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OS EFEITOS DA ASSOCIAÇÃO DO TRATAMENTO OSTEOPÁTICO A UM PROTOCOLO DE EXERCÍCIOS NA DOR E INCAPACIDADE DE INDIVÍDUOS COM DOR CERVICAL CRÔNICA INESPECÍFICA: ENSAIO CLÍNICO PRAGMÁTICO

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Tese submetida ao Programa de Pós-Graduação em Ciências da Saúde da Universidade Federal de Ciências da Saúde de Porto Alegre como requisito para a obtenção do grau de Doutor

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Dedico este trabalho...

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RESUMO

A dor cervical é considerada uma experiência sensorial e emocional desagradável na região do pescoço associada a danos teciduais reais ou potenciais. É um problema de saúde pública altamente prevalente com impacto no bem-estar geral, custos por ausência no trabalho e por despesas médicas. Existem muitas opções para o tratamento da dor no pescoço, incluindo terapia manual, fisioterapia, tratamentos medicamentosos, exercícios físicos e educação dos pacientes. As evidências atuais relatam que o Tratamento Manipulativo Osteopático (TMO) é mais eficaz que o tratamento placebo ou nenhum tratamento, para dor e funcionalidade, em pacientes com dor no pescoço crônica inespecífica. No entanto, nenhum estudo avaliou os efeitos do TMO associado a exercícios de fortalecimento e alongamento na dor e na funcionalidade de pacientes com dor cervical.

O objetivo deste estudo foi investigar os efeitos da associação TMO e exercícios físicos para região cervical, no alívio da dor e incapacidade para dores no pescoço inespecíficas. Utilizando um desenho pragmático de ensaio clínico randomizado com avaliadores cegados, os participantes foram divididos em dois grupos: Grupo de Exercícios (GE; n = 45) em que o tratamento foi realizado com exercícios isométricos e alongamentos passivos por quatro semanas e Grupo Exercícios associado ao Tratamento Manipulativo Osteopático (GE/TMO; n = 45) em que realizou tratamento com exercícios isométricos e alongamentos passivos associados ao TMO de acordo com as necessidades de cada indivíduo, também por quatro semanas. Após a avaliação, os participantes iniciaram o tratamento, que consistiu em 4 consultas com intervalos de 7 dias entre elas. A dor foi avaliada através do uso de uma

escala numérica de classificação da dor de 0 a 10 e do limiar de dor à pressão com o uso de um algômetro de pressão. A funcionalidade foi medida pelo Neck Disability Index e a amplitude de movimento de rotação do pescoço usando equipamento de goniometria gravitacional CROM®. O questionário Fear-Avoidance-Beliefs também foi utilizado para crenças e medos relacionados ao trabalho e atividade física. Todos os resultados foram coletados antes do tratamento, ao término do tratamento (30 dias após a primeira sessão), e após 3 e 6 meses do início do tratamento. Utilizou-se como modelo estatístico as Equações de Estimação Generalizada, que permite análises multivariadas, indicando que o Tratamento Manipulativo Osteopático associado a exercícios reduziu a dor (*P* = 0,007) e a incapacidade (*P* = 0.01) após 4 semanas de tratamento, com diferença significante comparado com grupo exercício, bem como a rotação ativa cervical foi significativamente maior no grupo que recebeu TMO (p=0,03). Não foram observadas diferenças, após 4 semanas de tratamento, entre os grupos na medida do limiar de dor à pressão e no questionário de crenças FABQ. Além disso, não foram encontradas diferenças significativas na intensidade da dor ou incapacidade funcional, quando os grupos foram comparados: aos 3 meses (p = 0,1 ; p = 0,2) ou 6 meses (p = 0,4 ; p = 0,9) e também não foi encontrada diferença entre os grupos nos desfechos secundários no mesmo período de acompanhamento.

A associação entre TMO e exercícios reduz a dor e melhora a capacidade funcional quando comparado com exercícios de forma isolada para indivíduos com dor crônica inespecífica no pescoço, esta melhora ocorreu apenas quando os resultados foram avaliados a curto prazo, ou seja, 30 dias após o início do tratamento.

Palavras-chave: Osteopatia. Tratamento Manipulativo Osteopático. Manipulação musculoesquelética. Terapia Manual. Cervicalgia. Dor Cervical.

ABSTRACT

Neck pain is considered to be an unpleasant sensory and emotional experience in the region of the neck associated with actual or potential tissue damage. Neck pain is highly prevalent public health problem in terms of overall well-being, cost of work absence and medical expenses. There are many options for the management of neck pain including manual therapy, physical therapy, drug treatments, exercises and education of patients. Current evidence has reported that OMT is more effective than placebo treatment or no treatment for pain and functionality in patients with nonspecific chronic neck pain. However, no study has evaluated the effects of OMT associated with strengthening and stretching exercises on pain and functionality of patients with cervical pain.

The aim of this study was to investigated the effects of association OMT and exercises in the relief of pain and disability for non-specific neck pain. Using a pragmatic design of a randomized clinical trial with blinded evaluators, participants were divided into two groups: Exercises Group (EG; n = 45) in which treatment was performed using isometric exercises and passive stretching for four weeks and TMO Group (TMO/EG; n = 45) in which held treatment with isometric exercises and passive stretching associated with TMO according to the needs of each individual during four weeks. After the evaluation, the participants began the treatment, that consisted of 4 consultations with 7 days intervals between them. The pain was evaluated in the following ways: through the use of a numeric pain rating scale (NPRS) of 0-10 and through pressure pain threshold (PPT) with the use of a pressure algometer. The functionality was measured by Neck Disability Index (NDI) and neck range of motion in rotation, which were collected before and at the end of

treatment. The Fear-Avoidance-Beliefs questionnaire (FABQ) was also used for beliefs and fears related to work and physical activity. All outcomes were collected pre-treatment 30 days after treatment and after 3 and 6 months after initiation of treatment.

Analysis with GEE was done and indicated that OMT/EG reduced pain and disability more than the EG alone after 4 weeks of treatment with statistically significant difference ($p<0,05$), as well as cervical active rotation was significantly improved ($p = 0.03$). There were no between-group differences observed in Pressure Pain Threshold (PPT) measure, Fear-Avoidance Beliefs Questionnaire and Pain-self efficacy. However, no statistically significant differences in pain intensity or disability were found when OMT/EG was compared with EG at 3 ($p = 0.1$ and $p = 0.2$, respectively) or 6 months ($p = 0.4$ and $p = 0.9$, respectively for pain or disability) and no difference was found between OMT/EG and the EG in the secondary outcomes at the same follow-up period ($p > 0.05$).

The association between OMT and exercises reduces pain and improves functional disability more than exercise alone for individuals with non-specific chronic neck pain short term only.

Keywords: Osteopathy. Osteopathic Manipulative Treatment. Musculoskeletal manipulation. Manual therapy. Neck Pain.

