsáveis pela aceleração da recuperação ainda não são claros. No entanto, há evidência de que o alongamento muscular controlado e os movimentos ativos aumentam a orientação das fibras de colágeno paralelamente às linhas de estresse das fibras colágenas normais, o que pode impedir a atrofia tecidual causada pela imobilização[61].

Outro fator importante que deve ser contemplado durante um protocolo de reabilitação de LEI é o fortalecimento dessa musculatura de forma integral, independente do músculo que foi lesionado. Obviamente, todo o exercício de extensão de quadril ou flexão de joelho ativa todos os três músculos isquiotibiais. No entanto, diferentes exercícios enfatizam músculos distintos[119]. Uma revisão sistemática recente[24] sugeriu que exercícios que envolvam movimentos de quadril geram maior engajamento do bíceps femoral, enquanto exercícios que envolvam movimentos de joelho geram maior ativação os isquiotibiais mediais (semimembranoso e semitendinoso). Portanto, para a realização de programa de reabilitação que contemple o fortalecimento dos isquiotibiais de forma integral, é necessário que exercícios que explorem tanto movimentos de quadril quanto de joelho sejam selecionados.

Para reabilitação de LEI's, há poucos protocolos disponíveis, porém alguns fatores importantes são conhecidos. Askling et al.[14] compararam dois protocolos de reabilitação da LEI em 75 atletas de futebol. Um protocolo foi composto de exercícios excêntricos e de estabilização tronco, enquanto o outro foi composto de exercícios convencionais (contrações isotônicas) e alongamentos. Os autores demonstraram que um protocolo de reabilitação com ênfase em contrações excêntricas diminui em aproximadamente 40% o tempo de retorno à prática esportiva. Há evidências de que o treinamento de força excêntrica (TFE) gera aumentos de força e da área de secção transversa muscular mais significativos quando comparados a treinamentos tradicionais (concêntrico/excêntrico)[94]. Outro benefício do TFE é a sua capacidade de aumentar o comprimento do fascículo muscular[3,25]. Considerando que atletas com menor comprimento de fascículo podem estar mais suscetíveis a lesões muscularesti[106], a utilização de contrações excêntricas durante programas de reabilitação/prevenção torna-se fundamental. Além disso, músculos que sofreram uma lesão tendem a apresentar diminuição da atividade eletromiográfica[82], o que pressupõe déficit de ativação da musculatura envolvida. O TFE é efetivo em aumentar a atividade eletromiográfica muscular[70], o que pode contribuir, em conjunto com outras variáveis (e.g. força e comprimento de fascículo), para a prevenção de novas lesões.

Outro componente importante durante a reabilitação da LEI é o condicionamento da musculatura do tronco e exercícios progressivos de agilidade. Sherry & Best[100] compararam dois protocolos de reabilitação da LEI em 24 indivíduos. O primeiro grupo realizou exercícios de estabilização de tronco e exercícios progressivos de agilidade, enquanto o segundo grupo realizou exercícios de resistência de isquiotibiais e alongamentos. Como resultado, o primeiro grupo retornou ao esporte em média 15 dias mais cedo que o segundo grupo. Além disso, o número de recidivas durante o primeiro ano após a lesão foi 63% maior no segundo grupo. Os mecanismos pelos quais o primeiro grupo teve uma reabilitação mais bem sucedida não são claros. No entanto, sabe-se que a estabilidade da musculatura do centro (*Core*) parece ser capaz de proteger atletas de LEI[99]. Portanto, incorporar exercícios de *Core* durante programas de reabilitação/prevenção parecer uma forma prática e segura de tornar o protocolo mais efetivo.

Quanto aos exercícios de agilidade progressiva, os mecanismos pelos quais inserir esse tipo de exercício durante a reabilitação não são completamente compreendidos. Entretanto, é plausível hipotetizar que esse tipo de tarefa, além de gerar efeitos diretos na musculatura pela ativação muscular inerente aos exercícios, também pode gerar repercussões do ponto de vista do preparo psicológico dos atletas. A relação entre medo de recidiva e retorno mal sucedido ao esporte levou à sugestão de que o estado psicológico poderia ser um critério de retorno ao esporte importante[53]. Além disso, muitos atletas mencionam o medo de recidiva como a principal razão para não retornar ao esporte[76]. As repercussões psicológicas (e.g. frustração, medo, insegurança) tendem a ser mais negativas imediatamente após a lesão[76]. Portanto, introduzir tarefas relacionados ao esporte no início do tratamento pode ser importante para a recuperação.

2.3. Laserterapia de baixa potência

Um recurso terapêutico que tem sido investigado de forma sistemática na atualidade é o LASER (*light amplification by stimulated emission of radiation*) de baixa potência[4]. A Laserterapia de baixa potência (LBP) gera um efeito conhecido como fotobiomodulação, que caracteriza-se com a indução de efeitos fotoquímicos nas células que absorvem luz por meio de fotorreceptores[56]. A LBP é realizada utilizando equipamentos com potência de saída inferior a 1 Watt[72,86]. Diferentemente dos LASERs de alta potência, os quais possuem finalidade cirúrgica através de efeito fototérmico[104], a LBP serve para propósitos terapêuticos, sendo utilizada no estímulo de processos fisiológicos através de efeitos atérmicos[97].

Os mecanismos de ação da LBP ainda não estão completamente elucidados. No entanto, sabe-se que a absorção da energia luminosa por parte de cromóforos específicos na mitocôndria é um evento chave para o desencadeamento de processos celulares responsáveis pelos potenciais efeitos terapêuticos nos tecidos tratados com a LBP[111]. A literatura tem demonstrando efeitos positivos da LBP na recuperação de feridas cutâneas[29,75], na regeneração tendínea[78] e nervosa[92], além de ação analgésica[22] e anti-inflamatória[118]. Todos os efeitos positivos demonstrados na literatura fizeram com que a LBP chegasse ao contexto do esporte e do exercício, por sua possível capacidade de ajudar na recuperação de lesão muscular[6] e atenuar os sintomas de dano muscular[64,77] .

A LBP tem sido amplamente utilizada em estudos animais para o tratamento lesão muscular[1,2,85,90]. A forma de aplicação da LBP varia consideravelmente entre os estudos[4], especialmente no que diz respeito ao comprimento de onda do aparelho, a energia total por tratamento e ao número de pontos tratados. Mesmo assim, uma revisão sistemática sobre assunto[4] concluiu que, embora a resposta da LBP seja dependente dos parâmetros utilizados, a LBP parece ser uma estratégia com bons efeitos no tratamento de lesões musculares. A LBP age através de respostas inerentes ao processo de regeneração/cicatrização tecidual. Após lesão muscular, a LBP parece ter a capacidade de modular o processo inflamatório[93] e o estresse oxidativo[15], estimular a angiogênese[103], melhorar a distribuição de colágeno[7], remodelar a matriz extracelular[15] (danificada durante o processo inflamatório) e estimular a proliferação e diferenciação de células satélites[15]. Além disso, a LBP também parece oferecer benefícios do ponto de vista funcional, aumentando a resistência à fadiga[90] e melhorando o desempenho na caminhada[96] após lesão muscular.

A LBP também tem se mostrado mais efetiva quando comparada a outros tratamentos. Carvalho et al. (2013)[85] avaliaram os efeitos de uma única aplicação de LBP, anti-inflamatório não esteroide (AINE) ou terapia combinada na recuperação de aspectos funcionais e bioquímicos de ratos que sofreram lesão muscular de tibial anterior. Os grupos que realizaram a LBP demostraram melhora significativa comparando aos grupos que realizaram a aplicação de anti-inflamatório, tanto nos níveis sanguíneos de prostaglandinas quando nos parâmetros funcionais. Os autores concluíram que a LBP é a alternativa mais indicada para a recuperação muscular após lesão. Outro estudo[2] do mesmo grupo de pesquisa comparou os efeitos da LBP (1, 3, 6 e 9 J) à aplicação de AINE tópico e à crioterapia na liberação de citocinas proinflamatórios em ratos que sofreram lesão muscular de tibial anterior. Os autores concluíram que a LBP (1 J) fornece melhores efeitos quando comparada ao AINE e à crioterapia na fase aguda do processo inflamatório após lesão muscular.

