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Efeitos da mobilização de tecidos moles assistida por instrumentos (IASTM) na dor e incapacidade em indivíduos com cervicalgia crônica inespecífica. Um ensaio clínico randomizado.

**Universidade Federal de Ciências da Saúde
de Porto Alegre**

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Um ensaio clínico randomizado.**

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“Existem homens que lutam um dia e são bons; existem outros que lutam um ano e são melhores; existem aqueles que lutam muitos anos e são muito bons. Porém, existem os que lutam toda a vida. Estes são os imprescindíveis”.

Bertold Brecht

RESUMO

Introdução: As doenças Musculoesqueléticas são a segunda causa de anos vividos com incapacidade em todo o mundo, sendo a dor cervical, a 4ª maior contribuinte para a incapacidade global. A Mobilização de tecidos moles assistida por instrumentos (IASTM) é um tratamento usado para restrição miofascial e vem sendo proposto como uma alternativa para redução da dor, incapacidade. Entretanto, há um número reduzido de estudos controlados randomizados (ECR). **Objetivos:** Comparar o efeito da mobilização de tecidos moles assistida por instrumentos (IASTM) na dor, incapacidade e ADM em indivíduos com cervicalgia crônica inespecífica. **Métodos:** 23 participantes com dor cervical crônica (DCC) recrutados participaram deste estudo. Os participantes foram aleatoriamente alocados para receberem seis sessões de tratamento com IASTM ou Terapia de Liberação Miofascial (TLM). Pesquisadores cegados para a alocação avaliaram os participantes quanto à intensidade de dor na cervical, incapacidade e ADM em dois momentos distintos: pré-teste e uma semana após o tratamento. A randomização foi realizada por um pesquisador não envolvido na determinação da elegibilidade, na avaliação inicial e na provisão de tratamento. A alocação oculta foi concedida usando envelopes opacos lacrados numerados, sequenciados e ordenados. **Resultados:** Após seis sessões de tratamento não houve efeito da interação entre os grupos para dor [$F(1,21) = 0,110$; $p = 0,743$], incapacidade [$F(1,21) = 0,393$; $p = 0,538$], mas a interação (tempo) teve um efeito significativo dos grupos do pré ao pós-tratamento e também o tamanho do efeito grande para as variáveis: dor: [$F(1,21) = 90,505$; $p = 0,000$], $d = 4,15$, incapacidade: [$F(1,21) = 107,538$; $p = 0,000$], $d = 4,53$, ADM (flexão) [$F(1,21) = 36,135$; $p = 0,000$], $d = 2,62$, (extensão) [$F(1,21) = 11,673$; $p = 0,003$], $d = 1,49$, (flexão lateral direita) [$F(1,21) = 25,124$; $p = 0,000$], $d = 2,18$, (flexão lateral esquerda) [$F(1,21) = 14,733$; $p = 0,001$], $d = 1,67$, (rotação direita) [$F(1,21) = 4,350$; $p = 0,049$], $d = 0,91$, (rotação esquerda) [$F(1,21) = 9,955$; $p = 0,005$], $d = 1,37$. **Conclusão:** Com base nos achados desse estudo, é possível concluir que a IASTM produziu efeitos clínicos positivos, mas não superiores a TLM. IASTM produz uma diminuição da dor local, incapacidade e aumento da ADM de pacientes com dor cervical crônica. A IASTM pode ser uma ferramenta terapêutica para auxiliar os clínicos no manejo da terapia manual.

Palavras-chave: *Dor Cervical, Manipulação Musculoesquelética, Tecido Subcutâneo, Síndrome Dolorosa Miofascial, Liberação Miofascial, Mobilização de Tecidos Moles Assistida por Instrumentos.*

ABSTRACT

Introduction: Musculoskeletal diseases are the second cause of years lived with disability worldwide, with neck pain being the 4th largest contributor to global disability. Instrument-assisted soft tissue mobilization (IASTM) is a treatment used for myofascial restraint and has been proposed as an alternative for pain reduction, disability. However, there are a small number of randomized controlled trials (RCTs). **Objectives:** To compare the effect of instrument-assisted soft tissue mobilization (IASTM) on pain, disability, and ROM in individuals with nonspecific chronic neck pain. **Methods:** 23 participants with recruited chronic neck pain (CNP) participated in this study. Participants were randomly allocated to receive six IASTM or Myofascial Release Therapy (TLM) treatment sessions. Researchers blinded to allocation assessed participants for neck pain intensity, disability, and ROM at two different times: pretest and one week after treatment. Randomization was performed by a researcher not involved in determining eligibility, initial assessment and provision of treatment. The hidden allocation was granted using numbered, sequenced and sorted sealed opaque envelopes. **Results:** After six treatment sessions there was no effect of interaction between groups for pain [$F(1,21) = 0.110$; $p = 0.743$], disability [$F(1,21) = 0.393$; $p = 0.538$], but the interaction (time) had a significant effect from the pre-posttreatment groups and also the large effect size for the variables: pain: [$F(1,21) = 90.505$; $p = 0.000$], $d = 4.15$, disability: [$F(1,21) = 107.538$; $p = 0.000$], $d = 4.53$, ROM (flexion) [$F(1,21) = 36.135$; $p = 0.000$], $d = 2.62$, (extension) [$F(1,21) = 11.673$; $p = 0.003$], $d = 1.49$, (right lateral flexion) [$F(1,21) = 25.124$; $p = 0.000$], $d = 2.18$, (left lateral flexion) [$F(1,21) = 14.733$; $p = 0.001$], $d = 1.67$, (right rotation) [$F(1,21) = 4.350$; $p = 0.049$], $d = 0.91$, (left rotation) [$F(1,21) = 9.955$; $p = 0.005$], $d = 1.37$. **Conclusion:** Based on the findings of this study, it can be concluded that IASTM produced positive clinical effects, but not superior to TLM. IASTM produces a decrease in local pain, disability, and increased ROM in patients with CNP. IASTM can be a therapeutic tool to assist clinicians in the management of manual therapy.

Key words: Neck Pain, Musculoskeletal Manipulations, Tissue Subcutaneous, Myofascial Pain Syndrome, Myofascial Release, Instrument-Assisted Soft Tissue Mobilization.

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LISTA DE ABREVIATURAS E SIGLAS

IASP	Associação Internacional para o Estudo da Dor
AH	Ácido Hialurônico
IASTM	Mobilização de Tecidos Moles Assistida por Instrumentos
LM	Liberação Miofascial
ADM	Amplitude de movimento
CB1	Receptor Canabinóide 1
CB2	Receptor Canabinóide 2
TLM	Terapia de Liberação Miofascial
ECM	Esternocleidomastóide
PPT	Limiar de dor à pressão
PGM	Ponto Gatilho Miofascial
END	Escala Numérica de Dor
MFT	Terapia de Liberação Miofascial
NPRS	Escala numérica de avaliação da dor
NDI	Neck Disability Index
ROM	Amplitude de movimento
CROM	Amplitude de movimento cervical

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1. INTRODUÇÃO

Doenças musculoesqueléticas, definidas como doenças que afetam o sistema locomotor incluindo músculos, ossos, articulações, tendões e ligamentos, têm um impacto crescente em todo o mundo. Este impacto pode ser mensurável através de anos vividos com incapacidade. Segundo o Global Burden of Disease, as doenças Musculoesqueléticas são a segunda causa de anos vividos com incapacidade em todo o mundo (SEBBAG et al., 2019). Uma das doenças mais prevalentes, dentro deste cenário, é a dor cervical, sendo a 4ª maior contribuinte para a incapacidade global (HOY et al., 2014).

A dor cervical e o comprometimento dessa região da coluna são comuns. Estima-se que 22% a 70% da população mundial terá dor na região cervical em algum momento da vida (CÔTÉ; CASSIDY; CARROLL, 2000), (LINTON e RYBERG, 2000). Quando relacionada a disfunção associa-se a prevalência de um ano variando de 2% a 11% na população em geral, e de 11% a 14% em trabalhadores que relataram limitação em suas atividades por causa da dor cervical (PETER et. al, 2017). No Brasil a prevalência de dor cervical é estimada em 20% ao longo da vida (GENEBRA et. al, 2017), sendo essa, muito relacionada com os dados socioeconômicos, como renda e educação (HOY et. al, 2014).

Sanna Kääriä et al. (2012) conduziram um estudo onde analisaram associações de fatores sociodemográficos, condições de trabalho, estilo de vida e dor prévia na coluna vertebral com dor cervical crônica (tradução de “*Neck Pain*”). Preditores potencialmente modificáveis de dor cervical crônica entre funcionários: assédio moral no trabalho, problemas de sono e índice elevado de massa corporal em mulheres e exaustão emocional relacionada ao trabalho em homens. Em ambos os gêneros, dor cervical aguda prévia e dor lombar crônica foram preditivos de dor cervical crônica, assim como, idade avançada, ex-tabagistas, alta demanda de trabalho e baixo apoio social (MCLEAN et al. 2010).

Devido à tendência de a dor no pescoço se tornar um problema crônico, é importante identificar os fatores de risco para que possamos incentivar a prevenção e o diagnóstico precoce. Baseado nisto, uma revisão sistemática investigou 10 estudos sobre fatores físicos e psicossociais. Os autores apontaram como maior fator de risco psicossocial o humor deprimido, alto

conflito de papéis e percepção de tensão muscular. Mas o fator de risco mais comumente relatado foi o trabalho em posturas inadequadas / sustentadas (KIM et al., 2018).