Sumário

APRESENTAÇÃO

Este trabalho intitulado “Os efeitos da associação do tratamento osteopático a um protocolo de exercícios na dor e incapacidade de indivíduos com dor cervical crônica inespecífica ensaio clínico pragmático”, consiste na tese de doutorado do aluno Sandro Groisman que será apresentada ao Programa de Pós-Graduação em Ciências da Saúde da Universidade Federal de Ciências da Saúde de Porto Alegre como parte para obtenção do título de Doutor em Ciências da Saúde. Essa pesquisa foi submetida ao Comitê de Ética em Pesquisa da Universidade Federal de Ciências da Saúde de Porto Alegre, conforme parecer número 1.970.517.

A tese é composta pelas seguintes partes: apresentação, revisão da literatura, justificativa, objetivos e o desenvolvimento que está apresentado na forma de dois artigos. O primeiro artigo foi apresentado para banca como artigo de qualificação para doutorado e posteriormente as correções sugeridas pela banca, foi publicado no Journal of Bodywork e Movement Therapies sob o título “*Osteopathic manipulative treatment combined with exercise improves pain and disability in individual with non-specific chronic neck pain: A pragmatic randomized contolled trial*” será submetido para apreciação do corpo editoria do mesmo periódico

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1. REVISÃO DA LITERATURA

1.1. Introdução

Dor cervical de origem musculoesquelética possui alta prevalência sendo a quarta causa de afastamento ocupacional, quando associada com dor lombar se torna a primeira causa de incapacidade medida através do tempo em anos que as pessoas vivem com incapacidade [1]. Estudos descrevem que até 50% das pessoas apresentarão algum episódio de dor cervical em algum momento da vida [2; 3; 4]. Destes, mais de um terço desenvolvem sintomas crônicos que persistem por mais de 3 meses [4; 5].

Na maior parte das vezes a causa da dor é desconhecida, sendo assim denominada dor cervical inespecífica [6]. No entanto, sabe-se que aspectos mecânicos, biológicos e psicossociais se relacionam com a queixa e seu prognóstico. Podendo causar diferentes níveis de incapacidade para o indivíduo afetado e um alto custo para a sociedade.

A abordagem clínica para o diagnóstico de dor cervical inespecífica deve primeiramente excluir outras causas, como, por exemplo: tumorais, infecciosas e as radiculopatias identificadas por sinais e sintomas específicos que são denominados de “bandeiras vermelhas” [7]. Os sinais e sintomas associados ao diagnóstico por imagem (ressonância magnética) e testes eletrofisiológicos (velocidade de condução nervosa, eletromiografia) são comumente usados como padrão ouro para o diagnóstico diferencial de dor cervical crônica de origem inespecífica [8; 9; 10; 11].

Em 2003, no estudo de Robert Wainner e col. usando a velocidade de condução neural foi derivada uma Regra de Predição Clínica (RPC) para

identificar a presença de radiculopatia cervical usando um subconjunto de variáveis a partir do exame clínico [11]. A RPC pode identificar radiculopatia cervical com os seguintes testes: teste Spurling, teste de distração, teste neural de tensão do membro superior (nervo mediano), e apresentar rotação cervical ipsilateral menor que 60 graus. A RPC exibiu uma especificidade de 94% (razão de verossimilhança positiva de 6,1, com intervalo de confiança de 95% [IC] 2,0-18,6), quando três de quatro destes critérios foram satisfeitos. Quando todos, dos quatro testes propostos, forem positivos, a probabilidade pós-teste de radiculopatia cervical é de 90%, se apenas três forem positivos a probabilidade é de 65%.

O impacto dos tratamentos na melhora da dor e da funcionalidade dos pacientes com dor cervical pode ser avaliado por uma gama de medidas e questionários autoaplicáveis como: NDI – Neck Disability Index [12; 13; 14], Escala numérica de percepção de dor ENPD[15], Avaliação da Percepção do efeito global, FABQ - Fear-Avoidance-Beliefs Questionnaire [16; 17] entre outras.

Existe evidência que mais de 50% dos pacientes com dor cervical são encaminhados para tratamentos manipulativos, compreendendo aproxima-damente 25% de todos os pacientes que procuram por tratamentos manipulativos ou fisioterapia [18; 19].

Existem várias opções para o manejo da dor cervical de origem inespecífica. As mais frequentes citadas na literatura são: terapia manual, eletroterapia, tratamento medicamentoso, exercícios e educação para dor [20].

A prescrição de exercícios físicos específicos para fortalecimento e alongamento dos músculos do pescoço é uma modalidade terapêutica que

apesar de muito utilizada na prática, possui evidências moderadas em relação à sua eficácia. Miller e col. em 2010 realizaram uma revisão sistemática que incluiu 27 estudos, concluindo com moderada evidência que exercícios físicos impactam na melhora da dor, da funcionalidade e satisfação do paciente com dor cervical crônica de origem inespecífica. Neste estudo foi avaliada a melhora da dor e da funcionalidade em quatro momentos: imediatamente após o tratamento (um dia), curto prazo (até três meses), prazo intermediário (de três meses a um ano) e longo prazo (um ano ou mais). Além disso os autores referem não existir uma superioridade de alguma modalidade de exercício. Esta revisão demonstra ainda a falta de evidência de alta qualidade, sugerindo com moderada evidência que exercícios de fortalecimento dos músculos escápulo-torácicos e cervicais associados a alongamentos podem diminuir a dor e melhorar a funcionalidade [21].

A terapia manual é uma abordagem amplamente utilizada apresentando um expressivo aumento no número de ensaios clínicos que investigam esta prática nos últimos anos. Entretanto, somente evidências de moderada qualidade suportam o uso de tratamentos manipulativos para tratamento da dor cervical. Em uma revisão sistemática, Gross e col. [22] encontraram efeitos a curto prazo na diminuição da dor quando utilizada unicamente manipulação ou mobilização. Estes efeitos também foram verificados por outros autores quando se utiliza uma manipulação torácica alta de forma isolada [23]. Além disso, muitos estudos investigam manipulações e/ou terapias manuais de forma isolada[22] o que não representa a prática clínica onde geralmente o terapeuta utiliza uma gama de técnicas, segundo seu julgamento clinico, realizando pragmaticamente um tratamento multimodal.

A associação de exercícios à terapia manual parece ser benéfica. Existem evidências de que essa associação impacta na diminuição da dor a curto prazo mais do que quando se usa manipulação ou mobilização como terapia isolada [21; 24].

A Osteopatia ou Tratamento Manipulativo Osteopático (TMO) é uma abordagem não invasiva que incorpora técnicas manuais de diagnóstico e tratamento seguindo princípios pré-estabelecidos, como inter-relação entre estrutura e função, capacidade intrínseca de autorregulação (homeostase) e o conceito de unidade corporal [25].

O TMO é descrito na literatura como benéfico para tratamento da dor e disfunção da região cervical [26; 27; 28]. Estes estudos, no entanto, realizaram tratamentos protocolados e não de forma pragmática o que limita a robustez das conclusões e aplicações clínicas. Em relação a associação de TMO com outras intervenções, como por exemplo a exercícios físicos, nenhum estudo foi encontrado. Franke e col (2015) [28], em uma revisão sistemática que objetivou avaliar os efeitos do TMO na dor e na funcionalidade de indivíduos com dor cervical crônica de origem inespecífica, concluíram que o TMO diminui a dor. Entretanto, além dos estudos incluídos possuírem diferentes parâmetros, nenhum estudo utilizou TMO associado a exercícios físicos, sendo este tópico sugerido pelos autores para futuras pesquisas. Dessa forma, é fundamental conhecer o impacto do TMO associado a exercícios físicos em pacientes com dor cervical de origem inespecífica.