Em seres humanos, há evidências de que a LBP contribui de forma significativa para melhora dos sintomas associados ao dano muscular induzido por exercício (DMIE)[64]. O DMIE é um fenômeno caracterizado por lesões nas miofibrilas, causadas por um exercício ao qual o sujeito não está habituado, especialmente na presença de contrações excêntricas[88]. As lesões microscópicas provocadas pelo exercício deflagram uma resposta inflamatória que é caracterizada pela presença de dor muscular de início tardio (DMIT)[31], edema, diminuição de ADM, redução na capacidade de produção de força[30], entre outros sintomas.

A LBP pós-exercício tem mostrado resultados positivos na aceleração da recuperação dos sintomas de DMIE[86]. Estudos recentes mostraram que uma aplicação de LBP após um protocolo de indução de DMIE acelera o reestabelecimento da força[72,86], diminui os níveis sanguíneos de creatina kinase[91]. Além disso, evidências tem demonstrado um efeito protetivo da LBP. A aplicação da LBP antes do exercício diminui os níveis de creatina kinase e lactato[16,65], aumenta a resistência muscular ao exercício[16,66], diminui a DMIT[8] e melhora a performance em atividades aeróbicas[71]. Outra resposta importante do LBP é a sua capacidade de potencializar as adaptações musculares ao exercício. Estudos que utilizaram a LBP durante treinamentos de força encontraram que a LBP potencializa o aumento na espessura muscular[17], circunferência muscular[43] e capacidade de produção de força[17,43,110].

Em síntese, as lesões musculares estão entre as lesões mais comuns no contexto esportivo[81]. No futebol profissional, essas lesões causam diminuição do desempenho dos atletas e prejuízos econômicos para o clube esportivo[20,46,117]. Atualmente, há evidências favoráveis da LBP para a recuperação de lesão muscular em estudos em modelo animal[1,34,74,90] e estudos com DMIE em humanos[65,72,86]. Com base nesses resultados, a LBP tem sido recomendada para a recuperação de lesões musculares[21,98] em humanos. No entanto, tal recomendação é inadequada, pois, até a presente data, não há ensaios controlados randomizados avaliando os efeitos da LBP na reabilitação funcional de humanos acometidos pela lesão muscular, o que justifica a realização do presente estudo.

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3. ARTIGO

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Effects of Low-level Laser Therapy on Hamstring Strain Injury Rehabilitation: A Randomized Controlled Trial

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Effects of Low-Level Laser Therapy on Hamstring Strain Injury Rehabilitation: A Randomized Controlled Trial

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ABSTRACT

STUDY DESIGN: A randomized, double-blinded, placebo-controlled trial.

BACKGROUND: Animal model studies have demonstrated positive effects of low-level laser therapy (LLLT) on tissue healing following muscle injuries. However, there are no randomized controlled trials analyzing the role of LLLT during muscle strain injuries rehabilitation in humans.

OBJECTIVE: To evaluate the effects of LLLT on functional rehabilitation following hamstring strain injury (HSI) in amateur athletes treated with an exercise-based rehabilitation program.

METHODS: Male athletes (18-40 years old) who sustained HSI were randomized into either LLLT group or placebo group. All patients were engaged in the same evidence-based rehabilitation program until they met specific criteria to return to sport. Hamstring muscles were treated with LLLT (wavelength: 850 nm; energy dose: 90 Joules) or placebo immediately after each rehabilitation session. The primary outcome was time-to-return to sport. Secondary outcomes were the number of rehabilitation sessions, hamstring flexibility, and hamstring strength. Flexibility and strength were measured through clinical tests using smartphone app and handheld dynamometer, respectively.

RESULTS: Twenty-four athletes began rehabilitation, and 22 (11 per group) completed the study schedule. Participants of LLLT and placebo groups had similar age, body size, injury characteristics, and baseline levels of hamstring flexibility and strength. The two groups increased flexibility and strength similarly along the rehabilitation program. Time-to-return to sport was the same for athletes treated with LLLT (23±9 days) and placebo (24±13 days). No re-injury happened up to 6 months after discharge.

CONCLUSIONS: LLLT, as used in this study, did not optimize functional rehabilitation following HSI in amateur athletes treated with an exercise-based rehabilitation program.

Level of Evidence: Therapy, Level 1b

KEYWORDS: Photobiomodulation therapy; physical agents; posterior thigh

INTRODUCTION

Hamstring strain injury (HSI) is the most prevalent non-contact injury in several sports.[32] Although knowledge about risk factors and prevention methods have been widely disseminated,[12,14] HSI's incidence continues to grow.[16] Elite athletes with full access to intensive rehabilitation programs have lost ~17 days of sports practice following a HSI, and 15% of all HSIs are more severe cases that require rehabilitation periods longer than 28 days.[16] Furthermore, many athletes return to sport with strength deficits[43] and still showing signs of tissue injury,[37] which may at least partly explain the high recurrence rate of HSI, especially when it affects the biceps femoris muscle (~18%).[18] Since the rehabilitation program's primary goal is the athlete's return to sport at the prior performance level with minimal risk of injury recurrence,[19] further work is required to establish effective therapeutic strategies that might be able to optimize HSI recovery.

In general terms, the initial focus of the HSI rehabilitation programs involves minimizing pain and edema, while protecting the scar formation and avoiding muscle atrophy that is followed by a progressive implementation of exercises aimed at reestablishing the athletes' range of motion, strength and functional capacity.[19] The importance of the early loading on the injured muscle has already been documented,[10] and evidence supports that HSI rehabilitation programs should prioritize eccentric exercises,[5,6] trunk stabilization,[39,40] and progressive agility drills.[39,40] These strategies tend to get the athletes back to sports practice faster[5,6], and with a decreased risk of re-injury[39]. However, the number of randomized clinical trials assessing specific rehabilitation programs for HSI is still scarce.

Low level-laser therapy (LLLT) is an electrophysical agent commonly used to treat musculoskeletal disorders, and with an increasing number of publications in highly ranked medical journals.[30] Animal model studies have shown positive effects of LLLT on the muscle repair process,[2] such as inflammation[36] and oxidative stress modulation,[7] angiogenesis increase,[41] satellite cells stimulation,[44] and collagen distribution improvement[3] following muscle injury. In humans, LLLT has been able to accelerate recovery following exercise-induced muscle damage (EIMD),[29] commonly referred as the "micro injuries" to the myofibrillar structure caused by unaccustomed exercise and responsible for delayed-onset muscle soreness.[24] The skeletal muscle regeneration process from macroscopic muscle injuries and EIMD is quite similar (each with specific duration times),[42] and therefore it seems reasonable to assume that LLLT may be a useful approach during HSI rehabilitation.

In summary, current evidence is promising with regard to the role of LLLT on muscle strain injuries rehabilitation, and a recent guideline[11] has recommended the use of LLLT to treat lower limb muscle injuries in athletes. However, we were unable to find a randomized clinical trial supporting the LLLT efficacy during muscle strain-injury rehabilitation in humans. Therefore, the aim of the current study is to evaluate the effects of LLLT on HSI functional rehabilitation in amateur athletes treated with an exercise-based rehabilitation program. We hypothesized that participants treated with LLLT would present faster functional recovery and earlier return to sport compared to those receiving placebo treatment.

METHODS

Study Design

This is a randomized, double-blind, placebo-controlled trial. Amateur athletes with HSI were randomly allocated to the LLLT or to the placebo group. All patients were engaged in the same evidence-based rehabilitation program[5,15,39,40] and received LLLT or placebo therapy after every session. The rehabilitation program was applied until the patient met specific criteria to return to sport. The study was approved by the Ethics Committee of the Federal University of Health Sciences of Porto Alegre (Porto Alegre, Brazil; #2.555.174), and prospectively registered at ensaiosclinicos.gov.br (#U1111-1222-2897).

Participants

Participants were recruited through digital media ads and treated at a partner physiotherapy clinic in Porto Alegre (Brazil) from April to December 2018. To be eligible, volunteers should be male amateur athletes, between 18 and 40 years of age, with acute sudden pain in the posterior thigh within five days prior to the initial evaluation session. HSI should be confirmed by clinical examination performed by a single physiotherapist (more details in "Initial evaluation" section). After initial evaluation, volunteers were excluded when: (1) the inciting event of pain was a direct trauma in the posterior thigh or events not related to sports practice; (2) they presented neurological symptoms (i.e., positive Slump test); or (3) they presented signs of a grade III injury. All eligible volunteers that agreed to participate in this study signed an informed consent before data collection.