Das definições sobre a dor cervical, a Associação Internacional para o Estudo da Dor (IASP) em sua classificação de dor crônica define dor espinhal cervical como dor percebida em qualquer parte da região posterior da coluna cervical, da parte superior da linha nuchal até o primeiro processo espinhoso torácico, baseia-se de uma análise topográfica dos sintomas e também sugere que a dor cervical pode ser subdividida em dor na coluna cervical superior e dor na coluna cervical inferior, acima ou abaixo de uma linha transversal imaginária através de C4. Para dores nos segmentos superiores da coluna cervical, a dor geralmente pode ser encaminhada para a cabeça, enquanto que dos segmentos cervicais inferiores, a dor pode ser referida à região escapular, parede torácica anterior, ombro ou membro superior. Eles também definem dor suboccipital como a dor localizada entre a linha nuchal superior e C2, uma área que parece ser a fonte de dor de cabeça cervicogênica (MISAILIDOU, V. et al. 2010).

Outros autores como Guzman J. et al. (2008) conduziram uma força-tarefa sobre dor cervical e suas desordens associadas e descrevem dor no pescoço como dor localizada na região anatômica do pescoço com ou sem irradiação para a cabeça, tronco e membros superiores. Define a região posterior do pescoço, da linha nuchal superior à espinha da escápula e da região lateral até a borda superior da clavícula e o encaixe supraesternal. A definição IASP limita os sintomas de dor até a vértebra T1 e não incluem as várias regiões que a dor no pescoço pode ser referida (MISAILIDOU, V. et al. 2010). A dor no pescoço é descrita como “um efeito desagradável” de experiência sensorial e emocional associada com real ou potencial “dano tecidual” na região do pescoço, que começa na linha superior da nuca e continua até o nível da espinha da escápula. A dor cervical inclui distúrbio associado a chicotada cervicogênica, dor de cabeça e radiculopatia cervical (BIER et al. 2018). Esta mesma diretriz de prática clínica classificou a dor cervical em 4 graus, sendo graus I e II incluem subgrupos específicos: dor cervical relacionado ao trauma (anteriormente conhecida como distúrbio associado ao chicote cervical (tradução de “*whiplash*”) e dor cervical relacionada ao trabalho. A primeira refere-se a dor cervical e distúrbios associados sem sinais ou sintomas sugestivos de patologia estrutural e nenhuma

ou pequena interferência nas atividades da vida diária, e a segunda sendo nenhum sinal ou sintoma de patologia estrutural importante, mas grande interferência das atividades do dia a dia.

Diretrizes de prática clínica, dão aos clínicos, recomendações para fornecerem as melhores práticas, no entanto essas recomendações são muitas vezes contraditórias. Parikh P. et al. (2019) realizaram uma revisão sistemática de Guias de Prática Clínica para avaliar essas recomendações de manejo para dor cervical (diagnóstico, tratamento, prognóstico e imaginologia). Foram selecionados um total de 46 diretrizes, onde se verificou uma grande heterogeneidade nas recomendações dentro de cada objetivo clínico.

Pacientes com dor cervical podem ter várias fontes simultâneas de dor, de articulações, músculos e ligamentos (JENSEN; HARMS-RINGDAHL, 2007). No entanto, como a origem da dor específica na coluna cervical às vezes não pode ser identificada, os termos dor cervical inespecífica e dor miofascial são freqüentemente usadas, embora estes diagnósticos são feitos para fins de exclusão e são baseados apenas em determinações clínicas. De fato, poucos estudos que descrevem objetivos e métodos clinicamente aplicáveis para identificar e classificar a dor miofascial (GERWIN, 2001).

Nos últimos anos, vários estudos surgiram sobre síndrome de dor miofascial (SDM) entre pacientes que sofrem de dor no pescoço (FERNANDEZ-DE-LAS-PENAS e cols. 2006, 2007). Os tratamentos dos tecidos fasciais tornaram-se cada vez mais populares nos distúrbios musculoesqueléticos. Isso pode ser devido a achados histológicos recentes. A descoberta de células contráteis, nervos livres e mecanorreceptores sugere que a fáscia, em contraste com suposições anteriores, desempenha um papel proprioceptivo e mecanicamente ativo (BHATTACHARYA, V. et al. 2010; STECCO et. al, 2007; YAHIA, L. et al. 1992). Vários terapeutas que abordam a fáscia se orientam para conceitos de cadeias miofasciais e tais abordagens originam-se da suposição de que os músculos do corpo humano não funcionam como unidades independentes (BARKER P.J. e cols. 2004; NORTON-OLD K.J. et al. 2013; STECCO A. et al. 2013).

A etiologia da dor miofascial não é certa. Alguns sugerem uma origem central, outros periféricos. Há sim evidência de sensibilização do sistema nervoso central e de hiperalgesia e somação temporal da dor em uma área.

Outra hipótese sugeriria um processamento facilitado de mensagens de dor no sistema nervoso central, talvez manifestado pela reorganização neural no cérebro, tronco cerebral e medula espinhal (YOUNGER J.W.L. et al. 2010).

Uma revisão sistemática elaborada por Wilke J. et al. (2016) sugere que a maioria dos músculos esqueléticos do corpo humano estão diretamente ligados pelo tecido conjuntivo. O exame da relevância funcional dessas cadeias miofasciais é a tarefa mais urgente de pesquisas futuras. A transmissão de tensão ao longo dos meridianos abriria uma nova fronteira para o entendimento da dor referida e forneceria uma justificativa para o desenvolvimento de abordagens terapêuticas.

Alguns autores definem a fáscia como um componente do tecido mole de tecido conjuntivo que permeia o corpo humano (HUIJING e LANGEVIN, 2009), também podendo descrevê-la como um tecido fibroso colagenoso que faz parte do sistema de transmissão de tensão em todo o corpo. A fáscia é vista como uma rede de tensão interligada que se adapta de acordo com as tensões locais e suas demandas (SCHLEIP; JAGER; KLINGLER, 2012). É sugestivo que a alteração da flexibilidade fascial, medida através do deslocamento do tecido fascial sobre os músculos cervicais, verificado por meio de imagens ecográficas, poderia ser uma fonte de desalinhamento corporal, causando rigidez em pacientes com dor cervical crônica (STECCO et. al, 2007). Estes apresentam melhora da ADM cervical e dor quando são utilizadas técnicas de mobilizações miofasciais em comparação com massagem, eletroterapia e laser terapia nos músculos Esternocleidomastóide e Escalenos principalmente a longo prazo, assim como, alterações estruturais como o aumento da espessura da fáscia profunda do pescoço também reduzem com a aplicação de técnicas de mobilizações fasciais (PIEHL-AULIN et. al, 1991 e SCOTT JE, HEATLEY F, 2002).

É relatado, como componente importante da matriz extracelular no tecido fascial, o Ácido Hialurônico (AH), que é produzido por células especiais tipo macrófagos que se assemelham aos fibroblastos e estão contidos na superfície da fáscia. A densidade do AH está relacionada a espessura da fáscia (MATTEINI et. al, 2009). Um estudo mostrou que quando a concentração de Ácido Hialurônico aumenta, as cadeias deste começam a se emaranhar, contribuindo para modificar a propriedade hidrodinâmica da solução gerando o

aumento da viscoelasticidade (TADMOR; CHEN; ISRAELACHVILI, 2002). O aumento dessa viscosidade pode explicar a diminuição do deslizamento entre as camadas de fibras de colágeno da fáscia, sendo percebido por pacientes com rigidez (TESARZ et. al, 2011). Um estudo baseado em um modelo matemático tridimensional avaliou o fluxo de AH em torno ou dentro da fáscia durante o deslizamento constante (técnicas miofasciais), vibração perpendicular (massagem com vibrador mecânico) e oscilação tangencial (manipulação fascial). Os autores sugerem que o uso de um massageador mecânico pode produzir um melhor deslizamento entre as diferentes estruturas anatômicas do que a terapia somente com as mãos e também, que os terapeutas que usam outras ferramentas mecânicas, como os instrumentos de aço inoxidável usados com a técnica de Graston (IASTM), podem também indicar maiores benefícios (ROMAN, M, 2013).

Pela relevância dos transtornos miofasciais, notadamente gerados por alterações mecânicas e neurofisiológicas da fáscia, há a necessidade de se agregar evidências sobre a temática, sobretudo no que diz respeito a sua abordagem terapêutica. Baseados nesses interesses, buscamos comparar duas alternativas de tratamentos bastante empregadas na fisioterapia clínica atual e no cenário da reabilitação musculoesquelética. Ambas são distintas quanto a sua aplicação e modo de atuação.

Os métodos de intervenção escolhidos – (IASTM) (*mobilização de tecidos moles assistida por instrumentos*) e a terapia de liberação miofascial (TLM) (*myofascial release therapy*), originaram-se pela motivação do autor da dissertação em adquirir o conhecimento de novas evidências científicas com relação aos efeitos que essas técnicas trariam para indivíduos com dor cervical crônica, apreciada através da análise da percepção da dor, incapacidade e mobilidade.

Com as conclusões baseada nos resultados do nosso estudo, pretendemos contribuir com informações sobre os efeitos clínicos do tratamento proposto, bem como auxiliar nas intervenções fisioterapêuticas relacionada ao tema.