1.2 Dor Crônica Cervical

Dor é considerada uma experiência desagradável e angustiante associada ao dano real ou potencial do tecido com componentes sensoriais, emocionais, cognitivos e sociais na região do pescoço [29]. A Associação Internacional para o Estudo da Dor (IASP) define dor crônica na coluna cervical como uma "dor percebida em qualquer lugar na região posterior da coluna cervical, que se estende da linha nucal superior ao primeiro processo espinhoso torácico". Corroborando com a definição, a IASP e a "*Bone and Joint Task Force on Neck Pain and Its Associated Disorders"* descrevem a dor no pescoço como "dor localizada na região anatômica do pescoço com ou sem irradiação para cabeça, tronco e membros superiores" [30].

Em relação à classificação, a dor é tipicamente classificada como dor aguda com duração de até 6 semanas, dor subaguda com duração de 6 a 12 semanas e dor crônica com duração acima de 12 semanas, e é entendida e manejada de forma diferente, dependendo da classificação. A dor aguda pode ser definida como uma dor de curto prazo com menos de 3 meses de duração que geralmente ocorre em resposta a lesões ou danos nos tecidos e, em termos simples, é geralmente considerado como um sinal de dano real ou potencial [31]. Já a dor crônica é definida quando tem duração de 12 semanas ou mais e geralmente se apresenta como hiperalgesia generalizada à palpação e nos movimentos (passivo e ativo) na área do pescoço e ombro [32]. A ocorrência da dor crônica não é geralmente o resultado de uma nova

lesão tecidual, embora possa ser associada a uma lesão que não tenha sido resolvida ou curada dentro de um período de tempo esperado [31].

Dor crônica cervical, como outras condições crônicas, geralmente é considerada de etiologia multicausal. Muitas vezes há vários tecidos implicados que contribuem para o quadro clínico geral. Podendo ser difícil determinar qual o tecido lesionado ou em disfunção. Estruturas, como tecido nervoso e muscular ou processos, como degeneração articular, contribuem de forma e intensidade diferentes para a disfunção global padrão. No entanto, na maioria dos casos de dor cervical crônica há pouca evidência de patologia ou causa específica, e a dor no pescoço é classificada como inespecífica [33].

Sendo a causa da dor crônica, freqüentemente, desconhecida e, como tal, difícil de tratar eficazmente, pode estar associada a uma condição subjacente ou ser consequência de processo de doença (por exemplo, artrite). Como na maioria dos casos a etiologia da dor crônica é desconhecida, uma explicação poderia ser o papel de fatores psicológicos e sociais. É importante salientar que os fatores psicossociais são relacionados não só como fatores etiológicos, mas também no prognóstico de incapacidade destes indivíduos. Com isso é importante associar fatores anatômicos, psicológicos, sociais e profissionais. Isso é consistente no modelo biopsicossocial , que considera a dor como uma interação dinâmica entre fatores biológicos, psicológicos e sociais exclusivos de cada indivíduo[34]. Existem evidências de que fatores psicossociais desempenham um papel fundamental na transição da fase aguda para crônica. A dor cervical pode começar aparentemente como um simples problema, podendo evoluir para uma condição complexa, na qual, uma gama de fatores psicológicos e sociais

interagem com fatores físicos, causando incapacidade, afetando a capacidade de um indivíduo de realizar atividades diárias normais e laborais. Isso tudo poderá afetar a qualidade de vida devido aos comportamentos de “medo-evitação”: isto é, evitar atividades ou movimentos por medo de causar dor [35].

1.3 Epidemiologia

A dor cervical, às vezes chamada de cervicalgia, é uma das queixas musculoesqueléticas mais frequentes, podendo afetar até 70% da população em algum momento da vida [36; 37]. Estima se que 30% dos pacientes com dor no pescoço desenvolverão sintomas crônicos, por mais de seis meses, afetando 14% de todos os indivíduos que tiveram um episódio de dor cervical. Dos indivíduos que experimentam dor no pescoço, 37% relataram problemas persistentes por pelo menos 12 meses [1]. E ainda, cinco por cento da população adulta com dor no pescoço desenvolverá importante incapacidade para o trabalho pela dor, representando um sério problema de saúde, pois não é apenas um problema de saúde pessoal com consequências na qualidade de vida de uma pessoa, mas sua alta prevalência a torna um grande problema de saúde pública em termos de bem-estar geral, custos de ausência no trabalho e despesas médicas [36] [37] [2].

Estudos consistentes relatam que a prevalência de dor cervical aumenta com a idade, sendo acima de 40 anos um ponto de corte considerado fator de risco. A maior incidência ocorre em mulheres do que em homens [4; 36], e tem sido sugerido que isso pode ser baseado em diferentes mecanismos fisiológicos para percepção da dor entre os sexos [38].

1.4 Medidas e escalas para avaliação da dor e incapacidade

A avaliação de indivíduos com dor cervical crônica de origem inespecífica deve seguir o exame usual da coluna cervical, com a identificação de situações clínicas denominadas “bandeiras vermelhas” e somente após utilizar ferramentas de medidas de dor e função. Os fisioterapeutas devem se utilizar de questionários validados, estas ferramentas são úteis para identificar o estado inicial do indivíduo, relativo à dor e função, com isso, além de prover uma previsão de prognóstico podemos acompanhar os resultados de tratamento.

Há uma variedade de ferramentas disponíveis para mensurar a dor e a capacidade funcional, e especialmente questionários autoaplicáveis, que detectam mudanças na percepção da dor e incapacidade dos indivíduos. Para este estudo, escolhemos para avaliar os desfechos primários medidas com boa confiabilidade. O Índice de Incapacidade do Pescoço (Neck Disability Index - NDI) é comumente usado para medir a incapacidade e a Escala Numérica de Percepção de Dor (ENPD) é comumente usado para medir a intensidade da dor. Outra medida utilizada para percepção de dor é a sensibilidade dolorosa à pressão. Outros desfechos que relacionam dor com aspectos mecânicos e biopsicossociais são importantes para poder quantificar outras dimensões da dor, que também influenciam na funcionalidade e qualidade de vida. A literatura refere medidas de amplitude de movimento utilizando um goniômetro validado (CROM), medidas de crenças e medos (escala FABQ), autoeficácia em relação à dor e avaliação da percepção do efeito global de um tratamento.