Sample size calculation

The sample size was estimated based on the time-to-return to sport after HSI, according to data provided by a previous investigation[5]. Based on a statistical power of 80% and a significance level of 5%, 11 patients were needed in each group. Due to the possibility of dropouts, we selected 24 participants (12 per group).

Randomization and blinding

The randomization was performed online (www.sealedenvelope.com) by an investigator not involved in the recruitment, assessment or the application of the rehabilitation protocol. The patients’ allocation to the two experimental groups was performed using 4-patient block randomizations. This randomization process allowed stratification of age (under or over 30 years old) and grade of injury (grade I or grade II).

Only the investigator responsible for LLLT and placebo treatments knew the subjects' allocation. This investigator was not involved with treatment or assessments. LLLT and placebo treatments were administered in a separate room where patients performed the rehabilitation program under the physiotherapist supervision. LLLT provoked no thermic or other perceptive effects, and LLLT and placebo treatments followed the same application procedures, including the use of protective eyewear during the therapy. Thus, the volunteers were blinded to their allocation into LLLT or placebo groups.

Outcomes

The primary outcome of this study was time-to-return to sport. Secondary outcomes were the number of rehabilitation sessions, hamstring flexibility, and hamstring strength. The treatment period and, consequently, the number of rehabilitation sessions, were variable among the participants since the patient's discharge was defined by his individual functional status assessed through specific criteria to return to sport (described in "*Discharge criteria*" section). Time-to-return to sport was calculated by the number of days between the injury event and the day after the patient's discharge. Both hamstring flexibility and strength outcomes were assessed in both limbs at the patient's first attendance and at his discharge, as described next.

Three lower limb posterior chain flexibility tests were used: passive straight leg raise (PSLR),[19,47] knee extension test (KET),[19] and maximal hip flexion active knee extension (MHFAKE).[47] For the PSLR test, the participant remained in supine with hips and knees fully extended. The assessor passively flexed the tested limb at the hip until the maximal tolerable stretch (uninjured limb) or the point where patient reported pain in the injure site (injured limb). For the KET, the participant remained in supine with the limb to be tested in 90° of hip and knee flexion (0° = full extension), while the contralateral limb remained resting on the stretcher in full hip and knee extension. The assessor passively extended the knee with the ankle relaxed until the maximal tolerable stretch (uninjured limb) or the point where patient reported pain in the injure site (injured limb). For the MHFAKE test, the participant remained in supine with the limb to be tested in full hip flexion (held by the participant), the contralateral limb remained resting on the table in full hip and knee extension. The participant actively extended the knee being tested until the maximal tolerable stretch or the point where pain was reported. All range of motion (ROM) measurements from the three flexibility tests were recorded using a validated smartphone app.[46]

Strength tests were performed in three different positions (inner, mid and outer range) using a handheld dynamometer (MicroFet 2, Hoggan Health, USA). The dynamometer was placed on the athlete's heel for all tests, and he was instructed to push against it with maximal effort for 3s in each attempt.[47] For the evaluation of the inner range, the athlete was in prone position with the knee to be tested flexed at 90°, while the contralateral limb was resting on the stretcher in full hip and knee extension.[47] For the mid-range assessment, the athlete was in prone position, and his leg was raised passively with the toes off the bed at a distance equal to the height of the foot length (~20-30° of knee flexion).[47] Thereafter, the outer range strength test was performed with the participant in a supine position with knee and hip at 90° of flexion, while the dynamometer was positioned between his heel and a step placed under his feet.[47] Three attempts of each test were performed and the peak force values were considered for statistical analysis.

Intervention

Initial evaluation

The patient was evaluated to verify his eligibility for the study in his first attendance at the clinic. The first part of the evaluation was an anamnesis, which included information regarding age, profession, daily-living routine, sports practice, history of previous injuries, and detailed description of the current injury. This injury description included: affected limb, injury mechanism, time elapsed since the injury, medication and/or other therapies taken since the injury, and self-reported functional impairment (e.g., gait, sit-up, climb-up and down stairs). Physical examination assessed the following items: (1) presence of edema/hematoma (visual inspection) and skin temperature (tactile inspection); (2) pain during palpation (assessed by Visual Analogue Scale - VAS)[47] and pain threshold (assessed by algometry);[28] (3) distance between site of peak pain and the ischial tuberosity[6] (skin over this site was marked with a dermographic pen to guide LLLT/placebo treatments); (4) Slump test;[19] (5) range of motion (as aforementioned);[19,47] and (6) maximum isometric strength (as aforementioned).[47] The same physiotherapist performed all initial evaluations.

Rehabilitation program

All patients were engaged in the same HSI rehabilitation program, whose was designed based in previous studies.[5,15,39,40] The rehabilitation sessions were held three times a week, with at least 48h between-session, and approximately 60 minutes in length. The rehabilitation program comprised three phases, all of them including exercises to enhance hamstring strength, trunk stabilization, and movement agility. Exercises were specific for each rehabilitation phase, while exercise workloads were individualized for each patient according to their conditioning status. In order to progress to the next phase, patients should meet pre-established criteria. The “Appendix” presents a guide used for the HSI rehabilitation program.

During all rehabilitation sessions, a pain-threshold approach was applied.[20] We started mobilization of the injured muscle at 48-96h following the injury event[10] using the "extender" exercise.[6] The participants were constantly asked about their pain during the proposed exercises. If the pain was <4, the participant was encouraged to continue; if at some point the pain was >4, the exercise was interrupted and resumed in the next session. Hamstring-based exercises consisted primarily of eccentric-focused exercises for the knee flexor muscles[6,40] and functional training exercises (e.g., squats and lunges). In addition, progressive agility drills[39,40] and trunk stabilization[39,40] exercises were inserted respecting the progression of each patient. All participants should have compliance higher than 75% to continue in the study.

Low-level laser therapy

LLLT treatment was administered immediately after each rehabilitation session using a commercially available device (Chattanooga Intelect Advanced; Chattanooga Corp., USA) with a LASER cluster probe consisting of five infrared diodes (850 nm). Since no previous study has described the LLLT settings used to treat HSI in humans, the LLLT treatment was designed by the researchers. The average HSI extension usually does not exceed 15 centimeters,[40] while the cluster probe covered a 7.54cm^2 area (diameter = 8.5 cm) per application site. In order to ensure irradiation for the full-injured area, LLLT treatment was applied at three sites: one at the site of peak pain, one above and the third below the site of peak pain (Figure 1). The LLLT parameters were based on a previous investigation that reported positive effects of LLLT on markers of exercise-induced muscle damage.[8] As detailed in Figure 1, each site was treated for 60 s, leading to a dose of 6 J per diode, 30 J per site, and 90 J per muscle. Placebo treatment was applied in the same way, but with the device turned off.

<< Figure 1 >>

Discharge criteria

The physiotherapist assessed the patient's pain during palpation of the injury site at the beginning of all sessions. In the stage where there was no more pain,[17,21] lower limb flexibility tests were applied as detailed above.[19,47] When flexibility level was restored (<10% between-limb asymmetry), the hamstring strength was assessed as previously detailed.[47] After recovery of muscle strength (<10% between-limb asymmetry), the patient was submitted to the functional evaluation through the single-leg hop test and the Askling-H test.[4,21]

The participant was considered ready to return to sports practice when he met the following criteria: 1) absence of pain/tenderness during palpation, stretching, maximal isometric contraction, single-leg hop test, Askling-H test, and during all high intensity running drills during the sessions; 2) between-limb asymmetry lower than 10% in all flexibility and strength tests ; 3) between-limb asymmetry lower than 10% in the single-leg hop test; 4) similar performance between affected and non-affected limbs in the Askling-H test.

After reaching the discharge criteria, the athletes were instructed to return to sport progressively, including specific training for one to two weeks before engaging in matches/competitions. They were warned about the importance of a continued preventive program to reduce the risk of re-injury. Recommendations included the performance of frontal, lateral and prone bridge, as well as the single-leg bridge exercise, two to three times a week, to decrease the chances of re-injury. These exercises were chosen because they do not need any special equipment or partner assistance, which favors the athletes' compliance. The athletes were asked to contact the research team in case of re-injury, and we contact them by phone ~6 months following discharge to access re-injury rate.