2. REVISÃO DE LITERATURA – CONTEXTUALIZAÇÃO

2.1 CONCEITOS BÁSICOS SOBRE MIOFÁSCIA

Estudos anatômicos macroscópicos da fáscia demonstram uma série de características baseadas na localização, densidade, direção e relação da fáscia com as estruturas circundantes (STECCO, C. 2008; STECCO, C. 2007). O Comitê Federativo Internacional de Terminologia Anatômica (FICAT) descreve as seguintes fáscias:

a) em relação às regiões do corpo:

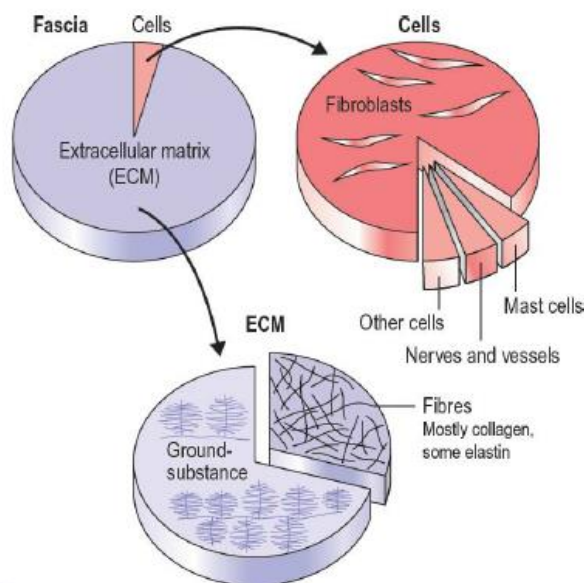
- Fáscia cabeça e pescoço, fáscia do tronco e fáscia dos membros,

b) em relação às estruturas vizinhas:

- Fáscia subcutânea, fáscia dos músculos, fáscia visceral, fáscia parietal, e fáscia extra-óssea, que representa qualquer outra fáscia que fica dentro da fáscia parietal e fora da fáscia visceral (KUMKA, M; BONAR, J. 2012).

Os tecidos conjuntivos fasciais consistem basicamente em dois componentes: células mais a matriz extracelular (ver Figura 1). Ao contrário da maioria dos outros tecidos, as células ocupam uma parte muito pequena do volume total (geralmente menos de 5%). A maioria das células são fibroblastos, que funcionam como trabalhadores de construção e manutenção da matriz circundante. A matriz consiste novamente em duas partes: substância fundamental e fibras. A substância fundamental consiste principalmente de água, que é ligada por proteoglicanos. A maioria das fibras são fibras de colágeno, com exceção de poucas fibras de elastina. Um equívoco comum é que, às vezes, a substância fundamental e a matriz são tomadas como sinônimos. No entanto, a rede de fibras de colágeno é um elemento importante da matriz (SCHLEIP, R. 2015).

Figura 1. Componentes da fáscia: os constituintes básicos são células (principalmente fibroblastos) e matriz extracelular (MEC), sendo que a última consiste em fibras mais a substância fundamental aquosa.



FONTE: fascialnet.com

2.1.1 Anatomia da Fáscia

A principal característica da fáscia, a continuidade, ajuda a explicar conceitos como transmissão da força miofascial (STECCO et al. 2009). Estudos descrevem características biomecânicas de transmissão de força extramuscular e intramuscular em amostras de ratos, os tecidos conjuntivos circundantes são vistos como influenciando a força potencial e conectam grupos musculares (HUIJING P e BAAN G. 2001; HUIJING et al. 2007). Posteriormente, foi revelado através da dissecação cuidadosa de que a fáscia geralmente ocorre como um sistema ondulado em camadas de diferentes tipos de tecidos conectivos (BENETAZZO L et al. 2011; HEDLEY G. 2008; STECCO C et al. 2009). Modelos tridimensionais das fáscias crural e tóracolombar demonstram que as fáscias são formadas por três subcamadas de tecido conjuntivo com diferentes densidades e orientações (BENETAZZO L et al. 2011; STECCO C et al. 2009). Cada subcamada as fibras de colágeno são paralelas entre si, enquanto as orientações entre as fibras das camadas adjacentes mudam, formando um ângulo de aproximadamente 70-80 graus uma com a outra. Isso permite que folhas fasciais mais densas deslizem livremente sobre as camadas subjacentes,

sem fricção significativa, e aumenta a capacidade da fáscia de assumir a tensão em praticamente todas as direções (BENETAZZO L et al. 2011).

Para o termo fáscia profunda, qualquer bainha fibrosa densa que interpenetra e envolve os músculos, ossos, nervos, e vasos sanguíneos do corpo, ligando todas essas estruturas juntos em uma massa compacta e firme. Sobre ossos, é chamada periósteo, em torno dos tendões, forma o paratendão, ao redor vasos e nervos, forma a bainha neurovascular. Então, podemos considerar o paratendão, a bainha neurovascular e o periósteo como especialização da fáscia profunda, não só porque eles estão em continuidade, mas também porque eles têm as mesmas características histológicas. Podemos distinguir dois tipos principais de fáscias musculares, no entanto, de acordo com sua espessura e seus relacionamentos com os músculos subjacentes: as fáscias aponeuróticas e as fáscias epimisiais (STECCO et al. 2013).

2.1.2 Inervação

Procedimentos especiais de coloração e microscopia eletrônica demonstram que a fáscia é povoada por fibras nervosas sensoriais, sugerindo que ela contribui para a propriocepção e nocicepção, e pode responder à pressão manual, temperatura e vibração (YAHIA et al. 1992; STECCO C. 2007; TESARZ J, 2011, LANGEVIN H, 2011). Conexões fasciais em diferentes unidades motoras e diferentes sinergistas funcionais podem fornecer uma explicação alternativa para distribuições de dores referidas, que muitas vezes não seguem nem as vias nervosas nem a morfologia de um único músculo (HAND, 2009). Muitas terminações encapsuladas encontradas na fáscia são mecanorreceptores que respondem à pressão mecânica ou deformação, e incluem receptores de Golgi, corpúsculos de Pacini e corpúsculos de Ruffini (YAHIA et al. 1992; STECCO C. 2007; SCHLEIP R, 2003).

Fede, C. et al (2016) demonstraram pela primeira vez a presença de receptores endocanabinóides em fibroblastos fasciais. A presença de receptores CB1 (cannabinoid receptor 1) e CB2 (cannabinoid receptor 2) em fibroblastos fasciais sugerem seu possível papel na modulação da dor fascial. A dor fascial geralmente está relacionada a uma inflamação fascial e/ou fibrose fascial, e ambas podem ser relacionadas a uma alteração do sistema endocanabinóide.

De fato, a ativação de receptores CB1 e CB2 é capaz de suprimir citocinas pró-inflamatórias, tais como IL-1 beta e TNF-alfa e aumentar citocinas anti-inflamatórias, e fornecer uma atividade anti-fibrótica.

Diferentes técnicas de mobilização de tecidos moles podem estimular os receptores acima: as manipulações axiais de alta velocidade e as técnicas vibratórias provavelmente estimulam os receptores de Paccini, enquanto técnicas de tecidos moles lentas e profundas provavelmente atingem Ruffini (KUMKA, M; BONAR J, 2012). Saber o que os receptores são mais significativamente concentrados em um tecido alvo particular pode ajudar um praticante manual a escolher o método de estímulo (por exemplo, pressão profunda, estiramento, tensão ou vibração) (SCHLEIP R, 2003). Entendendo que certos tipos de fáscias são mais densamente povoados com certos receptores podem ajudar na compreensão geral do corpo e criar abordagens mais eficazes para tratamentos manuais.

A presença de rigidez tem sido apontada por alguns autores com relação a espessura e mobilidade da fáscia. Stecco et al. (2014) documentaram que existe uma correlação entre a diminuição na amplitude de movimento da coluna cervical e o aumento da espessura da fáscia profunda do pescoço após análise de ultrassonografia dos músculos Escaleno Médio e Esternocleidomastóide em indivíduos com dor cervical crônica. Outros autores encontraram correlações significativas em indivíduos do sexo masculino com dor lombar crônica entre a tensão de cisalhamento da fáscia toracolombar e as seguintes variáveis: espessura do tecido conjuntivo perimuscular, ecogenicidade, variável de amplitude de movimento (ADM) da flexão e extensão do tronco, demonstrando que 20% dos indivíduos com dor lombar crônica apresentam diminuição da mobilidade da fáscia quando comparados com indivíduos sem dor (LANGEVIN et. al, 2011).

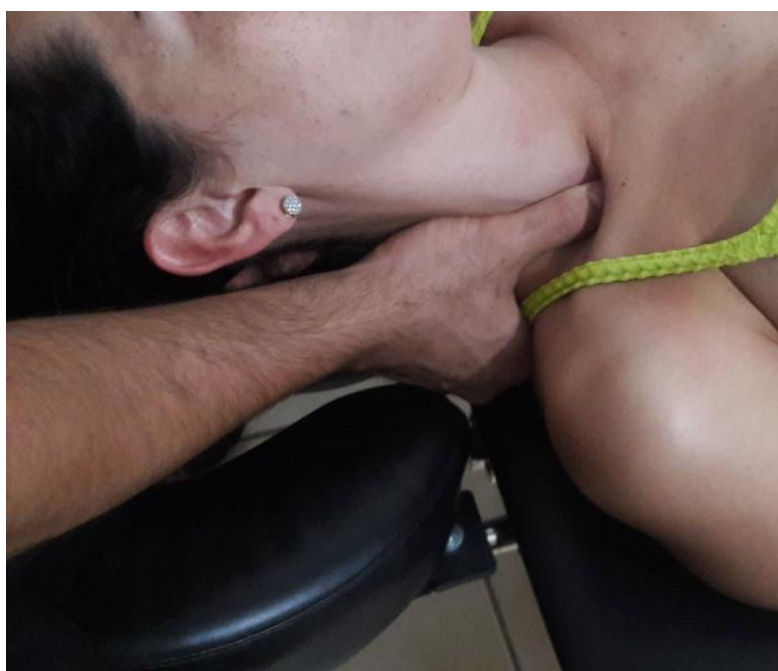
2.2 TÉCNICAS DE TECIDOS MOLES

2.2.1 Terapia de Liberação Miofascial

A Terapia de Liberação Miofascial (TLM) é uma forma de terapia manual que envolve a aplicação de um alongamento de longa duração e baixa carga ao

complexo miofascial, destinado a restaurar o comprimento ideal, diminuir a dor e melhorar a função (AJIMSHA M; et al. 2015). Acredita-se que pelo alongamento restrito da fáscia, a TLM é capaz de normalizar o comprimento e as propriedades de deslizamento dos tecidos miofasciais liberando também a pressão das estruturas à sensibilidade a dor, e assim, restaurar a mobilidade das articulações (KATRI, L et al, 2018).