1.4.1 Escala Numérica de Percepção da Dor (ENPD)

A dor é uma medida de desfecho primário na maioria dos estudos de intervenção músculoesquelética. A abordagem mais comum para a mensuração da dor é através do autorrelato do paciente, usando escala visual analógica ou de avaliação numérica da dor. Embora a intensidade da dor autorrelatada seja importante, é composto de características fisiológicas e psicológicas da pessoa e do problema de saúde, mediada por aspectos sociais. A ENPD é uma escala simples que avalia a intensidade da dor, é solicitado que o indivíduo dê uma nota em uma escala numérica de percepção à dor de 0-10, onde zero é sem dor e 10 uma dor insuportável. A escala foi relatada como um dos melhores métodos disponíveis para estimar a intensidade da dor. Uma diferença mínima de 2 pontos é necessária para ser clinicamente significativa, através do espectro da gravidade da dor. A ENPD tem sido usada em muitos outros estudos além de ser uma ferramenta de avaliação padrão na prática clínica [39; 40].

1.4.2 Avaliação do Limiar Pressórico de Sensibilidade Dolorosa (LPSD - Algometria)

LPSD ou limiar de dor à pressão é definido como a quantidade de pressão necessária para que um sujeito relate o início da dor, enquanto que tolerância à dor é a intensidade de estímulo necessário para que o sujeito perceba a dor insuportável[41]. Provocar dor mecanicamente, em particular o LPSD, é um modelo popular para induzir agudamente dor experimental. É um procedimento manual que requer uma resposta perceptiva do participante ou paciente. A confiabilidade dos dados LPSD é, por conseguinte, dependente

não só da aplicação técnica do examinador, mas também da capacidade do paciente ou participante em fornecer uma resposta verbal consistente da indicação do nível de dor. No decorrer dos anos, inúmeros autores vêm estudando a confiabilidade na repetição das medições do LPSD. Eles demonstram, que a repetibilidade das medições entre os ensaios apresentam boa confiabilidade [42].

A avaliação desta medida é relativamente simples, para tal, utiliza-se um algômetro de pressão digital, que consiste em um transdutor de pressão com capacidade de 10kg/força e deformação de compressão de 10cm. O algômetro para uso deve ser calibrado previamente[43]. Presença de dor com baixas pressões pode representar aumento da sensibilidade local sugerindo uma hipersensibilidade mecânica. A medida apresenta excelente repetibilidade interexaminadores (ICC = 0,96 95% IC 0,69-0,91) e intraexaminadores (ICC = 0.89; 95% IC: 0.83- 0.93) [41]

1.4.3 Questionário NDI: Neck Disability Index

O “Neck Disability Index” consiste em um questionário autoaplicável com objetivo de medir o quanto a dor e a disfunção cervical afetam as habilidades em realizar atividades de vida diária. Um grandre número de estudos relacionados ao tratamento da dor cervical utiliza o questionário NDI como medida de resultado [44; 45]. É uma ferramenta fortemente estudada em relação a suas propriedades psicométricas. A escala já foi traduzida para vários idiomas, o que permite a comparação dos estudos em países diferentes. O NDI gradua a intensidade de disfunção em cinco níveis [12; 44]. É um questionário autoaplicável com 10 itens sobre a vida diária, dor e capacidade de

concentração. Cada item é pontuado de 0 a 5; sendo 0, representando nenhuma incapacidade e 5, significando incapacidade extrema. Uma diferença mínima clinicamente importante de pelo menos 5 pontos de um total de 50 é necessária para ser clinicamente significativo. O NDI tem demonstrado ter alto grau de confiabilidade de teste-reteste (CCI = 0,91). Além disso, os escores do NDI se correlacionam com escores das escalas de dor e também com a Pontuação do McGill Pain Questionnaire [46].

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1.4.4 Avaliação da mobilidade de rotação cervical (CROM)

A amplitude de movimento de rotação cervical é um importante indicador de função da mecânica cervical avaliada por meio do aparelho CROM, desenvolvido e comercializado pela Performance Attainement Associates (EUA). O aparelho é posicionado com apoios sobre o nariz e as orelhas do participante, como um capacete fixado à cabeça por uma cinta de velcro. Um colar magnético é colocado no pescoço durante a medida de rotação para calibrar o goniômetro, que varia de 2 em 2 graus, e convencionalmente nos estudos, o norte (N) é voltado para o lado esquerdo. O participante deve ser posicionado com o CROM na posição em pé ou sentado com a cabeça apoiada em uma parede para evitar movimentos de protusão ou retração. Uma revisão sistemática [47] de alta qualidade revisou 36 estudos que utilizaram o "*Cervical Range of Motion"* e concluíram que o CROM pode ser utilizado como ferramenta para medida de amplitude de movimento em várias afecções da coluna cervical. Williams e col. 2010 revisaram 46 artigos sobre confiabilidade e

21 artigos sobre validade da avaliação da ADM cervical, encontrando boa confiabilidade e validade para o dispositivo CROM [48].

1.4.5 Questionário FABQ: Fear Avoidance Beliefs

O Fear Avoidance Beliefs Questionnaire (FABQ) autoaplicável [16; 17; 49] , originalmente desenvolvido e validado na língua inglesa [17], foi traduzido e validado para vários idiomas incluindo o português em uma versão brasileira. Consiste em 16 questões divididas em duas subescalas: a que aborda os medos e as crenças dos indivíduos em relação ao trabalho (FABQ-Work) e a que aborda seus medos e crenças em relação às atividades físicas (FABAQ-Phys). Cada item é graduado de 0 (discordo completamente) a 6 (concordo completamente). A escala possui uma consistência interna de α = 0,88 para a subescala relacionada ao trabalho e de α = 0,77 para a relacionada às atividades físicas [17].

1.4.6 Avaliação da percepção do efeito global

É uma escala de 11 pontos que varia de menos cinco pontos (muito pior), zero (nenhuma mudança) e cinco pontos (recuperado completamente). O participante deve ser questionado comparando o início do tratamento com o final. Esta escala é adaptada transculturalmente para o português e testada para suas propriedades de medidas [50 51; 52].

1.4.7 Autoeficácia para dor crônica

O conceito de autoeficácia é útil no manejo da dor crônica pois identifica comportamentos mal adaptativos. Está relacionado com a percepção de dor e

com as características funcionais dos indivíduos com dor. Para avaliação da autoeficácia é utilizada uma versão adaptada para a língua portuguesa do questionário. O instrumento possui cinco questões sobre o manejo da dor pelo próprio paciente, ou seja, o quanto o paciente consegue lidar com sua dor de forma a não interferir nos aspectos de atividades de vida diária. As respostas variam de 10 por cento de certeza até 100 por cento de certeza [53].

1.4.8 Escala de depressão e ansiedade (HADS)

É sabido que os fatores biopsicossociais podem contribuir para a dor e incapacidade persistentes do indivíduo, e influencia na transição de uma condição aguda para uma condição crônica e incapacitante [54]. Certas medidas de resultados podem ser usadas para avaliar fatores psicossociais, entre elas a avaliação da presença de ansiedade e depressão que deve ser observada em pesquisa clínica, com objetivo de verificar a homogeneidade dos grupos investigados. Uma ferramenta largamente utilizada é a escala HADS para ansiedade e depressão.