Statistical analysis

Shapiro-Wilk test was carried out to check the normality of the data. Independent t-tests were used to compare LLLT and placebo groups for subjects' characteristics (age, body mass, and height), injury characteristics (distance to ischiatic tuber, pain on palpation, and pain threshold), and baseline between-limb asymmetry for flexibility and strength outcomes. Qui-square tests were used to compare groups for involved muscle (biceps femoris or semitendinosus), injury grade (grade I or grade II), and injury site (proximal, medial, or distal). The two-way ANOVA [group (LLLT and placebo) x time (baseline and discharge)] was used to analyze lower limb flexibility and strength outcomes, followed by Bonferroni post-hoc test. LLLT and placebo groups' time-to-return to their sport was compared using the independent t-test, as well as the number of rehabilitation sessions. A significance level of 5% ($\alpha = 0.05$) was applied to verify statically significant differences. Between-group effect size (ES; Cohen's *d*) was calculated for time-to-return to sport, number of rehabilitation sessions, and flexibility and strength values at discharge.[22] Effect sizes were considered as "trivial" (ES<0.2), "small" (ES>0.2) "moderate" (ES>0.5), or "large" (ES>0.8).

RESULTS

Twenty-seven individuals were recruited to this study, and 24 met the inclusion criteria and were enrolled in the study. They were amateur athletes of soccer (n=14), futsal (n=5), American football (n=2), track and field (n=2), and rugby (n=1). Two athletes allocated in the LLLT group and one in the placebo group had previous HSI history. Two participants dropped out, leading LLLT and placebo groups to a sample size of 11 participants each (Figure 2). There were no between-group differences regarding subjects and injuries characteristics, as well as for flexibility and strength baseline deficits (Table 1).

<< Figure 2 >>

<< Table 1 >>

There was no significant group-by-time interaction ($p>0.05$) for any flexibility or strength outcome, but treatments produced a significant time effect ($p<0.05$) for all outcomes (Table 2). Only trivial between-group ES were found at patients' discharge: SLR, ES=0.21; KET, ES=0.61; MHFAKE, ES=0.12; inner range strength test, ES=0.29; mid-range strength test, ES=0.12; and outer range strength test, ES=0.19.

Volunteers from both groups attended a similar number of physiotherapy sessions: LLLT group, 9.18±3.31 (CI95% = 6.96 – 11.40); placebo group, 9.36±4.78 (CI95% = 6.15 – 12.57); p=0.92, ES= 0.04. Finally, time-to-return to sport was similar between groups: LLLT group, 23.09±9.08 days (CI95% = 16.99 – 29.19); placebo group, 23.82±12.62 days (CI95% = 15.34 – 32.30); p=0.88, ES=0.07 (Figure 3).

<< Table 2 >>

<< Figure 3 >>

At six months' follow-up, all athletes declared to have returned to their sports at the pre-injury level and none of them had sustained re-injuries.

DISCUSSION

To the best of our knowledge, this is the first randomized controlled trial aimed at investigating the effect of LLLT on the rehabilitation of any type of muscle strain injury in humans. In synthesis, our findings demonstrated that LLLT, as used in this study, does not optimize functional rehabilitation following HSI in amateur athletes *treated with an* exercise-based rehabilitation program.

Skeletal muscle repair after an acute injury is a slow process that ideally, but not always, leads to the structural and functional recovery of the injured muscle.[42] Thus, therapeutic approaches that can optimize the muscle repair process are welcome in sports rehabilitation. In face of the lack of clinical trials, the efficacy of LLLT on the rehabilitation of muscle strain injuries has been supported solely by findings in mice submitted to different experimental models of muscle injury (for a review, see Alves et al.[2]). Animal studies have demonstrated positive effects of LLLT on histological and biochemical markers of tissue healing[2], and there is evidence of positive LLLT effects on a few functional outcomes (e.g., walking track analysis[38] and peak force[35]). However, the efficacy of LLLT seen in mice was not evidenced on the functional outcomes assessed in the current human trial.

Some animal studies[1,3,7,33] started the LLLT treatment within 24h after the muscle injury, and it could be speculated that our treatment started too late (48-96h after injury) for the improvement of the healing effects to occur. The first 24-hour period is crucial for the inflammatory process,[42] so LLLT effects might have been potentiated with the early therapy implementation in these animal studies. However, it would be hard to reproduce that in clinical practice, especially with amateur athletes who do not have medical staff available full time. Another aspect that needs to be pointed out is that the target tissue is deeper in humans than in mice, so LLLT is attenuated (i.e., reflection and refraction) by surrounding tissues,[13] which impairs the absorption of light energy at the mitochondrial level and, consequently, reduces the LLLT physiological effects on the injured tissue.[25] Since LLLT has a marked dose-response effect, higher doses perhaps would be necessary to generate the expected therapeutic benefits in humans. However, this needs to be determined in future studies, as we tested a single LLLT dose.

Differently from the previous animal studies,[1,3,7,33] we applied the LLLT as an adjunct therapy to an exercise-based rehabilitation program. This is a key difference between studies since exercise seems to be a powerful stimulus for muscle healing.[26] Although muscle healing cannot explain the athletes' functional recovery and return-to-sport,[9] an early-loading approach has demonstrated advantages over more conservative treatments in some musculoskeletal disorders.[10,27,31] Bayer et al.[10] reported that athletes who started rehabilitation 2 days after muscle injury rather than waiting for 9 days returned to sport 3 weeks earlier. In addition, our rehabilitation program followed the most recent evidence for HSI treatment, including progressive employment of eccentric exercises,[5,6] trunk stabilization exercises,[39,40] and agility drills.[39,40] No drugs or other electrophysical agents were used together with the rehabilitation program, which highlights that an evidence-based exercise protocol is enough for a successful HSI rehabilitation.

The averaged time-to-return to sport for both groups was in accordance with what was previously reported for amateur athletes (~23 days).[40] However, it is interesting to note that this previous study[40] reported 4 re-injuries, while we had none up to 6 months after return-to-sport. The rigorous discharge criteria possibly contributed to the absence of re-injuries in the present study. Differently than Silder et al.,[40] who used a subjective strength assessment (i.e., manual muscle test grading scale), we used a hand-held dynamometer to objectively assess strength in joint positions previously recommended.[47] Furthermore, the Askling-H test, used in our study as the final discharge criterion, has been proven to be effective in decreasing the HSI recurrence rate.[21] These objective discharge criteria and the functional drills performed in the clinical setting tend to increase the athletes' confidence in their recovery, which is a key factor for returning to sport.[23] Lastly, the recommendation of a continuous home-based exercise program following discharge also may also have contributed to the fact that no athlete experienced a re-injury, and all of them returned to their pre-injury competitive level and weekly volume of sports practice after rehabilitation.

The present study has limitations that should be highlighted. First, the two-arm design prevented us of identifying if other LLLT dosages would have different effects on the outcomes. Second, despite magnetic resonance imaging and ultrasonography do not add value in predicting return to sport after HIS,[34,45] imaging exams would provide additional information regarding the injury characteristics and the effect of LLLT on structural repair of the muscle. However, physiotherapists treating amateur athletes often do not have access to imaging exams, and this trial was fully carried out within this clinical setting. Third, the number of participants does not constitute a large-scale study, but it is in accordance with our sample size calculation and close to previously randomized clinical trials in this field.[39,40]

CONCLUSIONS

LLLT, when applied with the parameters used in the current study (*850 nm, 90 J per session,* three sessions per week), does not optimize the recovery of muscle flexibility or strength, and does not accelerate the return-to-sport following HSI rehabilitation in amateur athletes *treated with an* exercise-based rehabilitation program. In view of the potential benefits of LLLT on muscle healing evidenced by animal model studies, as well as the dose-response effect of this therapy, more clinical trials are encouraged. However, there is currently no evidence to support the efficacy of LLLT on the rehabilitation of HSI in humans.

KEY POINTS

Findings: LLLT was not superior to placebo when added to an exercise-based rehabilitation program for HSI. Our intervention protocol returned athletes to their sports in ~23 days, and no re-injury happened up to 6 months after discharge.