Figura 2. Aplicação da TLM sobre as fibras do músculo Escaleno Médio. Polegar direito colocado posteriormente ao músculo Esternocleidomastóide (fibras claviculares) e mão esquerda posicionada na base do Occipital.



FONTE: arquivo pessoal do autor (2016)

Diversas alternativas de tratamento têm sido propostas para o manejo das disfunções faciais. Nos últimos anos, o crescente interesse no sistema miofascial gerou um aumento nos estudos sobre a eficácia da terapia de liberação miofascial (TLM) para reduzir a dor e corrigir postura (PICELLI, A. et al. 2011). Revisões sistemáticas têm mostrado resultados variáveis em condições musculoesqueléticas, e também com relação a variabilidade da qualidade metodológica dos estudos, porém os autores referem que a TLM está emergindo como uma estratégia com uma base sólida de evidências e um tremendo potencial (KATRI, L et al, 2018; AJIMSHA M; AL-MUDAHKA NR, AL-MADZHAR

JÁ, 2015; MCKENNEY, K, 2013). Um estudo mostrou que a TLM reduziu 20% a mais a dor e limiar de dor à pressão nos músculos trapézio e esplênios, em indivíduos com dor cervical quando comparados a um programa multimodal de Fisioterapia (ultrassom, TENS e massagem) (HUGUET, R, 2018). Da mesma forma, a liberação obtida por TLM nas estruturas miofasciais superficiais e profundas do pescoço permite um melhor movimento dos órgãos relacionados a essas estruturas. Cerca de 23,33% dos indivíduos com dor cervical tiveram uma mudança "radical" no movimento de deslizamento da fáscia, enquanto que nenhuma mudança foi encontrada no grupo Controle (TOZZI, P; BONGIORNO, D; VITTURINI, C, 2011). A mobilização de tecidos moles pode trazer benefícios para estruturas adjacentes. Kim J. e Lee J. (2018) conduziram um estudo verificando os efeitos da mobilização de tecidos moles nos músculos Suboccipitais e Esternocleidomastóide (ECM) sobre a rigidez muscular e limiar de dor à pressão nos músculos Trapézio Superior e Esternocleidomastóide. Os autores sugerem que, para reduzir a dor no músculo Trapézio Superior, a intervenção não deve ser aplicada apenas diretamente ao músculo, mas também deve ser aplicado a TLM ao músculo ECM inervado pelo mesmo nervo, mostrando os efeitos das técnicas fasciais também nas estruturas adjacentes.

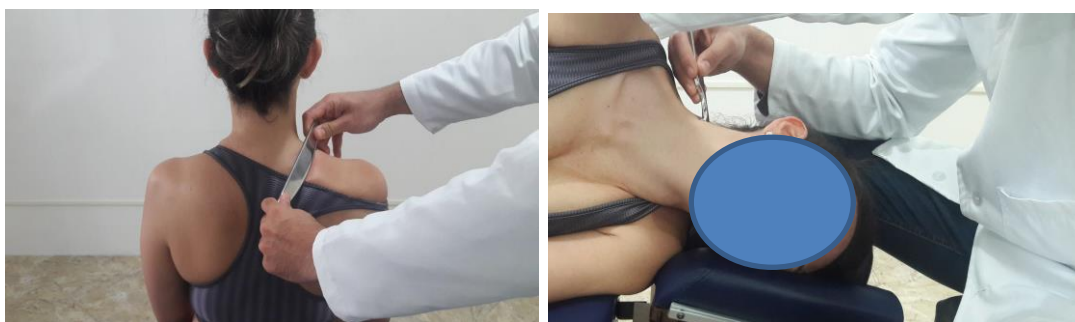
Do ponto de vista sistêmico, a TLM não tem apenas uma resposta neurológica local, mas as respostas podem ser desencadeadas por reflexos autonômicos (CATHCART, E et al 2019). Quando estimulados, os corpúsculos de Ruffini (nervos mecanossensíveis) têm sido associados à diminuição da inatividade do sistema nervoso autônomo (SNA), uma vez que a fáscia possui alta densidade de terminações nervosas livres que pertencem ao sistema nervoso simpático (SCHLEIP R, 2003).

2.2.1 IASTM (*mobilização de tecidos moles assistida por instrumentos*)

A mobilização de tecidos moles assistida por instrumentos (IASTM) é um tratamento utilizado mundialmente para restrição miofascial com base no raciocínio introduzido por James Cyriax (BAKER et. al, 2015), (BAKER et. al, 2013) . Ao contrário da Abordagem Cyriax utilizando fricção cruzada digital, o IASTM é aplicado usando instrumentos sobre a pele em ângulos de 30° e 60°

para detectar irregularidades nos tecidos moles através da ondulação das ferramentas (HOWITT et al., 2006; SEVIER et. al, 1995) que são especialmente projetadas para fornecer um efeito mobilizador sobre tecido mole (tecido cicatricial, adesão miofascial), assim promovendo melhora da sensação de dor e da amplitude de movimento (ADM) (BAKER et. al, 2013). Existem várias abordagens diferentes para o IASTM, cada uma das quais fornecem suas próprias ferramentas, certificação ou programas de treinamento, como a técnica Graston®, Técnica Gavilán®, Hawk Grips®, Functional and Kinetic Treatment and Rehab (FKTR)®, Adhesion Breakers® e Fascial Abrasion Technique® (SCOTT et.al, 2016). O uso dos instrumentos, em oposição às mãos do Fisioterapeuta, é indicado para proporcionar uma vantagem mecânica ao clínico permitindo uma penetração mais profunda e possivelmente aumentando a especificidade da aplicação do tratamento (PAPA, 2012), enquanto promove a redução do estresse manual ao terapeuta imposto pelos tratamentos manuais (SEVIER e STEGINK-JANSEN, 2015), (STRUNK; PFEFER; DUBE, 2014).

Figura 3. Aplicação da IASTM sobre as fibras dos músculos Trapézio Superior e Escaleno Médio. A esquerda a técnica de Fanning e a direita a técnica de Varredura.



FONTE: arquivo pessoal do autor (2017)

Alguns estudos mostram resultados com IASTM na ADM e funcionalidade em patologias músculoesqueléticas crônicas (SCHAEFER J; SANDREY M, 2012), (BURKE et. al, 2007) e (BLANCHETTE, M; NORMAND M, 2011). IASTM tem sido proposto para aumentar a proliferação de fibroblastos da matriz extracelular, melhorar o transporte de íons e diminuir as aderências da matriz (HOWITT et al., 2006; GEHLSSEN et al., 1999; LOGHMANI M, WARDEN S,

2009). Assim, o IASTM tem sido sugerido como uma intervenção para patologias, como fibrose crônica, epicondilite lateral, síndrome do túnel do carpo, dedo em gatilho, fascite plantar e pontos-gatilhos miofasciais (PGM) na coluna cervical (HOWITT et al., 2006; SEVIER et al., 1995; MELHAM et al., 1998; GULICK, D, 2014; GULICK, D, 2017).

Podemos observar os efeitos da IASTM sobre a dor em diferentes condições clínicas. Um estudo identificou efeitos importantes sobre o limiar de dor à pressão (PPT) (*tradução de pain pressure threshold*) dos músculos isquiotibiais após protocolo de IASTM em comparação com técnicas como FNP e contração-relaxamento (KIM, D. et al. 2018). Outros autores conduziram um ensaio clínico randomizado sobre o efeito da IASTM sobre a dor e PPT em jogadores amadores de futebol com PGM ativos nos músculos Quadrado Lombar e Glúteo Máximo. Eles observaram uma redução significativa na dor e aumento no PPT após três sessões com IASTM em comparação à pressão isquêmica e ventosaterapia (FOUSEKIS K, 2016). Lee et al. (2016) relataram que quando a IASTM foi aplicada por 4 semanas em 30 pacientes com dor lombar crônica, a dor diminuiu significativamente. Outros autores também demonstraram que a aplicação de oito sessões de tratamento da IASTM durante 4 semanas em pacientes com polegar em gatilho foi útil na redução da dor (HOWITT S et al. 2006).

Em indivíduos com dor cervical crônica, poucos estudos foram conduzidos. Braun, M. et al (2011) realizaram um ensaio clínico randomizado e utilizaram Gua Sha como tratamento em comparação com uma terapia de controle térmico após 1 semana de follow-up. Um único tratamento de Gua sha diminuiu significativamente a intensidade da dor e melhorou a incapacidade em pacientes com dor cervical crônica, em comparação com pacientes que recebem a terapia termal. Outro estudo também observou diminuição da intensidade da dor e aumento do PPT em pacientes com dor cervical crônica após o uso do Gua Sha (LAUCHE, R. 2012). Gua Sha têm sido citado como uma técnica de IASTM, mesmo tendo aplicações diferentes (CHEATHAM, S, 2016). Gulick, D (2017) também verificou o efeito sobre o PPT da IASTM sobre PGM no músculo trapézio superior após 6 sessões em 3 semanas, identificando um aumento significativo no PPT após o tratamento em comparação ao grupo controle.