A escala HADS foi desenvolvida por Zigmond e Snaith (1983) [55], e validada para língua portuguesa [56]. A escala objetiva identificar e medir a intensidade de depressão e ansiedade em várias condições clínicas [57; 58]. Esta escala é composta por 14 itens, subdivididos em duas escalas: 7 itens medem a ansiedade (HADS-A) e os outros 7 a depressão (HADS-D). Com isso, fornece indicadores de ansiedade e depressão separadamente [55]. A escala é autoaplicável e solicita-se que o participante escolha a alternativa que mais se aproximava do que sentia na última semana. A pontuação varia de 0 a 3, podendo apresentar uma soma máxima de 21 pontos para ansiedade e 32 para

depressão. A interpretação dos resultados se faz por blocos estratificados, resultado final de 0 a 7 é indicativo de ausência de ansiedade ou depressão, entre 8 a 10 demonstra provável ansiedade ou depressão, e valores iguais ou superiores a 11 indicam grande possibilidade de ansiedade ou depressão. Os estudos, demonstram que a HADS possui boa sensibilidade, consistência interna e especificidade para avaliar os sintomas de ansiedade e depressão em populações com dor crônica [54; 55; 56].

1.5 Manejo da dor cervical crônica

1.5.1 Exercícios físicos

Os exercícios específicos para região do pescoço demonstram efeitos positivos no manejo da dor, demonstrando ser mais eficaz quando comparado com intervenções mais passivas, como terapia manual e massagens ou eletroterapia de forma isolada [37] . As evidências demonstram que exercícios de fortalecimento e resistência são benéficos quando associados com exercícios de alongamento e estabilização do pescoço. A terapia por exercícios objetiva, principalmente, melhorar a amplitude de movimento (ADM), a propriocepção cervical, a força e a resistência. Nenhum regime de exercícios se destaca; no entanto, as diretrizes clínicas são claras, indicando que exercícios direcionados às regiões cervical e escápulo-torácica são um componente necessário do manejo de pacientes com dor cervical crônica com déficits de mobilidade [37].

Miller e col. em 2010 realizaram uma revisão sistemática que incluiu 27 estudos, concluindo com moderada evidência, que exercícios físicos impactam na melhora da dor, da funcionalidade e satisfação do paciente com dor cervical crônica de origem inespecífica. Neste estudo foram avaliadas a melhora da dor e da funcionalidade em quatro momentos: imediatamente após o tratamento (um dia), curto prazo (até três meses), prazo intermediário (de três meses a um ano) e longo prazo (um ano ou mais). Além disso, é importante salientar que os autores referem não existir uma superioridade de alguma modalidade de exercício. Esta revisão demonstra ainda a falta de evidência de alta qualidade, sugerindo com moderada evidência que exercícios de fortalecimento dos

músculos escápulo-torácicos e cervicais associado a alongamentos, podem diminuir a dor e melhorar a funcionalidade [21].

1.5.2 Terapia manual

A terapia manual vem apresentando evidências positivas quanto a sua eficácia para tratamento da dor. Foi definida como uma abordagem clínica com as mãos (hands-on) para tratar problemas de saúde de diversas etiologias, com técnicas de movimento passivo incluindo manipulação, mobilização e massagem dos tecidos moles [59]. O termo manipulação descreve terapias manipulativas usadas por quiropraxistas, fisioterapeutas, osteopatas e outros terapeutas manuais. Muitos pesquisadores usam o termo manipulação para descrever técnicas de manipulação em alta velocidade e baixa amplitude (AVBA), na qual se aplica uma força numa articulação que a faz mover-se além de sua amplitude ativa e passiva de movimento, muitas vezes produzindo um som articular audível [60]. Em contraste com a manipulação, a mobilização usa movimentos passivos de baixa velocidade, com variadas amplitudes. É uma forma de movimento sem impulso, em que a força manual é aplicada em direção às articulações dentro de sua amplitude passiva de movimento [61]. Tanto manipulação como mobilização da coluna cervical são técnicas comuns de terapia manual para o tratamento da dor no pescoço, e demonstraram efeitos positivos na dor, na disfunção e na amplitude de movimento cervical [22].

As terapias manuais são comumente usadas no tratamento de dores cervicais crônicas, apresentando um expressivo aumento no número de ensaios clínicos que investigam esta prática nos últimos anos [37], além de inúmeras revisões sistemáticas que utilizam a terapia manual como tratamento

da dor cervical [62] [22] [30] [63]. Gross e col. [22] encontraram efeitos a curto prazo na diminuição da dor quando utilizada unicamente manipulação ou mobilização. Estes efeitos também foram verificados por outros autores quando se utiliza uma manipulação torácica alta de forma isolada [23]. Entretanto as evidências existentes são de moderada qualidade, para suportar o uso de tratamentos manipulativos no tratamento da dor cervical crônica, pois a qualidade metodológica dos estudos, incluídos em muitas dessas análises, apresentam falhas quanto ao método.

Apesar dos estudos investigarem manipulações e/ou terapias manuais de forma isolada [22], essas práticas não representam o dia-a-dia na clínica onde geralmente o terapeuta utiliza uma gama de técnicas segundo o seu julgamento clínico, realizando pragmaticamente um tratamento multimodal.

1.5.3 Tratamento Manipulativo Osteopático - TMO

A Osteopatia ou Tratamento Manipulativo Osteopático (TMO) é uma abordagem de saúde não invasiva, que incorpora técnicas manuais de diagnóstico e tratamento seguindo princípios pré-estabelecidos como inter-relação entre estrutura e função, capacidade intrínseca de autorregulação (homeostase) e o conceito de unidade corporal [25].

Embora pacientes com dor no pescoço procurem tratamento osteopático, o número de pacientes que procuram este tipo de tratamento no Brasil é desconhecido. No Reino Unido estima-se que 4,38 milhões de tratamentos são realizados por ano [64].

Existem pesquisas muito limitadas a respeito da eficácia do tratamento osteopático no tratamento da dor crônica no pescoço, com apenas alguns poucos artigos publicados na literatura [28; 45; 65; 66; 67].

O estudo de Fryer e col., (2005) [67] empregaram cuidados multimodais em sua intervenção terapêutica para a diminuição da dor crônica e subcrônica, em 17 participantes. A intervenção no estudo está clara e consistia em várias técnicas, incluindo tecidos moles, músculo-energia, contra-tensão e impulso de baixa amplitude e alta velocidade (HVLA) aplicados a coluna cervical e torácica, bem como a inclusão de aconselhamento postural e prescrição de exercícios (mobilidade do pescoço e alongamento), a critério do praticante. Este estudo demonstrou redução média (± DP) na intensidade da dor ao longo do tempo em uma escala analógica visual de 11 pontos, de (6,5 ± 3,1 cm) no pré-tratamento para (2,4 ± 2 cm) 2 semanas após tratamento e de (1,4 ± 2 cm) na quarta semana após o tratamento. A principal limitação do estudo de Fryer e col., (2005) é que, como coorte não apresentou grupo controle além de avaliar os resultados somente a curto prazo.

Mandara e col., (2010) investigaram os efeitos do tratamento em 28 indivíduos com dor crônica no pescoço. A intervenção no estudo de Mandara e col., (2010) foi menos clara, com uma descrição dizendo 'tratamento padrão' e impede uma análise mais aprofundada, pois não se sabe se o tratamento foi multimodal e se foi exatamente dentro do conceito osteopático [45].