Implications: LLLT, with the parameters used in the present study, cannot be recommended for enhancing functional rehabilitation following HSI in athletes treated with an exercise-based rehabilitation program.

Caution: Since this study assessed only functional outcomes, it is still unclear if LLLT improves the morphological repair of injured human muscles. Moreover, our findings are restricted to subjects engaged in an exercise-based rehabilitation program and treated with a specific LLLT dosage.

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TABLE 1. Baseline characteristics of subjects, injuries and symptoms.

	LLLT group	**Placebo group**	**p-value**
Age (years)	30.36 ± 7.06	28.00 ± 7.42	0.453
Weight (kg)	78.36 ± 11.12	81.64 ± 10.11	0.479
Height (m)	1.76 ± 0.06	1.76 ± 0.07	0.905
Involved muscle			
Biceps femoris	10	11	0.434
Medial hamstrings	2	1	
Injury grade			
Grade I	2	3	0.434
Grade II	10	9	
Injury site			
Proximal	3	2	0.717
Distal	9	10	
Distance to tuber (cm)	19.72 ± 5.49	20.54 ± 7.18	0.767
Pain on palpation (cm)	6.82 ± 0.98	6.00 ± 1.10	0.080
Pain threshold (kg)	8.30 ± 2.63	7.61 ± 2.60	0.542
Flexibility deficit†			
SLR (%)	-16.19 ± 20.59	-12.79 ± 14.64	0.66
KET (%)	-20.74 ± 22.84	-13.41 ± 18.11	0.41
MHFAKE (%)	-18.08 ± 7.03	-15.34 ± 12.51	0.53
Strength deficit†			
Inner range (%)	-30.07 ± 15.35	-29.07 ± 26.66	0.61
Mid-range (%)	-26.53 ± 18.90	-33.55 ± 29.73	0.63

Outer range (%)	-16.47 ± 16.49	-21.66 ± 26.45	0.91

† Asymmetry between injured and uninjured limb.

TABLE 2. Hamstring flexibility and strength outcomes by group, within-group change, and between-group change score.

	LLLT group			Placebo group			Between-group change score†
	Baseline	Discharge	Within-group change	Baseline	Discharge	Within-group change	
Flexibility outcomes							
SLR (degrees)*	62.45 ± 18.73	79.72 ± 10.26	17.27 ± 13.96	71.09 ± 11.73	81.63 ± 7.44	10.55 ± 14.79	6.72
KET (degrees)*	53.81 ± 17.69	76.00 ± 8.10	22.22 ± 16.02	65.72 ± 15.46	80.90 ± 7.90	15.18 ± 16.43	7.04
MHFAKE (degrees)*	93.09 ± 14.06	116.90 ± 10.25	23.83 ± 9.98	102.90 ± 16.57	118.00 ± 6.41	15.18 ± 15.17	8.65
Strength outcomes							
Inner range (N)*	128.18 ± 49.39	183.65 ± 39.20	55.46 ± 47.33	110.44 ± 46.64	173.85 ± 26.36	63.30 ± 35.08	-7.84
Mid-range (N)*	162.58 ± 54.29	254.70 ± 52.33	92.12 ± 60.85	144.25 ± 59.48	248.13 ± 55.95	103.78 ± 63.11	-11.66
Outer range (N)*	166.99 ± 42.33	241.57 ± 65.56	74.40 ± 46.55	158.27 ± 37.53	230.98 ± 39.20	72.61 ± 39.29	1.79

LLLT = Low-level laser therapy; KET = Knee extension test; MHFAKE = Maximal hip flexion active knee extension; SLR = Straight leg raise; * Significant time-effect ($p<0.05$); † Change of LLLT group minus change of placebo group.

FIGURES CAPTIONS

FIGURE 1. LLLT parameters and application sites used in this study

FIGURE 2. Flow diagram of participants' recruitment and retention

FIGURE 3. Time to return to sport, in days, in either LLLT group (n=11) or placebo group (n=11)

LLLT Parameters	
Number of sites	3 sites
Treatment time (per site)	60 s
Number of diodes (cluster probe)	5 diodes
Wavelength	850 nm
Frequency	Continuous
Probe size	7.5 cm^2
Spot size (per diode)	0.029 cm^2
Peak power (per diode)	100 mW
Power density (per diode)	3.44 mW/cm^2
Energy density (per diode)	206.9 J/cm^2
Energy (per diode)	6 J
Energy (per site)	30 J
Energy (per leg)	90 J