Observamos efeitos importantes da IASTM sobre a ADM e alguns estudos sugerem isso (BAKER et al., 2013; Kim et al., 2014; Laudner et al., 2014; HUSSEY, M et al. 2018; ROWLETT, C et al. 2019; IKEDA, N et al. 2019). Um estudo mostrou que a intervenção com IASTM induziu aumentos agudos estatisticamente significantes e praticamente relevantes na ADM de joelho e quadril que ainda estavam presentes 24 horas após a aplicação. Os autores descrevem um aumento duas vezes maior quando comparados com auto-liberação miofascial (*Foam Roller*) (MARKOVIC, G 2015). Merkle et al. (2016) indicaram que a aplicação de duas sessões da IASTM por semana, durante 3 semanas, em jogadores de beisebol colegiais saudáveis, melhorou significativamente a ADM dos isquiotibiais, enquanto Heinecke et al. (2014) mencionaram que a aplicação de duas sessões do IASTM por semana, durante 4 semanas, na área do ombro de jogadores de beisebol e voleibol colegiais, foi útil na prevenção de uma perda de ADM. Uma única sessão da IASTM ou alongamento nos músculos Gastrocnêmios e Sóleo aumentou a ADM de dorsiflexão do tornozelo em sessenta participantes saudáveis. Tanto o IASTM como o alongamento parecem ter um efeito maior sobre a flexibilidade do músculo Sóleo (ROWLETT, C et al. 2019). Gamboa, A (2019) também encontraram diminuição do ângulo do tornozelo no grupo experimental mostrando que o IASTM aumentou a ADM, permitindo maior flexão dorsal durante a parte mais profunda do agachamento com maiores ganhos na ADM encontrada ao longo do tempo durante o período de manutenção.

Embora observamos um crescente aumento de pesquisas nessa área, ainda precisamos avançar no que diz respeito a qualidade metodológica dos estudos na área da IASTM. As 3 últimas revisões sistemáticas sobre o tema são divergentes com relação aos seus resultados em condições musculoesqueléticas. Lambert, M (2017) recomendam a utilização da IASTM como sendo uma intervenção e tratamento eficazes para reduzir a dor e melhorar a função em um período menor de três meses. Já Cheatham, S et al. (2016) e Nazari, G et al. (2019) apontam que as evidências atuais não suportam o uso do IASTM para melhorar a dor, a função ou a amplitude de movimento. Esse último estudo mostra que todas as pesquisas incluídas na revisão eram de baixa qualidade metodológica, deixando uma lacuna para novas evidências (NAZARI, G et al. 2019).

3 OBJETIVOS

3.1 OBJETIVO GERAL

Verificar e comparar o efeito da mobilização de tecidos moles assistida por instrumentos (IASTM) na dor, incapacidade e ADM em indivíduos com cervicalgia crônica inespecífica.

3.2 OBJETIVOS ESPECÍFICOS

- Descrever a caracterização de indivíduos com cervicalgia crônica inespecífica.
- Descrever e comparar em ambos os grupos, os momentos pré-intervenção, pós-intervenção num período de 3 semanas de acompanhamento, a intensidade de dor cervical utilizando a escala numérica de dor (END); a autopercepção de incapacidade utilizando o *Neck Disability Index* (NDI); as amplitudes de movimento (ADM) da coluna cervical – flexão, extensão, rotações e inclinações direita e esquerda através de um flexímetro pendular.

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5 ARTIGO

Effects of instrument-assisted soft tissue mobilization (IASTM) on pain and disability in individuals with non-specific chronic neck pain. A randomized clinical trial.

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ABSTRACT

Introduction: Musculoskeletal diseases are the second cause of years lived with disability worldwide, with neck pain being the 4th largest contributor to global disability. Instrument-assisted soft tissue mobilization (IASTM) is a treatment used for myofascial restraint and has been proposed as an alternative for pain reduction, disability. However, there are a small number of randomized controlled trials (RCTs). **Objectives:** To compare the effect of instrument-assisted soft tissue mobilization (IASTM) on pain, disability, and ROM in individuals with nonspecific chronic neck pain. **Methods:** 23 participants with recruited chronic neck pain (CNP) participated in this study. Participants were randomly allocated to receive six IASTM or Myofascial Release Therapy (TLM) treatment sessions. Researchers blinded to allocation assessed participants for neck pain intensity, disability, and ROM at two different times: pretest and one week after treatment. Randomization was performed by a researcher not involved in determining eligibility, initial assessment and provision of treatment. The hidden allocation was granted using numbered, sequenced and sorted sealed opaque envelopes. **Results:** After six treatment sessions there was no effect of interaction between groups for pain [$F(1,21) = 0.110$; $p = 0.743$], disability [$F(1,21) = 0.393$; $p = 0.538$], but the interaction (time) had a significant effect from the pre-posttreatment groups and also the large effect size for the variables: pain: [$F(1,21) = 90.505$; $p = 0.000$], $d = 4.15$, disability: [$F(1,21) = 107.538$; $p = 0.000$], $d = 4.53$, ROM (flexion) [$F(1,21) = 36.135$; $p = 0.000$], $d = 2.62$, (extension) [$F(1,21) = 11.673$; $p = 0.003$], $d = 1.49$, (right lateral flexion) [$F(1,21) = 25.124$; $p = 0.000$], $d = 2.18$, (left lateral flexion) [$F(1,21) = 14.733$; $p = 0.001$], $d = 1.67$, (right rotation) [$F(1,21) = 4.350$; $p = 0.049$], $d = 0.91$, (left rotation) [$F(1,21) = 9.955$; $p = 0.005$], $d = 1.37$. **Conclusion:** Based on the findings of this study, it can be concluded that IASTM produced positive clinical effects, but not superior to TLM. IASTM produces a decrease in local pain, disability, and increased ROM in patients with CNP. IASTM can be a therapeutic tool to assist clinicians in the management of manual therapy.

Key words: Neck Pain, Musculoskeletal Manipulations, Tissue, Subcutaneous, Myofascial Pain Syndrome, Myofascial Release, Instrument-Assisted Soft Tissue Mobilization.

INTRODUCTION

Musculoskeletal diseases are the second cause of years experiencing some kind of disability worldwide (Sebbag et al., 2019). Within this scenario, the cervical pain is one of the most prevalent diseases; reaching the status of fourth largest contributor to global disability (Hoy et al., 2014). In recent years, there have been several studies on Myofascial pain syndrome (MPS) among patients suffering from neck pain (Fernandez-de-Las-Penas and cols., 2006, 2007).

The treatments of fascial tissues have become increasingly popular in musculoskeletal disorders, which may be due to recent histological findings. The discovery of contractile cells, free nerve endings and mechanoreceptors suggest that fascia, in contrast to previous assumptions, plays a proprioceptive and mechanically active role (Bhattacharya et al., 2010; Stecco et al., 2007; Yahia et al., 1992).

A lot of the encapsulated terminations found in fascia are mechanoreceptors that respond to mechanical pressure or deformation, and include Golgi tendon organs, Pacinian corpuscles and Ruffini corpuscles (Yahia et al., 1992; Stecco 2007; Schleip 2003). Fede et al (2016) demonstrated, for the first time, the presence of cannabinoid receptors in fascial fibroblasts. The presence of receptors in fascial fibroblasts suggests its possible role in the modulation of fascial pain. Different tissue manipulation techniques can stimulate the aforementioned receptors: high-speed spinal manipulation and vibratory techniques are likely to stimulate Pacinian corpuscles, whereas slow-deep soft tissues techniques are likely to reach Ruffini (Kumka and Bonar, 2012).

Instrument Assisted Soft Tissue Mobilization (IASTM) is a treatment used worldwide for myofascial restriction based on the line of reasoning introduced by James Cyriax (Baker et. al, 2015). IASTM is applied using instruments on skin at 30° and 60° angles in order to detect irregularities on soft tissues (Howitt et al., 2006; Sevier et al., 1995). There are several different approaches for IASTM, each of which provides its own tools, certifications or training programs (Scott et al., 2016). It's possible to observe the effects of IASTM on pain in different clinical conditions. Lee et al. (2016) reported that when IASTM was applied on 30 patients with chronic low back pain for 4 weeks, the pain significantly decreased.

Few studies have been conducted on individuals with chronic neck pain. Braun, M. et al (2011) performed a randomized controlled trial using Gua Sha as treatment in comparison to a thermal therapy after 1 week of follow-up. A single Gua Sha treatment significantly decreased the intensity of pain and improved the disability of patients with chronic neck pain. Another study also observed decreased pain intensity and increased PPT on patients with chronic neck pain after using Gua Sha (Lauche, 2012). Gulick, (2017) also verified the effect on PPT of IASTM on MTP in the upper trapezius after 6 sessions in 3 weeks. The author identified a significant increase in PPT after the treatment compared to the clinical control group.

As far as is known, no randomized controlled trial (RCT) has compared the hypoalgesic effects of IASTM on neck muscles and its impact on disability and mobility; therefore, this study aims to evaluate the effects of IASTM on pain, disability and ROM of individuals with nonspecific chronic neck pain.

METHODS

The study was a single-blind randomised controlled trial, which was prospectively registered with in the International Clinical Trials Registry (ClinicalTrials.gov Identifier: NCT03563079) and received approval from the Ethics and Research Committee of the Federal University of Health Sciences of Porto Alegre (registration number: 2.547.877 - 18/03/2018).

Participants

Participants were recruited from the general public, using electronic announcements, flyers, and Facebook advertising. A randomized single-blind clinical trial was carried out with participation of 23 volunteers (mean age 39 ± 12.4 years; 95.6% women). Inclusion criteria were: Individuals of both sexes, aged between 18 and 60 years, who present as main complaint chronic neck pain, manifested for at least twelve weeks, without irradiation to the upper limbs distally to the shoulders, that present scores in the NPRS (numerical pain rating scale) above 3, NDI (neck disability index) above 30% and Spurling test negative (specificity, 98.53%) (Juyeon et.al, 2017).

Exclusion criteria were: some severe clinical condition (such as fracture, neoplasia or systemic diseases); history of previous surgery in the cervical or thoracic spine; injury due to whiplash trauma in the six months prior to evaluation; diagnosis of cervical stenosis; diagnosis of myelopathy; pregnancy; signs and symptoms of moderate to severe temporomandibular dysfunction, hematoma in the cervical region, burn scars in the cervical region, severe osteoporosis, open lesions or recent ruptures in the cervical region, generalized infections, coagulation disorders, acute inflammatory conditions or fever. Also excluded are patients who have undergone physical therapy or massage up to one month prior to the evaluation. Participants were asked not to take pain-relieving medications.