Ambos os estudos, apesar das falhas no método, concluíram que a dor e a incapacidade autoavaliadas reduziram significativamente após 6 tratamentos osteopáticos.

No estudo de Fryer e col. (2015) [28], que objetivou avaliar os efeitos do TMO na dor e na funcionalidade de indivíduos com dor cervical crônica de origem inespecífica, foram incluídos somente 3 estudos e concluíram que o TMO diminui a dor sem efeitos na funcionalidade, e também salienta que existe uma falta de evidência em relação aos efeitos a médio e longo prazo.

A associação de exercícios à terapia manual parece ser benéfica. Existem evidências de que essa associação impacta na diminuição da dor a curto prazo mais do que quando se usa manipulação ou mobilização como terapia isolada [21; 24].

Galindez-Ibarbengoetxea e col. (2017) estudaram indivíduos com dor no pescoço, analisando os efeitos imediatos na dor de um tratamento osteopático em comparação ao uso do protocolo de exercícios [66]. Observou-se que ambas as intervenções foram associadas à melhora imediata da amplitude de movimento e dor após o tratamento. Houve também uma mudança significativa no limiar de dor por pressão no trapézio superior após as duas intervenções (Galindez-Ibarbengoetxea e col., 2017). É importante salientar que esses autores não utilizaram o tratamento osteopático de maneira pragmática. Além disso, osteopatia e exercícios foram utilizados separadamente, então até o momento não foi encontrado algum estudo que investigue TMO e exercícios de forma combinada.

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2 JUSTIFICATIVA

Como visto anteriormente, a dor cervical de origem inespecífica possui alta incidência e prevalência, representa uma parcela significativa dos pacientes que procuram tratamento manipulativo osteopático.

Tanto a Terapia Manual quanto o TMO são descritos na literatura como benéficos para tratamento da dor e disfunção da região cervical. Apesar de existir escassa literatura sobre o TMO e dor cervical, os estudos existentes são desenhados com tratamentos protocolados e não de forma pragmática, o que limita a robustez das conclusões e aplicações clínicas.

Apesar de ser indicado associar terapia manual com terapia por exercícios, a associação do TMO com outras intervenções, como por exemplo a exercícios físicos, ainda não havia sido pesquisada. Nenhum estudo foi encontrado avaliando os efeitos do tratamento manipulativo osteopático associado ao exercício físico em pacientes com dor cervical de origem inespecífica.

Dessa forma, verificou-se a necessidade de investigar a eficácia e o impacto do TMO associado a exercícios em pacientes com dor cervical de origem inespecífica.

3 OBJETIVOS

3.1 Objetivos gerais

O objetivo do presente trabalho foi avaliar a curto e médio prazo os efeitos do tratamento manipulativo osteopático associado a exercícios cervicais, na dor e na funcionalidade de participantes com dor cervical de origem inespecífica.

3.2 Objetivos específicos

Comparar o efeito das duas formas de intervenção terapêutica sobre os valores obtidos na escala numérica de dor, imediatamente após o término do tratamento proposto, em participantes com dor cervical crônica de origem inespecífica.

Comparar o efeito das duas formas de intervenção terapêutica sobre o limiar pressórico de sensibilidade dolorosa, em participantes com dor cervical crônica de origem inespecífica.

Comparar o efeito das duas formas de intervenção terapêutica sobre a percepção dos efeitos funcionais da dor através do questionário *Neck Disability Index* (versão portuguesa do NDI)

Comparar o efeito das duas formas no impacto exercido na cinesiofobia (TAMPA), nas crenças em relação à dor associada ao trabalho e atividade física (*Fear-Avoidance-Believes Questionnaire* - FABQ-Brasil).

Comparar os impactos do TMO na escala de autoeficácia e na percepção de efeito global, em participantes com dor cervical crônica de origem inespecífica.

Comparar o efeito das duas formas de intervenção terapêutica à amplitude de movimento rotacional medida com CROM (*cervical range motion meter*), em participantes com dor cervical crônica de origem inespecífica.

4 DESENVOLVIMENTO

A seção de desenvolvimento será apresentada na forma de dois artigos. O primeiro foi apresentado para banca como artigo de qualificação para doutorado e posteriormente às correções sugeridas pela banca, foi publicado no Journal of Bodywork and Movement Therapies sob o título "*Osteopathic manipulative treatment combined with exercise improves pain and disability in individual with non-specific chronic neck pain: A pragmatic randomized contolled trial*" O segundo artigo está na forma de manuscrito e será submetido para publicação somente após as correções da banca.

5 ARTIGO I

Osteopathic manipulative treatment combined with exercise improves pain and disability in individuals with non-specific chronic neck pain: a pragmatic randomized controlled trial

Osteopathic manipulative treatment combined with exercise improves disability in non-specific chronic neck pain patients

Abstract

Study Design: pragmatic randomized controlled trial.

Objective: To investigate the clinical effectiveness of osteopathic manipulative treatment combined with stretching and strengthening exercises in the cervical region for individuals with non-specific chronic neck pain.

Summary of Background Data: The comparative effectiveness of the osteopathic manipulative treatment combined with stretching and strengthening exercises in the cervical region for individuals with non-specific chronic neck pain has not yet been investigated.

Methods: The numeric pain-rating scale (NPRS), Pressure Pain Threshold (PPT) and neck disability index (NDI) were the primary outcomes. Secondary outcomes included range of motion cervical spine (ROM) for rotation, Fear-Avoidance Beliefs Questionnaire work and physical activity (FABQ-W/FA) and self-efficacy pain. Outcomes were collected at baseline (pre-treatment) and after 4 weeks of treatment (post-treatment). Patients were randomly assigned to receive either osteopathic manipulative treatment associated with exercises (OMT/ exercise) or only exercises. Techniques and dosages of OMT were selected pragmatically by an osteopath. Generalized Estimating Equations were used to assess clinical outcomes at 2 time points between-group differences.

Results: Ninety (90) individuals were included in the analysis (OMT/ exercise group, n = 45 and exercise group, n = 38). The between-group analysis revealed differences in outcomes on the NPRS (*P* = .007), NDI (*P* = .01), ROM (*P* = .03). and revealed no differences in outcomes on the PPT (*P* = .4), FABQ

W (*P* = .6), FABQ FA (*P* = .2). pain self-efficacy (*P* = .8), for individuals with non-specific chronic neck pain.

Conclusion: The association of OMT with exercises improves pain and functions better than just exercise alone for pain and disability for individuals with non-specific chronic neck pain.

Keywords: Osteopathy. Osteopathic Manipulative Treatment. Musculoskeletal manipulation. Manual therapy. Neck Pain.