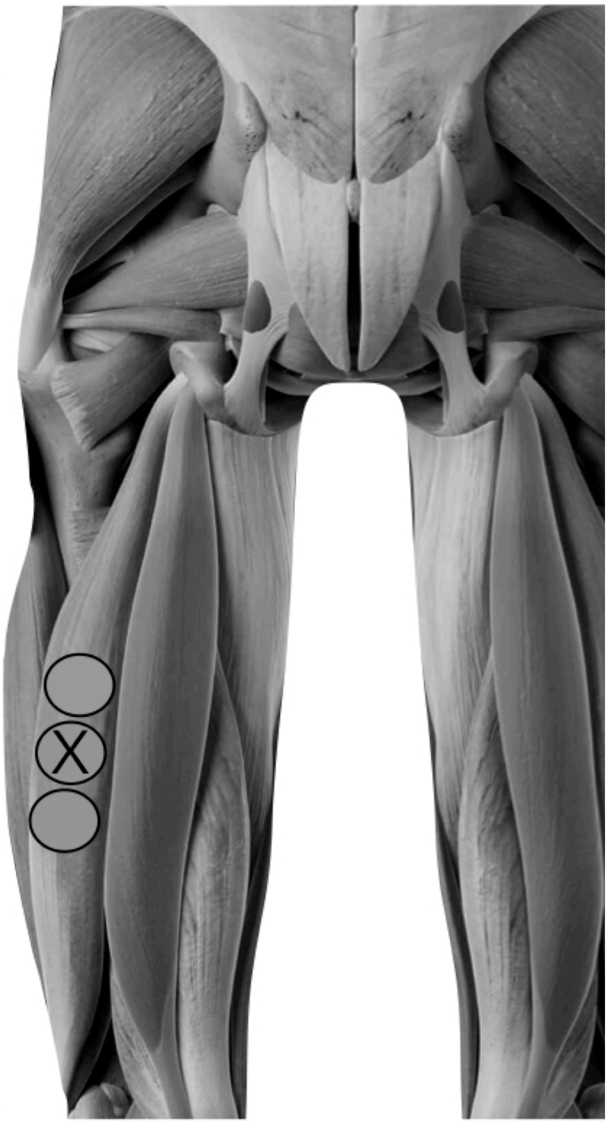

Figure 1

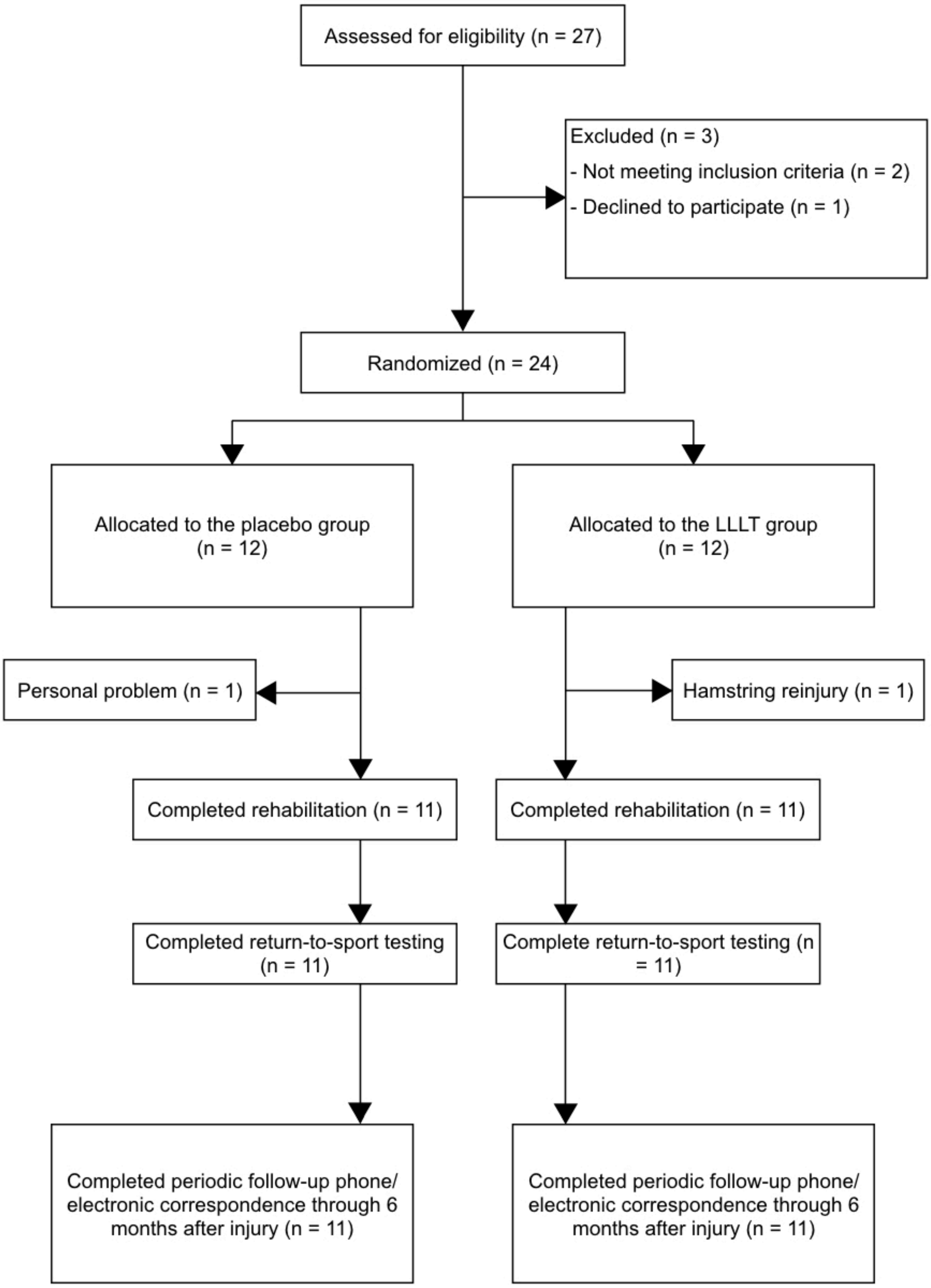
Assessed for eligibility (n = 27)
Excluded (n = 3)
- Not meeting inclusion criteria (n = 2)
- Declined to participate (n = 1)
Randomized (n = 24)
Allocated to the placebo group (n = 12)
Allocated to the LLLT group (n = 12)
Personal problem (n = 1)
Hamstring reinjury (n = 1)
Completed rehabilitation (n = 11)
Completed rehabilitation (n = 11)
Completed return-to-sport testing (n = 11)
Complete return-to-sport testing (n = 11)
Completed periodic follow-up phone/ electronic correspondence through 6 months after injury (n = 11)
Completed periodic follow-up phone/ electronic correspondence through 6 months after injury (n = 11)

Figure 2

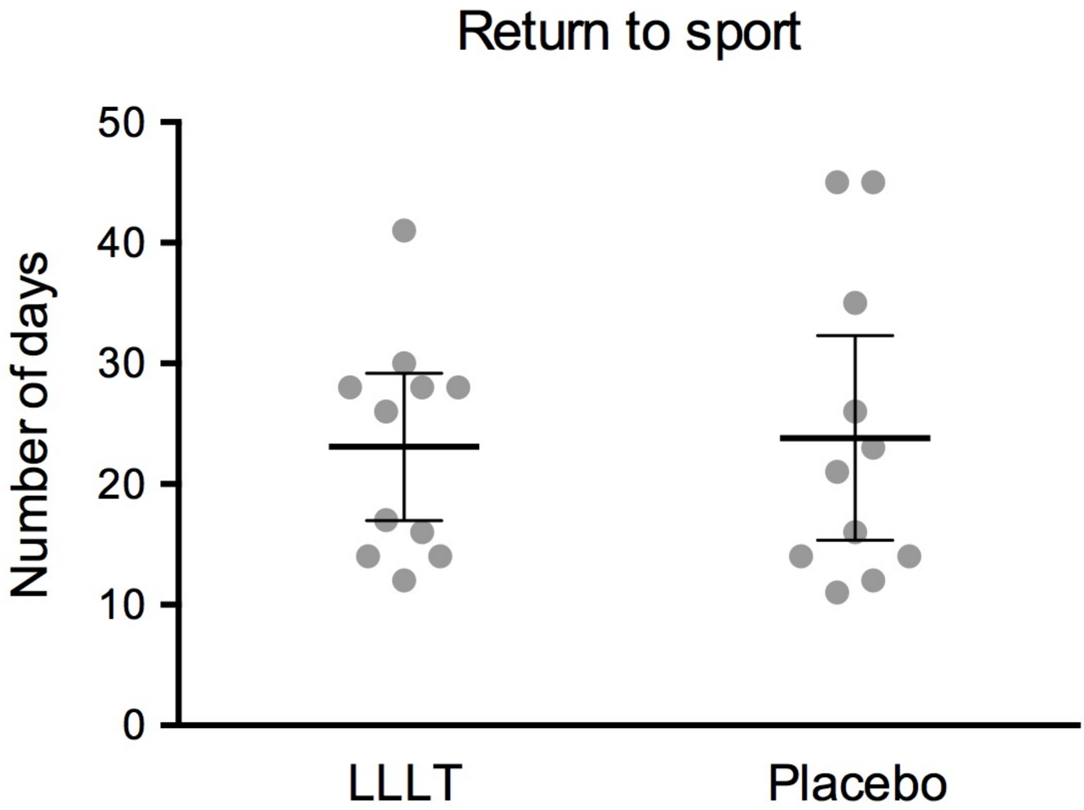

Figure 3

4. CONSIDERAÇÕES FINAIS

O presente estudo é o primeiro ensaio clínico randomizado placebo-controlado a avaliar os efeitos da LBP na recuperação funcional após lesão muscular. Nossos resultados mostraram que a LBP, quando aplicada com os parâmetros utilizados no presente estudo (850 nm, 90 J por sessão, três sessões por semana), não otimiza a recuperação da flexibilidade ou força muscular e não acelera o retorno ao esporte após LEI em atletas amadores tratados com um programa de exercícios baseado em evidências. Tendo em vista os potenciais benefícios da LBP na cicatrização muscular evidenciada por estudos com modelos animais, bem como o efeito dose-resposta dessa terapia, mais ensaios clínicos randomizados são encorajados. No entanto, não há, atualmente, nenhuma evidência para apoiar a eficácia do LBP na reabilitação de LIT em humanos.

5. ANEXOS

5.1. Anexo 1 – Protocolo de exercícios utilizado durante a reabilitação

PHASE 1	PHASE 2	PHASE 3
Hamstring-based exercises - The extender - Wall squat (2 x 10-15 reps) - Isometric 6-sec contractions (knee at 15°, 45° and 90° - 15 reps in each position) **Trunk stabilization exercises** - Frontal plank (1 x 30-45 sec) - Lateral plank (1 x 30-45 sec) - Supine bridge (1 x 10-15 reps) - Bird-dog (1 x 10-15) - Monster walk (1 x 10-15 reps) - Wall sit (1 x 30-45 sec) **Agility exercises** - Ladder drills: - Single foot in each square - Two feet lateral stepping **Plyometric exercises** - Jump up to a 30 cm step - Jump down from a 30 cm step -------------------------------------- **Progression criteria to phase 2** - Single-leg squat without pain - 5 min at bike without pain - Full knee extension in prone without pain	**Hamstring-based exercises** - High kicks - Kettlebell front squat (2 x 15 reps) - Lunge (2 x 10-15 reps) - Seated hamstring curl (2 x 10-15 reps) - Single-leg bridge (2 x 10-15 reps) - Nordic hamstring exercise (2 x 8-10 reps) **Trunk stabilization exercises** - Frontal plank (1 x 45-60 s) - Lateral plank (1 x 45-60 s) - Supine bridge (2 x 15 reps) - Isometric supine bridge (2 x 1min) - Bird-dog (2 x 15 reps) - Monster walk (2 x 10-15 reps) - Wall-sit (1 x 30-60s) **Agility exercises** - Ladder drills: - Single foot in each square - Two feet lateral stepping - Lateral in-in-out-out - Straddle squat hops - Ali shuffle - Resistance band running (moderate intensity) **Plyometric exercises** - Squat jumps with support	**Hamstring-based exercises** - Single-leg bridge (3 x 15 reps) - Nordic hamstring exercise (3 x 8-12 reps) - Swing (2 x 15 reps) **Trunk stabilization exercises** - Frontal plank (1 x 45-60 sec) - Lateral plank (1 x 45-60 sec) - Supine bridge (2 x 15 reps) - Isometric supine bridge (2 x 1min) - Monster walk (2 x 10-15 reps) - Wall-sit (1 x 60-90 sec) **Agility exercises** - Resistance band running (high intensity) - X-drill - W-drill - 10m sprint **Plyometric exercises** - Squat jumps -------------------------------------- **Discharge criteria** - Pain free for any activity - Between-limb ROM asymmetry <10% - Between-limb strength asymmetry <10% - Askling-H test similar to unaffected limb

5.2. Anexo 1 – Author Guidelines (Journal of Orthopaedics and Sports Physical Therapy)

All manuscripts must meet the following basic requirements to be eligible for review by *JOSPT*®.