Stratified randomization in blocks was created to generate balanced groups. Randomization was performed by a researcher not involved in eligibility determination, baseline assessment and treatment provision. The procedure was adopted with blocks of four and six. Allocation was stratified by baseline pain intensity in two strata (stratum 1: pain ranging from three to six; stratum 2: pain ranging seven to ten). Concealed allocation was granted by using numbered, sequentially ordered, sealed opaque envelopes. Both randomization and allocation concealment followed the procedures described by Doig et al. (2005). Data collection was conducted by a physical therapist who was blinded as to which participants received IASTM or a MRT intervention. After the pretests, 23 participants with NP were randomly allocated to either the IASTM group ($n = 13$) or the MRT group ($n = 10$).

Sample Size Determination

The sample size was calculated using MedCalc® 16.4 program, the minimum sample size was calculated by comparing means to allow the detection of differences between two groups submitted to different treatments with a power of 80% and an alpha error of 5%. Using data provided by Huguet, et. al, (2017) for a difference between two groups of 20% and a standard deviation of 0.10 in each group, requiring 20 patients per group, totaling 40 individuals. Allowing a 15% dropout rate, we plan to recruit at least 46 patients.

Outcomes Measures

Assessments at baseline and after intervention were performed by a blind physiotherapist. Socio-demographic data on age, sex, schooling, income, physical activity, self-perception of pain, disability and range of motion were collected in the initial interview. The evaluation was performed before the intervention and 1 week after the end of treatment.

Pain

The primary outcome was the intensity of self-perceived neck pain at rest, verified by a numerical pain rating scale (NPRS) which consists of an 11- point numerical scale (0-10). Test-retest reliability proved to be good (ICC= .76, 95% CI .51-.87) and minimum clinically important difference (MCID) was 2.3 points (Cleland, J.A. et al. 2008 and Olsen, M. F., 2018).

NDI

Another primary outcome was the percentage of the Neck Disability Index, which consists of 10 items -7 related to activities of daily living, 2 related to pain, and 1 related to concentration. Each item is scored from 0 to 5, and the total score is expressed as a percentage (total possible score, 100%), with higher scores corresponding to greater disability. Thresholds for the (MCID) for the NDI were 19-percentage points. Test-retest reliability proved to be good (ICC= .83, 95% CI, .75–.90) (Cleland, J.A. et al. 2008).

Cervical Range of Motion (CROM)

The secondary outcome was evaluated by a Sanny brand pendulum fleximeter. A systematic review has shown that the fleximeter is one of the most widely used tools for measuring cervical ROM (Snodgrass et al, 2014). Test-retest reliability proved to be good (ICC=0,89-0,98).

Interventions

All patients received six treatments according to the designated group. The sessions were held twice a week at least two days apart (Gulick, 2014). Patients were also advised not to use analgesics, muscle relaxants or anti-inflammatory drugs during the study period.

IASTM Group: The treatment was performed using steel IASTM pieces in the cervical spine, bilaterally, in the following muscles: upper trapezius, splenius, middle scalene and sternocleidomastoid (SCM). An established time of 3 minutes was used in each region or if the patient presented with a patch. The instrument was used at a 45° angle. As it was observed, through the instrument, regions of greater adhesion, the researcher would use most of this time to release this condition.

The researcher initially positioned himself behind the patient and was seated, where mobilizations (sweeping) were performed in the Upper Trapezius muscle region. Subsequently, mobilizations were performed for the sternocleidomastoid muscle with the patient in a dorsal decubitus. Afterwards, the mobilizations were performed for the middle scalene muscle with the patient in lateral decubitus, and finally, with the patient in the ventral decubitus position, the mobilizations of the splenius muscles.

MRT group: Like the seated patient, the release of the upper trapezius muscle was performed by starting with slips using a roller with the back of the fingers (Trapezius Roll) and ending with the myofascial pumpage of the trapezius (Trapezius Opening) with the patient in the supine position. Later the sternocleidomastoid muscles were released using a roller with the dorsum of the fingers (proximal interphalangeal joints) and myofascial pumpage, respectively, bilaterally. Shortly thereafter, techniques were performed for the middle scalene muscles with the patient in the supine position, with sliding with the index, middle and ring fingers, finishing with myofascial pumpage, tilting the head to the opposite side. Finally, techniques for the splenius muscles were made with slips with the index and middle fingers, ending with the posterior cervicothoracic release with the patient also in the supine position. The same time of 3 min was used for the treatment in each region bilaterally. Myofascial release techniques were used according to (Earls, J., Myers, T., 2010).

Statistical analyses

Descriptive statistics were calculated for patient demographics data. All calculations are performed after checking the underlying assumptions for parametric or nonparametric testing. Statistically significant differences between NPRS, NDI e CROM measurements, as well as the three conditions are tested with repeated measurements ANOVA with 2 factors (group and time). When the assumption of sphericity was not met, the Greenhouse-Geisser correction was used. For outcome variables with a significant interaction, follow-up Bonferroni-adjusted post hoc tests were used. The within group differences in baseline in pain, disability and ROM were performed using paired t test. A P value < 0.05 was considered significant. All analyses were performed in SPSS Statistics Version 23.0. The effect size was also calculated through Cohen's "d" coefficient. An effect size greater than 0.8 was considered large, less equal to 0.2 small and around 0.5 moderate.

RESULTS

There was no significant difference on the baseline demographic data between groups: gender ($t(21) = .872$; $p = .393$), age ($t(21) = .126$; $p = .901$), income ($p = .399$), schooling ($p = .516$), physical activity ($p = .400$), psychological diseases ($p = .400$), NPRS ($t(21) = .308$; $p = .761$), NDI ($t(21) = .985$; $p = .336$), CROM ($t(21) = 1.166$; $p = .257$ (flexion)), $p = .940$ (extension), $p = .423$ (right lateral flexion), $p = .602$ (left lateral flexion), $p = .685$ (right rotation), $p = .816$ (left rotation). (table 1).

Table 2 provides before and after treatment session data as well as between groups statistical differences for with 2 factors (group and time) for NPRS, NDI and CROM. After the six treatment session significant differences between groups in the NPRS, NDI and CROM not were found ($p > 0.05$).

Mixed ANOVA with repeated measurements did not indicate a statistically significant interaction for NPRS: group/time [$F(1,21) = 0,110$; $p = 0,743$], effect size $d = 0.14$, NDI: [$F(1,21) = 0,393$; $p = 0,538$], $d = 0.27$, CROM (flexion) [$F(1,21) = 0,655$; $p = 0,427$], $d = 0.35$, (extension) [$F(1,21) = 0,713$; $p = 0,408$], $d = 0.36$, (right lateral flexion) [$F(1,21) = 2,877$; $p = 0,105$], $d = 0.74$, (left lateral

flexion) [F (1,21) = 1,00; p = 0,327], d = 0.43, (right rotation) [F (1,21) = 0,113; p = 0,740], d = 0.14, (left rotation) [F (1,21) = 0,033; p = 0,857], d = 0.08. But the interaction (time) had a significant effect of the groups from the pre to the post treatment and also effect size large for the variables: NPRS: [F (1,21) = 90,505; p = 0,000], d = 4,15, NDI: [F (1,21) = 107,538; p = 0,000], d = 4.53, CROM (flexion) [F (1,21) = 36,135; p = 0,000], d = 2.62, (extension) [F (1,21) = 11,673; p = 0,003], d = 1.49, (right lateral flexion) [F (1,21) = 25,124; p = 0,000], d = 2.18, (left lateral flexion) [F (1,21) = 14,733; p = 0,001], d = 1.67, (right rotation) [F (1,21) = 4,350; p = 0,049], d = 0.91, (left rotation) [F (1,21) = 9,955; p = 0,005], d = 1.37. (table 2)

Analyzing the percentage of variation between means of NPRS after baseline, IASTM group has shown an decrease of 35,4% immediately after treatment and of 33,0% for MRT group respectively. For NDI after baseline, IASTM group has shown an decrease of 20% immediately after treatment and of 22,6% for MRT group respectively. Minimum clinically important difference and statistically significant differences were observed for the NPRS and NDI outcomes after the intervention.