Introduction

Neck pain is a common pain condition, with a reported prevalence ranging from 22% to 70% among the general population, and it is more common in women than men.[1] Associated with low back pain, it is the leading cause of disability measured in years lived with disability.[2-5] Studies show that up to 54% of people will suffer from cervical pain at some point in their life, and almost all of them will still have symptoms one to five years after the first episode of pain.[6-8] Consequently, neck pain results in major health costs, mainly due to absenteeism from work.[1,9]

Since the cause of the pain is unknown in most cases, neck pain is labeled as non-specific chronic neck pain (NCNP)[10]. However, several factors may contribute to NCNP, such as mechanical and biological aspects (age, gender, history of trauma or musculoskeletal diseases), and other factors related to psychosocial characteristics (physical activity, beliefs, expectations and job satisfaction). These factors are known to have an influence on the transition from acute to chronic pain.[9-11]

There are several NCNP management options, including manual therapy, conventional physiotherapy, drug treatment, exercise, and pain education, among others.[12-15] Manual therapy is a widely used approach, and there has been a significant increase in the number of clinical trials investigating this practice in recent years.[16-18] However, only moderate evidence supports the use of manipulative treatments for cervical pain and that it is more effective than no intervention or placebo treatment.[19-21]

A combination of several treatment modalities is referred to as multimodal care. Combined manual therapy and exercise has also led to

improved patient outcomes when compared to manual therapy or exercise alone.[22]

Osteopathic manipulative treatment (OMT) is a noninvasive approach that incorporates manual diagnostic and treatment techniques in accordance with pre-established principles, such as the interrelation between structure and function, intrinsic self-regulation and homeostasis, and the concept of body unity.[23]

Current evidence indicates that OMT is more effective than placebo treatment or no treatment for pain and function.[24-26] A recent systematic review from Franke et al.[26] demonstraed clinically relevant effects of OMT for reducing pain in patients with chronic nonspecific neck pain. However, these studies did not have investigate the effectiveness and impact of OMT when combined with exercise in NCNP patients.

Therefore, the objective of this clinical trial was to assess the effectiveness of osteopathic manipulative treatment combined with stretching and strengthening exercises in the cervical region for conservative treatment of individuals with non-specific chronic neck pain.

Materials and Methods

Study Design

This study was a pragmatic randomized controlled trial conducted from March 2016 to December 2018.[27] The study protocol was approved by the local human research ethics committee and filed with ClinicalTrials.org under Registration No. NCT02956863. The general study design is presented in a flowchart (Fig 1). This paper was reported according to the CONSORT statement.[28]

After verifying eligibility, each participant was randomly assigned to either the exercise group or the exercise group combined with osteopathic manipulative treatment (OMT). The protocol for each group lasted four weeks, with four exercises sessions for exercise group and four exercises sessions combined with osteopathic manipulative treatment for OMT group.

Prior to the study, an assistant used an online software from RANDOM.ORG to generate a randomization list, and participants were allocated into two treatments groups: exercise or OMT. The sequentially generated numbers were placed in 90 sealed opaque envelopes, informing the group to which each participant would belong. The envelope was only opened after the participant had completed all the baseline assessments.[29] All the participants were told about the existence of the exercise and OMT groups. The therapists who performed the treatments could not be blinded. The evaluators who carried out the assessments were blinded regarding the groups to which the participants belonged.

Participants

Adults with NCNP were recruited using advertisements and social media throughout the period of the study. NCNP was defined at baseline as neck pain without any specific identifiable etiology (i.e. infection, trauma, inflammatory disease, tumor or radiculopathy).[30] The eligibility criteria were assessed by evaluators who were blinded to the randomization list. The inclusion criteria were: be from 18 to 65 years of age, have neck pain that has lasted at least three months, and have a neck pain rate score (NPRS) of two or more on a scale from 0 to 10 and 10/50 points on the Neck Disability Index (NDI).[31]

Participants were excluded if they had done a neurological examination and there was at least one positive neurological finding, including the following signs and symptoms: pain or altered sensation in one or more dermatomes, decreased muscle strength, or reflex alteration. Besides these signs and symptoms, individuals who manifested three of the following four criteria from the clinical prediction rule for diagnosis of cervical radiculopathy were excluded from the study:[32] positive Spurling test, positive distraction test, positive upper limb tension test A, and ipsilateral cervical rotation less than 60 degrees. Individuals reporting previous cervical surgery, previous history and medical diagnosis of spondylolisthesis, spinal stenosis, cancer or degenerative osteomioarticular diseases of the upper limbs, or pregnancy at the time of the study were also excluded. Participants who had received some form of manipulative treatment in the last three months and/or who engage in physical activity on a regular basis were likewise excluded.

Initial assessment

The eligibility criteria data was collected during the initial assessment after the participant had read and signed the Informed Consent Form and the protocol had been approved by the university's research ethics committee. Psychological factors are known to be highly linked with neck pain [33]. Then Depressive mood and anxiety, were measured by the Hospital Anxiety and Depression Scale (HADS) [34-36]. It consists of two subscales with seven items each. Possible subscale scores range from 0 to 21. According to the German test manual, patients with a depression score > 8 were considered depressive, patients with an anxiety score > 10 were considered anxious.

Outcome Measurements

The outcomes of the participants were collected at baseline (pre-treatment) and after 4 weeks of treatment (post-treatment). Primary outcomes were pain and disability and were evaluated the Numeric Pain Rate Scale (NPRS) and neck disability index (NDI). Secondary outcomes were Pressure Pain Threshold (PPT), range of motion (ROM) for cervical spine rotation, Fear-Avoidance Beliefs Questionnaire (FABQ), pain self-efficacy. Each group followed the same measurement protocol.

- NPRS: cervical pain was assessed using the 11-point Numeric Pain Rating Scale (0 = no pain, 10 = worst possible pain) for the previous week; The minimum clinically important change (MCIC) of the NPRS has been reported as 1.3 points for patients with neck pain.[37,38] The question on pain referred to worst pain within the last week.

- NDI: The Neck Disability Index score was used for the disability assessment. The NDI is widely used for assessing disability caused by neck pain, and has high test-retest reliability.[39] It is a validated 10-item questionnaire where each item is rated on a 0 to 5-point scale,[39,40] and has a reported from 3.5 to 9.5 points represents a minimal clinically important change MCIC. [37,41,42 43]
- PPT: Pressure pain threshold was measured using a handheld electronic pressure algometer (model DD-2000, Instrutherm®) presented a probe of 1.0cm2 (base tip) which was calibrated before testing began. The measurements were taken in the suboccipital region, according to the trigger point map proposed by Dreyfuss et al.[44]: one at a midpoint between the occipital bone and the region corresponding to the C2 vertebra and the other at a medial point just below the atlanto-occipital joint; a measurement was also taken in the region corresponding to the C5 spinal process. All the measurements were done with the participant lying prone on a table. Perpendicular pressure was applied with the algometer. Participants were instructed to say when they felt the sensation of pain, at which point no further force was applied, and the maximal pressure was recorded. Three measurements were taken, with a break of at least 30 seconds between each one, and the mean of the three values represented the PPT for that participant.[24]
- Cervical Spine ROM: a cervical range of motion instrument (CROM®) was used to assess cervical mobility. Range of motion (ROM) for cervical rotation was obtained with the individual in the sitting position to left and to right side. The CROM was placed on the subject's head. The measurement was repeated three times, and the final score was the arithmetic average of the

three measurements. The CROM has good intratester and intertester reliability and validity.[45]

- FABQ was used to assess the patients' beliefs regarding the effect of physical activity and work on their pain. Fear-Avoidance Beliefs Questionnaire (FABQ) is a 16-item, self-reporting questionnaire. The FABQ contains 2 scales, a 7-item scale assessing fear-avoidance beliefs about work (FABQ work scale; score range, 0-42) and a 4-item scale assessing fear-avoidance beliefs about physical activity (FABQ physical activity scale; score range, 0-24). Higher scores on the FABQ work scale and FABQ physical activity scale indicate that the individual has elevated fear-avoidance beliefs This test has good test-retest reliability[46-49]
- Pain self-efficacy: this outcome consists of 05 questions about the patient's confidence in carrying out various normal activities despite the pain. The questionnaire has five questions about pain management by the patient. Responses range from 10 percent sure to 100 percent sure[50].