- Written in English
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- Present findings or data that have not been previously published either in print or electronic (online) format or widely disclosed in a form other than published abstracts of oral presentations at scientific conferences and meetings
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- Written in accordance with the recommendations found in the ***Uniform Requirements for Manuscripts Submitted to Biomedical Journals: Writing and Editing for Biomedical Publication*** by the International Committee of Medical Journal Editors, April 2010 (http://www.icmje.org/urm_main.html and http://www.icmje.org/urm_full.pdf)
- Formatted according to AMA style guidelines (*American Medical Association Manual of Style, 9th Edition*)

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When required by the appropriate Institutional Review Board or Ethics Committee, case reports should include either a statement that each subject was informed that data concerning the case would be submitted for publication or a statement indicating approval by the Board. In all cases, patient confidentiality must be protected.

Use of Animals

Manuscripts with experimental results in animals must include a statement on the title page and in the Methods section that an animal utilization study committee approved the study.

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Roman, or Courier. All measurements in the manuscript should be presented in SI units, except for angular measures, which should be presented in degrees rather than radians.

The manuscript should be arranged as follows:

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- Institution, city, state/province, country for each author
- Statement of the sources of grant support (if any)
- Statement of Institutional Review Board or Ethics Committee approval of the study protocol
- Name of the public trials registry and the registration number
- Corresponding author's name, address, and e-mail address

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- Title of manuscript
- Statement of financial disclosure and conflict of interest (see item 6 of the **Author Agreement and Publication Rights Form**)
- Acknowledgements (on a separate page)

Abstract

- **Structured Abstract:** *Research reports (including systematic literature reviews) and brief reports* require an abstract containing a maximum of 250 words, divided into 6 sections with the following headings in this order: Study Design, Background, Objectives, Methods, Results, Conclusion. Abstracts for *case reports*should have 5 sections with the following headings and order: Study Design, Background, Case Description, Outcomes, and Discussion. Abstracts for *resident's case problems* should have 4 sections with the following headings and order: Study Design, Background, Diagnosis, and Discussion.

- **Unstructured Abstract:** *Clinical commentaries and narrative literature reviews* require an abstract (called synopsis) that is not structured and that contains a maximum of 250 words.
- **All abstracts should include, where appropriate, a line item called "Level of Evidence,"** which indicates the study type and level of evidence, according to the classification system listed at the Oxford Centre for Evidence-based Medicine website (http://www.cebm.net). This final line in the abstract should be in the following format example: "Level of Evidence: Therapy, level 2a." When the study does not fit any of the study type and level of evidence descriptors included in the above classification system, this line may be omitted. A list of suggested study design names and the Oxford Center for Evidence-Based Medicine levels of evidence table are provided for reference **here**.
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- *Case reports* require the body of the manuscript to be divided into 4 sections: Background, Case Description, Outcomes, and Discussion.
- *Resident's case problems* require the body of the manuscript to be divided into 3 sections: Background, Diagnosis, and Discussion.
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For all of these manuscript categories except brief reports, the text should be less than 4,000 words and be supplemented by a reasonable number of figures and tables. Brief reports should be less than 2,000 words (excluding no more than 20 references) and have no more than 4 tables or figures.

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The brief Key Points section of the manuscript is needed for ***research reports only, including systematic literature reviews***. Key Points should be provided at the end of the text, prior to the references. These points should be written in user-friendly language, consist of brief sentences, and summarize the most important information related to the findings, implications, and caution directly resulting from the work. These 3 subheading should be used:

- **Findings:** One or 2 statements on what the study adds to current knowledge.
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References

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- References must be cited in the text by using the reference number in superscript at the end of the sentence or the referenced portion of the sentence. The reference goes after the author's name when the author's name is listed (eg, Davies[1]). If there are only 2 authors in the reference, then the text should include both authors (eg, Davies and Ellenbecker[1]). If the reference has more than 2 authors, the text should include "et al" after the first author's name (eg, Davies et al[1]).
- In the Reference section, when a reference has 7 or more authors, list the first 3 authors, followed by "et al."
- References must include only material that is retrievable through standard literature searches. References to papers accepted but not published or published ahead of print should be designated "in press" or use the

PubMed/MEDLINE [Epub ahead of print] status until an updated citation is available. Doctoral and master's theses are considered published material. Information from manuscripts not yet accepted for publication and personal communications will not be accepted. The use of abstracts and proceedings should be avoided unless they are very recent and the sole source of the information.

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Books

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NFHS Associations. 2007-2008 National Federation of State High School Associations Participation Survey. Available at: http://www.nfhs.org. Accessed May 17, 2010.

Paper Presented at a Symposium

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- See *AMA Manual of Style* (9th ed.), section 2.13, to organize and format tables.
- Table titles should list the table number in uppercase bold (eg, "**TABLE1.**"), followed by a period, then the title of the table in sentence case.
- Abbreviations used in each table must be spelled out below the table.
- Footnotes must be listed below the table, after the abbreviations, in order of occurrence in the table (left to right, row to row). According to AMA style, footnotes are cited with the following superscript symbols in this order: *, †, ‡,

§, ||, ¶, #, **, ††, ‡‡. Where these symbols are unavailable, superscript numbers may be used.

- All tables must be referred to somewhere in the text.
- All tables go after the reference list.

Figures

- Figure captions should list the figure number in uppercase bold (eg, "**FIGURE 1.**") followed by a period, and continue with the text of the caption in sentence case.
- All abbreviations appearing in the figures should be defined in the caption for each respective figure, and abbreviations appearing only in the figure caption must be defined at first use.
- Digital figures must be at least 350 dots per inch (dpi).
- Charts and graphs generated from spreadsheet programs must accompany, or allow access to, the data.
- Photographs must be in JPEG file format (JPG) and graphic art in GIF file format and at a resolution of at least 350 dpi.
- All figures must be referred to in the text.
- Each view (eg, A, B, C) within the figure must be defined in the figure caption.
- Color figures and graphics are welcome.
- All figures go after the tables at the end of the manuscript.

Preparing Your Supplementary Material

Videos

Authors may wish to consider including supplemental videos to be published online with their manuscript. These videos can describe intervention or examination techniques as well as surgical procedures or other material pertinent to the manuscript. Intent to include videos may be mentioned in the cover letter with the initial manuscript submission or may be discussed with the editor-in-chief once the manuscript is accepted.

Videos should be:

- MPEG-1, MPEG-2, or AVI files
- No longer than 2.5 minutes
- Introduced with a title screen and include audio narration

There is no limit on the number of videos that may be submitted with a manuscript.