DISCUSSION

Our study appears to be the first to analyze the effects of IASTM and MRT on levels of pain and disability in patients with chronic neck pain. Our results provide evidence that the six-session treatment with the IASTM induced positive results in levels of self-perception of pain, disability and cervical mobility at a 1-week follow-up. In intergroup analysis, similar results were observed for pain, disability and range of motion after treatment. We found results similar to the study conducted by Gulick (2018) in an RCT that verified the effect of 6 sessions of IASTM on PPT on upper trapezius muscle at 3 weeks of intervention, the author identified a significant effect of treatment on pain threshold and pain levels. Patients with chronic low back pain also benefit from the use of the IASTM, performing 4 weeks of intervention, the pain decreased significantly (Lee, et al., 2016). These patients also improve the flexibility of the hamstrings with the use of the IASTM (Moon et al., 2017). Our results also corroborate with the findings of another RCT in individuals with non-specific thoracic spine pain who underwent

10 interventions with IASTM for 4 weeks compared to joint manipulation and placebo. Outcomes such as pain and disability levels did not have interaction between groups over time at 1 week and 1, 3, 6 and 12 months of follow-up, showing only time effects (Crothers 2016). Another research with 4 weeks of intervention, being 2 per week using IASTM in individuals with chronic ankle instability, was performed in association with dynamic balance training, where the authors did not identify a clinically important improvement in pain levels when compared to other treatments such as IASTM simulated, but there was an important improvement in the function. (Schaefer and Sandrey, 2012). A quasi-experimental study analyzed the effects of a single 10-minute session of IASTM on the activities of mechanosensitive neurons in the skin. The activities of the mechanosensitive neurons were measured before and after the application of the IASTM. The mean of the 2-point discrimination was 40.2 (SD 9.4) mm before the IASTM and increased to 44.9 (SD 12.0) mm after the IASTM. The increase was statistically significant before and after the IASTM. The authors did not find significant differences in relation to the PPT (Ge and Sansone 2017). The effects on pain appear from the second session using IASTM (Fousekis et al., 2016). A study conducted by Daniels and Morrell (2012), the pain was reduced in young soccer players with plantar fasciitis applying the IASTM once a week for 6 weeks. In a case report, patients with subacromial pain syndrome also benefited from hypoalgesic effects on active shoulder flexion, generated by IASTM techniques when applied to the pectoral and periscapular muscles in 3 treatment sessions (Coviello et al., 2017). In 3 studies, the IASTM did not demonstrate clinically important differences in terms of improvement in pain levels in patients with lateral epicondylitis, non-specific thoracic spine pain or low back pain compared to other 6-week treatments at 3, 6 and 12 months follow-up. (Crothers et al., 2016, Moon et al., 2017, Blanchette and Normand, 2011). Merkle et al. (2016) indicated that the application of two sessions of IASTM per week for 3 weeks in healthy collegiate baseball players significantly improved the flexibility of the hamstrings, while Heinecke et al. (2014) mentioned that the application of two sessions of the IASTM per week for 4 weeks to the shoulder area in volleyball players was useful in preventing ROM loss. Decreases in rotator cuff stiffness have been associated with acute ROM gains in baseball players. The 60 asymptomatic players who received IASTM and elongation showed higher ROM gains in the shoulder

(internal rotation, $5^{\circ} \pm 2^{\circ}$, $P = .010$, total movement arc, $8^{\circ} \pm 6^{\circ}$, $P = .010$, horizontal adduction, $7^{\circ} \pm 2^{\circ}$, $P = .004$, compared to players who received only self-stretching (Bailey et al., 2015). Acute gains from a single IASTM session over ROM are also observed. Statistically significant differences were identified between the IASTM and control, as well as the stretching group increased the ROM of ankle dorsiflexion, which had an effect on the flexibility of the soleus muscle, as evidenced by ROM gains measured with the knee in a flexed position (Rowlett et al. 2019). However when compared with manual technique of myofascial release the ROM of the ankle increases more compared to a single intervention of IASTM (Stanek 2018).

Study limitations

The number of participants was one of the limiters of our study. Longer follow-up to verify long-term effects in patients with chronic neck pain. Some variables were not controlled in our study, such as previous levels of catastrophizing pain, fear, avoidance or kinesiophobia levels. Further studies are needed to compare the effects of IASTM with key recommendations from the neck pain clinical practice guidelines.

CONCLUSION

The application of six intervention with IASTM produced clinical positives effects, but not superior to MRT. IASTM produce an decrease in local pain and disability of patients with chronic neck pain. The effects of IASTM was strong and MRT showed similar response levels for pain and disability. IASTM has positive effects in patients with neck pain and may be a therapeutic tool to assist clinicians in the management of manual therapy, thus reducing mechanical stress of the hands.

Conflicts of interest

None.

Funding

None.

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ANEXOS

ANEXO A- Table 1: Baseline Demographics data for the 2 groups*.

Variables	Groups		p value
	IASTM (13)	MFT (10)	
Gender (male/female)	1/12	0/10	0.393
Age (years)	38,9 ± 12,7	39,6 ± 12,8	0.901
Income (wage)			
1 to 3 (%)	61,5 (8)	80 (8)	0.399
3 to 6 (%)	23,1 (3)	20 (2)	
6 to 10 (%)	15,4(2)	0	
Scholling			
Elementary school (%)	7,7(1)	10(1)	0.516
High school(%)	53,8(7)	30(3)	
Higher education(%)	38,5(5)	60(6)	
Physical activity			
Yes(%)	15,4(2)	30(3)	0.400
No(%)	84,6(11)	70(7)	
Psychological diseases			
Yes(%)	15,4(2)	30(3)	0.400
No(%)	84,6(11)	70(7)	
NPRS (score range 0–10)	6,1±0,98	6,0±1,41	0.761
Disability (NDI)(%)	37,62±7,81	41,65±11,7	0.336
CROM (flexion)(°)	49,4±11,0	43,7±12,6	0.257
CROM (extension)(°)	51,5±10,4	51,1±12,3	0.940
CROM (right lateral flexion)(°)	37,5±10,0	40,8±8,88	0.423
CROM (left lateral flexion)(°)	38,0±10,5	40,1±8,22	0.602
CROM (right rotation)(°)	55,4±11,0	57,4±12,2	0.685
CROM (left rotation)(°)	56,0±9,7	54,7±15,6	0.816

Abbreviations: NPRS, 11-point numerical pain rating scale; NDI, Neck Disability Index; CROM, Cervical Range of Motion.

* Data are mean + SD, except for gender, income, schooling, physical activity and psychological diseases.

p-value of independent T-test analysis.

ANEXO B - Table 2: Preintervention, and 1 week follow-up data*

Variables	Groups		p value		d
	IASTM (13)	MFT (10)	p†	p‡	
NPRS (score range 0–10)					
Pre	6,1±0,98	6,0±1,41	0.761		
1week post	2,6±1,32	2,7±1,82	0,743	0,000	4,15
Disability (NDI)(%)					
Pre	37,62±7,81	41,65±11,7	0.336		
1week post	17,60±9,65	19,06±9,53	0,538	0,000	4,53
CROM (flexion)(°)					
Pre	49,4±11,0	43,7±12,6	0.257		
1week post	59,23±12,16	56,49±9,35	0,427	0,000	2,62
CROM (extension)(°)					
Pre	51,5±10,4	51,1±12,3	0.940		
1week post	65,91±13,94	59,86±12,79	0,408	0,003	1,49
CROM (right lateral flexion)°					
Pre	37,5±10,0	40,8±8,88	0.423		
1week post	46,44±11,79	45,23±10,46	0,105	0,000	2,18
CROM (left lateral flexion)(°)					
Pre	38,0±10,5	40,1±8,22	0.602		
1week post	47,86±14,92	45,93±7,65	0,327	0,001	1,67
CROM (right rotation)(°)					
Pre	55,4±11,0	57,4±12,2	0.685		
1week post	61,73±10,95	61,99±11,73	0,740	0,049	0,91
CROM (left rotation)(°)					
Pre	56,0±9,7	54,7±15,6	0.816		
1week post	64,32±12,98	64,09±10,23	0,857	0,005	1,37

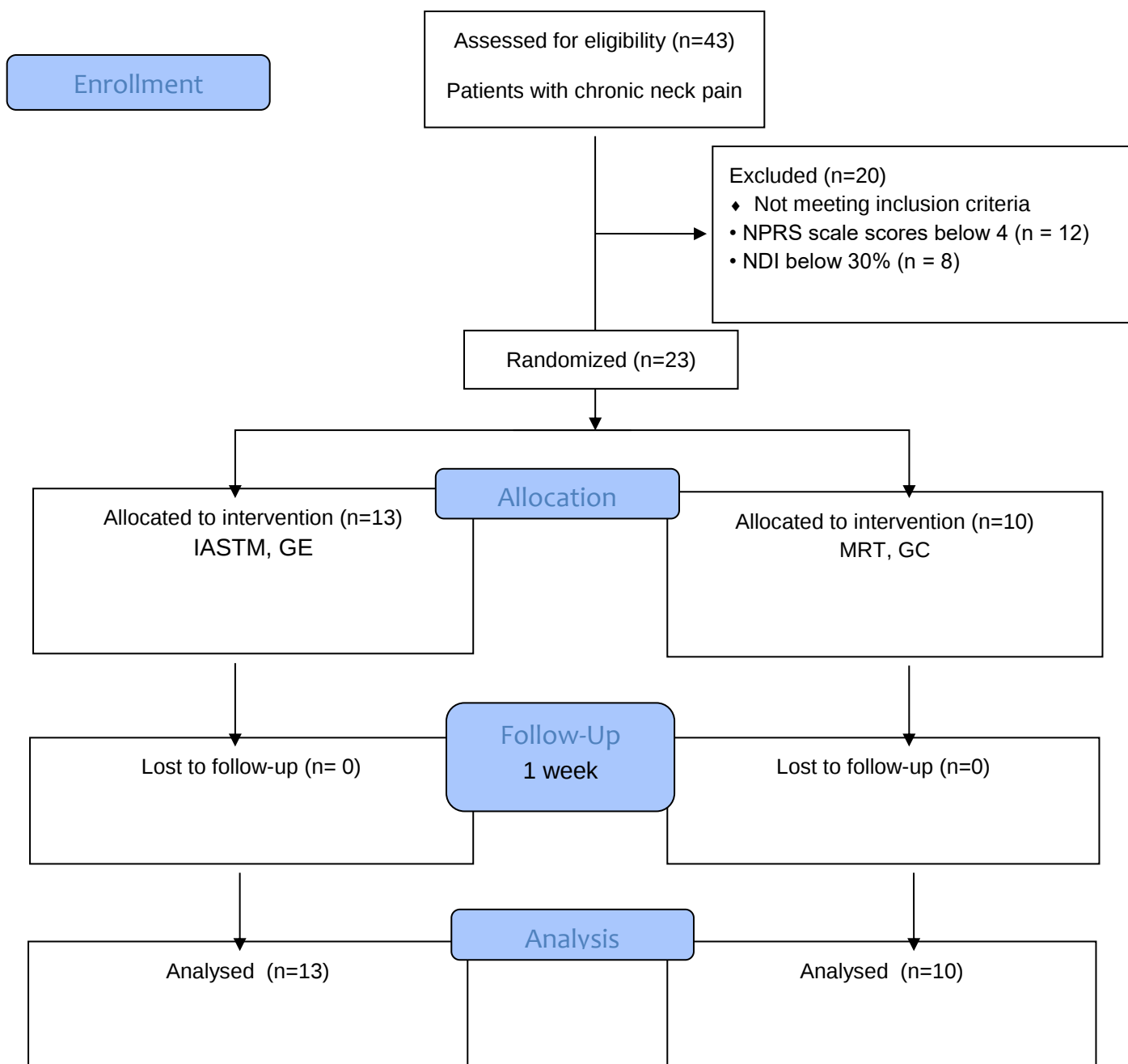
* Date are mean + SD for preintervention, and 1 week postintervention follow-up.

† p-value of independent T-test analysis at baseline;

Mixed Anova for repeated measures (inter-group) – post hoc Bonferroni p<.05 for interaction group-by-time - 1 week follow-up.

‡ interaction effect (time) - pre and post.

Cohen's d ^{""}: effect size.

ANEXO C - Figure 1. FLOW DIAGRAM OF SUBJECTS

ANEXO D – Parecer do CEP

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PARECER CONSUBSTANCIADO DO CEP

DADOS DO PROJETO DE PESQUISA

Título da Pesquisa: Efeitos da mobilização de tecidos moles assistida por instrumentos (IASTM) na dor e incapacidade em indivíduos com cervicalgia crônica inespecífica. Um ensaio clínico randomizado.

Pesquisador: Marcelo Faria Silva

Área Temática:

Versão: 3

CAAE: 79923917.8.0000.5345

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

Patrocinador Principal: Financiamento Próprio

DADOS DO PARECER

Número do Parecer: 2.547.677

Apresentação do Projeto:

INTRODUÇÃO: A dor cervical é uma condição clínica muito comum na população mundial, podendo chegar a afetar 70% das pessoas em algum momento da vida. Muitas dessas condições são provenientes de alterações músculo-esqueléticas, podendo essas serem causadas por disfunções miofasciais. A mobilização de tecidos moles assistida por instrumentos (IASTM) pode ser uma ferramenta terapêutica importante como meio de tratamento sob essas condições. **OBJETIVO:** Verificar o efeito da mobilização de tecidos moles assistida por Instrumentos (IASTM) na dor, Incapacidade e ADM em indivíduos com cervicalgia crônica inespecífica. **DELINEAMENTO:** Ensaio Clínico Randomizado. **MÉTODOS:** A amostra será composta por 46 indivíduos voluntários com dor cervical crônica inespecífica de ambos os sexos, com idade entre 18 e 60 anos, que apresentem dor manifestada há pelo menos doze semanas, sem irradiação para os membros superiores distalmente aos ombros. Desses, os que não forem excluídos, serão alocados randomicamente em um dos dois grupos presentes: Grupo Experimental (GE) - IASTM na região cervical e Grupo Controle (GC) – Liberação Miofascial manual na região cervical. Um avaliador cego será

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Continuação do Parecer: 2.547.877

designado para conduzir o processo de avaliação de ambos os grupos. **DESFECHOS:** Os desfechos serão a dor cervical, a incapacidade da coluna cervical e a amplitude de movimento da coluna cervical.

Objetivo da Pesquisa:

Objetivo Primário:

Verificar o efeito da mobilização de tecidos moles assistida por Instrumentos (IASTM) na dor, incapacidade e ADM em indivíduos com cervicalgia crônica inespecífica.

Objetivo Secundário:

Caracterização de indivíduos com cervicalgia crônica inespecífica. Descrever e comparar, nos momentos pré-intervenção, pós-intervenção num período de 3 semanas de acompanhamento, a intensidade de dor cervical utilizando a escala numérica de dor (END); a autopercepção de incapacidade utilizando o Neck Disability Index (NDI); as amplitudes de movimento (ADM) da coluna cervical – flexão, extensão, rotações e inclinações direita e esquerda através de um flexímetro pendular.

Avaliação dos Riscos e Benefícios:

Riscos:

Riscos: Devido aos movimentos realizados pelos instrumentos nos músculos, deverá haver desconforto muscular no momento da realização, bem como, poderá haver desconforto até 3 dias após o tratamento, porém isso é uma resposta normal do tratamento.

Benefícios:

Benefícios: O uso dos instrumentos, em oposição às mãos do fisioterapeuta, traz benefícios por proporcionar uma vantagem mecânica ao clínico permitindo uma penetração mais profunda e possivelmente aumentando a especificidade da aplicação do tratamento, enquanto promove a redução do estresse manual ao terapeuta imposto pelos tratamentos manuais. Para o paciente: Diminui o tempo total de tratamento, redução da dor, promove uma reabilitação / recuperação mais rápida, reduz a necessidade de medicação anti-inflamatória e resolve problemas crônicos.

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Continuação do Parecer: 2.547.877

considerados permanentes.

Comentários e Considerações sobre a Pesquisa:

Carta resposta com todas as adequações requeridas na primeira análise: No projeto, na página 13 no item 6.1 foi realizada a correção do termo equivocado "multicêntrico" para unicêntrico, devido a pesquisa ser realizada somente em um local, na cidade de Viamão. No projeto, na página 14 foi inserido o item 6.4.3 colocando os riscos e benefícios conforme solicitação. No cronograma, na página 20 foi mencionado que somente serão recrutados os pacientes após a aprovação do projeto perante o CEP. No TCLE, na página 25 foi retirado o termo ANEXO B, assim como, foi apresentado somente uma vez o título "Termo de Consentimento Livre e Esclarecido". Também conforme solicitação, foi deslocado para o final na página 27 o trecho do TCLE onde solicita ao participante colocar seus dados de identificação, da mesma forma ao qual foi retirado a inserção para os números de RG e CPF do participante. Foram reavaliados os termos e enfatizado o convite de forma mais clara. Foi descrito claramente os riscos e benefícios e as providências cautelares para evitar efeitos adversos. Foi acrescentado no início da página 26 a garantia do ressarcimento e cobertura das despesas tidas pelos participantes, assim como, indenização para eventuais danos.

Considerações sobre os Termos de apresentação obrigatória:

TCLE e demais termos adequados

Recomendações:

Aprovar

Conclusões ou Pendências e Lista de Inadequações:

Aprovado

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 INFORMACOES BÁSICAS DO PROJETO 1031820.pdf	16/01/2018 12:59:21		Acelto
Orçamento	ORCAMENTO2.docx	16/01/2018 12:52:18	Marcelo Faria Silva	Acelto
TCLE / Termos de Assentimento / Justificativa de	Termo de Consentimento Livre e Esclarecido3.docx	16/01/2018 12:51:30	Marcelo Faria Silva	Acelto

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Ausência	Termo_de_Consentimento_Livre_e_Esc	16/01/2018	Marcelo Faria Silva	Acelto
	arecido3.docx	12:51:30		
Outros	carta_resposta.pdf	23/12/2017	Marcelo Faria Silva	Acelto
		17:59:41		
Outros	AXEXO_E_folder_divulgacao.pdf	23/12/2017	Marcelo Faria Silva	Acelto
		17:35:01		
Projeto Detalhado / Brochura Investigador	Efeitos_da_mobilizacao_de_tecidos_mol	23/12/2017	Marcelo Faria Silva	Acelto
	es_assistida2.docx	17:32:42		
Cronograma	CRONOGRAMA.docx	23/12/2017	Marcelo Faria Silva	Acelto
		17:30:07		
Outros	ANEXO_D_Neck_Disability_Index.pdf	13/11/2017	Marcelo Faria Silva	Acelto
		16:36:31		
Outros	ANEXO_C_Escala_Numerica_de_Dor.p	13/11/2017	Marcelo Faria Silva	Acelto
	df	16:36:05		
Outros	ANEXO_A_questionario.pdf	13/11/2017	Marcelo Faria Silva	Acelto
		16:35:28		
Outros	relatorio.pdf	13/11/2017	Marcelo Faria Silva	Acelto
		16:19:16		
Declaração de Instituição e Infraestrutura	anuenda.pdf	13/11/2017	Marcelo Faria Silva	Acelto
		16:13:52		
Folha de Rosto	Folha_Rostoassinada.pdf	13/11/2017	Marcelo Faria Silva	Acelto
		16:09:36		

Situação do Parecer:

Aprovado

Necessita Apreciação da CONEP:

Não

PORTO ALEGRE, 16 de Março de 2018

Assinado por:
ELIANE DALLEGRAVE
(Coordenador)

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ANEXO E: Normas de formatação do periódico



MUSCULOSKELETAL SCIENCE AND PRACTICE

AUTHOR INFORMATION PACK

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For further information please contact:

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All those individuals who provided help during the research (e.g., providing language help, writing assistance or proofreading the article, etc.) that do not meet criteria for authorship should be acknowledged in the paper.

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Reference to a chapter in an edited book:

Toupet M, Gage P, Heuschen S. Vestibular patients and aging subjects lost use of visual input and expend more energy in static postural control. In: Veillas B, Toupet M, Rubenstein L, et al., editors. *Balance and gait disorders in the elderly*. Paris: Elsevier; 1988. p. 183-98.

Note shortened form for last page number. e.g., 51-9. For further details you are referred to "Uniform Requirements for Manuscripts submitted to Biomedical Journals" (*J Am Med Assoc* 1997;277:927-34), see also http://www.nlm.nih.gov/bsd/uniform_requirements.html

Journal abbreviations source

Journal names should be abbreviated according to

Index Medicus journal abbreviations: <http://www.nlm.nih.gov/tsd/serials/tjl.html>;

List of title word abbreviations: <http://www.lssn.org/2-22661-LTWA-online.php>