Additional Required Documents

For manuscript submissions to qualify for review, the following documents must be submitted along with your manuscript on *JOSPT*'s manuscript submission website here or sent directly to the editorial office by e-mail (manuscripts@jospt.org), mail (*JOSPT*, 1033 N Fairfax St, Ste 304, Alexandria, VA 22314-1540), or fax (703-891-9065):

- **Author Agreement and Publication Rights Form:** This document must have original signatures of all authors. Author signatures may be on separate copies or 1 copy of the form.
- **Photograph/Video Release Statement:** Signed photograph/video release forms should accompany photographs/videos of patients and subjects. A photograph/video release statement should contain the following (1) manuscript title; (2) names of all authors; (3) statement placed below the manuscript title and author names as follows: *"I hereby grant to the Journal of Orthopaedic & Sports Physical Therapy the royalty-free right to publish photographs and/or videos of me for the stated journal and the above manuscript in which I appear as subject, patient, or model, and for the stated Journal's website (www.jospt.org). I understand that any figure in which I appear may be modified."*; and (4) the original signature and date signed by each subject who appears in the figures.
- **Patient/Author Release Statement:** A release form should accompany all Musculoskeletal Imaging cases, Case Reports, and Resident's Case Problems. This release must be signed either by the patient/subject or by the submitting author, accompanied by a proxy declaration by the author(s) that all necessary efforts have been made to ensure that Standards for Privacy of

Individually Identifiable Health Information have been upheld, and that the author accepts any and all liability for any failure to uphold the necessary Standards for Privacy of Individually Identifiable Health Information in the final version of the manuscript. The release statement should contain the following: (1) manuscript title; (2) names of all authors; (3) a statement from the submitting author, placed below the manuscript title and author names, as follows: "I hereby declare that the patient/subject has granted the author(s) permission to report his or her case in this report; or, in the absence of such permission, that all necessary efforts have been made to ensure that Standards for Privacy of Individually Identifiable Health Information have been upheld, and accept any and all liability for any failure to uphold the necessary Standards for Privacy of Individually Identifiable Health Information in the final version of the manuscript"; and either (4a) the original signature and date signed by each patient/subject presented in the report or: (4b) the original signature and date signed by the submitting author. This original signed statement must be submitted to the JOSPT office with the manuscript. Important notes on the Standards for Privacy of Individually Identifiable Health Information, from the US Department of Health & Human Services, can be found here under De-Identified Health Information.

Preparing Other Contributions—Musculoskeletal Imaging, Letters, Invited Commentaries

- **Musculoskeletal Imaging:** This feature focuses on the use and interpretation of medical imaging related to a case scenario relevant to musculoskeletal or sports physical therapy practice. In most instances, these cases will emphasize how information from imaging can affect physical therapy management of the patient. In some instances, however, this feature may be used to share information on unusual medical conditions, or to simply illustrate commonly used imaging techniques and their interpretation. Contributions should include no more than 3 authors, 250 words, 3 figures, and 3 references (if any). See the Figures section above for instructions on preparing the images for submission.

- **Letter to the Editor-in-Chief:** Letters should relate to professional issues or articles published in the *Journal*. Letters will be reviewed and selected for publication by the editor-in-chief based on the relevance, importance, appropriateness, and timeliness of the topic. Letters to the editor-in-chief are copy edited, and the correspondent is not typically sent a version to approve. Letters should include a summary statement of any conflict of interest, including financial support related to the issue addressed.
- **Invited Commentary:** Invited commentaries are expert points of view concerning articles published in *JOSPT*. Commentaries are invited by the editor-in-chief and immediately follow the article discussed. Authors of the manuscript under commentary are given the opportunity to respond to the expert's point of view.

Preparing Your REVISED Manuscript

When the editors suggest that a manuscript be revised and resubmitted, the same guidelines outlined above for the preparation of the original manuscript apply. All resubmitted manuscripts must be accompanied by a cover letter. The cover letter must include a list of all revisions made in response to suggestions from reviewers and editors contained in the review materials provided to you by the editorial office. Changes made to the text and tables must be highlighted in the manuscript.

5.3. Parecer consubstanciado do Comitê de Ética em Pesquisa (CEP)

PARECER CONSUBSTANCIADO DO CEP

DADOS DO PROJETO DE PESQUISA

Título da Pesquisa: Efeito da terapia de fotobiomodulação na reabilitação da lesão muscular de isquiotibiais em atletas: um ensaio clínico randomizado

Pesquisador: Bruno Manfredini Baroni

Área Temática:

Versão: 2

CAAE: 80287517.3.0000.5345

Instituição Proponente: Universidade Federal de Ciências da Saúde de Porto Alegre

Patrocinador Principal: Financiamento Próprio

DADOS DO PARECER

Número do Parecer: 2.555.174

Apresentação do Projeto:

Foi enviada resposta ao parecer nº 2.446.527 a respeito do projeto que envolve atletas homens com diagnóstico de lesão muscular de isquiotibiais, em um ensaio clínico randomizado, duplo-cego e placebo-controlado para avaliação da Terapia de Fotobiomodulação (TFBM), ativa ou placebo.

Objetivo da Pesquisa:

A pesquisa busca avaliar o efeito da Terapia de Fotobiomodulação (TFBM) sobre a recuperação de lesão muscular de isquiotibiais em atletas.

Avaliação dos Riscos e Benefícios:

O projeto informa que os riscos durante as avaliações e/ou durante o programa de reabilitação são mínimos, e esses podem ser desconforto muscular decorrente da realização de exercícios durante os testes e sessões de tratamento.

Quanto aos benefícios, esses consistem na possibilidade de os participantes se engajarem, gratuitamente, em um programa de reabilitação física baseado em evidências científicas e sob a supervisão de um profissional treinado para sua execução.

Comentários e Considerações sobre a Pesquisa:

Não foi possível abrir o arquivo com o projeto reformulado. Apesar disso, conforme a carta-resposta, observa-se que as solicitações feitas no parecer anterior – a saber, (1) "[...] caso o tratamento com a TFBM ativa seja exitoso, ao participante que se submeteu ao tratamento placebo deve ser garantida a possibilidade de tratamento"; e (2) "[...] deve haver garantia de ressarcimento dos custos de deslocamento/transporte do participante à clínica" – foram atendidas.

Considerações sobre os Termos de apresentação obrigatória:

Os termos de anuência da clínica e do laboratório estão de acordo, bem como o termo de compromisso de entrega de relatórios.

O TCLE foi reformulado e simplificado, o que acarreta em maior clareza para o leitor voluntário.

Recomendações:

Sugere-se a substituição da palavra "início" por "final" na seguinte frase no TCLE: "Se surgir qualquer dúvida referente a esta pesquisa, favor contatar os pesquisadores nos telefones indicados no início desse termo de consentimento ou o Comitê de Ética em Pesquisa com Seres Humanos [...]" - já que os dados mencionados estão na posição final do documento.

Conclusões ou Pendências e Lista de Inadequações:

Não há pendências.

Considerações Finais a critério do CEP:

De acordo com o parecer do Relator.

Este parecer foi elaborado baseado nos documentos abaixo relacionados:

Tipo Documento	Arquivo	Postagem	Autor	Situação
Informações Básicas do Projeto	PB_INFORMAÇÕES_BÁSICAS_DO_PROJETO_1035359.pdf	07/01/2018 11:13:07		Aceito
Outros	Resposta_CEP_round2.pdf	07/01/2018 11:04:07	Diulian Muniz Medeiros	Aceito
Projeto Detalhado / Brochura Investigador	Projeto_pesquisa_round2.pdf	07/01/2018 11:03:11	Diulian Muniz Medeiros	Aceito
TCLE / Termos de Assentimento / Justificativa de Ausência	TCLE_round2.pdf	07/01/2018 11:01:22	Diulian Muniz Medeiros	Aceito
Declaração de Pesquisadores	Termo_Entrega_Relatorios.pdf	21/11/2017 16:50:10	Bruno Manfredini Baroni	Aceito
Declaração de Instituição e Infraestrutura	Termo_Anuencia_Laboratorio.pdf	21/11/2017 16:49:37	Bruno Manfredini Baroni	Aceito
Declaração de	Termo_Anuencia_Clinica.pdf	21/11/2017	Bruno Manfredini	Aceito

Instituição e Infraestrutura	Termo_Anuencia_Clinica.pdf	16:49:21	Baroni	Aceito
Folha de Rosto	Folha_rosto_assinada.pdf	21/11/2017 16:48:21	Bruno Manfredini Baroni	Aceito

Situação do Parecer:
Aprovado

Necessita Apreciação da CONEP:
Não

PORTO ALEGRE, 21 de Março de 2018

Assinado por:
ELIANE DALLEGRAVE
(Coordenador)

Catalogação na Publicação

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