Interventions

Exercise Group: The participants undertook supervised exercise program by an experienced physical therapist and consisted of one weekly session in addition to home exercise, over the course of four weeks. Each exercise session lasted approximately 40 - 45 minutes. It was composed of 10 min warm-up exercises, 30 min exercises focused on strengthening and stretching cervical for the neck muscle. This program included stabilization, flexion, extension and rotation exercises for the cervical region and self-mobilization targeting the deep neck muscles.[1] The exercises had low isometric resistance

and consisted of three sets of 10 repetitions in supine and sitting positions. Participants were instructed to perform the exercises at home 3 times a week in a way that did not cause pain.

OMT/ exercise Group: The exercise protocol of the OMT/ exercise group was the same as the one for the exercise group. Apart from the exercises, the participants in the OMT/ exercise group also received full osteopathic treatment, once a week over the course of four weeks, with each session lasting 50 to 60 minutes. Ten registered osteopaths performed all the treatments. At each visit, participants received a full-body osteopathic examination in accordance with osteopathic principles, which included clinical exams, observation, screening tests, palpation and motion testing. The osteopathic manipulative treatment entailed: direct (high-velocity low-amplitude; muscle energy; and myofascial release), indirect (functional techniques and balanced ligamentous tension), visceral and cranial techniques (Glossary of Osteopathic Terminology).[51] The osteopaths were free to assess the participants and decide which techniques were better to use.

Data Analysis

Sample size was determined in advance, based on the expected two-point difference for the main NPRS outcome, which was considered statistical significant [37], 70 participants were stipulated considering a standard deviation of the NPRS of ± 1.6. A level of significance of 0.05 (0.5%) was stipulated, statistical power of 80%, and 20% of losses could occur.

The statistical analysis was performed by a statistician who was blinded to the randomization, measurement and intervention protocols according to

intention-to-treat principle. Statistical analyses were conducted using SPSS Statistics 20 for Windows (IBM, Armonk, NY, USA). Demographic data and initial assessment results were compared using independent t-tests. The normality of the data was verified by visual inspection and the standard deviation size was also considered in relation to the mean and also considered if the skewness and kurtosis analysis of the values of the pre- and post-treatment variables. Mean values and standard deviation were calculated for each study variable. Generalized Estimating Equations was used to evaluate the effects of treatment. This test considers the missing data allowing for intent-to-treat analysis. Effects on time, group and time-by-group interaction were considered. Statistical analysis was conducted with a 95% confidence interval, an α value of 5%, thus representing a value of $p \leq 0.05$.

Finally, Cohen's *d* was used to calculate effect size. A Cohen's d score of approximately 0.2 was considered a small effect; a moderate effect was defined as a Cohen's *d* score of approximately 0.5; and a score of approximately 0.8 identified a large effect. The alpha level was set at 0.05.

Results

In total, 90 individuals were assessed for eligibility, from March 2016 to December 2018, and then randomly assigned to the exercise (n=45) and OMT/ exercise (n=45) groups (Fig 1). The subjects of the both groups showed similar baseline characteristics. There were no significant differences patient´s baseline characteristics between the two groups in terms of gender, age, weight, height and body mass index, numeric pain rating scale (NPRS), NDI, FABQ (W and FA), HADS (A and D) ($p>0.05$; Tab 1). No adverse events were reported during study.

In comparison with baseline values, after treatment, in both groups, there was a reduction of the values obtained in numeric pain rating scale (NPRS; $p<0.05$) and neck pain disability index (NDI; $p<0.05$; Tab 2). In addition, patients of the OMT/EG showed an increase of the values of the cervical rotation range of motion to both sides (ROM; $p<0.05$; Tab 3). This increase in the range of motion did not occur in patients in the exercise group ($p>0.05$; Tab 3). In the comparison between groups it was possible to verify that after 4 weeks of treatment patients of the OMT/EG showed lower NPRS and NDI values and higher cervical rotational range of motion values when compared to patients of the exercise group ($p<0.05$; Tab 2,3).

In comparison with baseline values, after treatment, in both groups, there was an increase of the values obtained in Self-efficacy ($p<0.05$), however no significant differences were observed in the comparisons between groups ($p>0.05$; Tab 2). To PPT and Fear Avoidance Beliefs (FABQ) outcomes no significant differences were observed in either group, or in the comparisons between groups ($p>0.05$; Tab 2, 3).

Discussion

The main purpose of the present study was to assess the combination of OMT and strengthening and stretching exercises in subjects with non-specific chronic neck pain and disability. The results demonstrated that combining both treatments led to improvements in pain and function. Multiple factors may contribute to improved function and pain in individuals with chronic neck pain after osteopathic manipulative treatment in combination with exercise, including mechanical, neurophysiological, and psychosocial effects.[10]

Several studies have shown that manual therapy combined with exercises is more effective for patients with neck pain than treatment by a general practitioner or than manipulation or exercises alone.[9,52] As far as we known, this is the first study to investigating the effects of OMT combined with exercises on individuals with non-specific chronic neck pain. The findings showed an improvement in pain and function in both groups and support to the use of combined OMT and exercises in achieving clinically important but modest pain reduction and functional improve.

In previous clinical trials, patients with neck pain treated with OMT experienced a reduction in pain of at least 1.5 points.[20,25,53] However, these studies compared osteopathic treatment with placebo treatment. Similarly, another randomized trial, which included participants with neck pain, found that OMT improved quality of life compared with placebo treatment.[20] In contrast to those trials, the present study compared OMT on its own and OMT combined with exercises, and found that neck pain was significantly reduced in both groups.

When comparing the two groups, statistically significant difference was noted for pain. The difference in pain between the groups was significant in the study. Moreover, the effect size for the NPRS score was larger in the OMT/ exercise group (r = 0.50), demonstrating a 3-point reduction, which constitutes a clinically significant difference. This result suggests that people suffering from neck pain can benefit from OMT.

In a recent systematic review, it was suggested that OMT improves functionality. This coincides with the findings of the present study where improvement in functionality only occurred in the OMT group.[26] The authors of this review suggested that future studies should consider adding exercises to enhance OMT effectiveness.[26] This was also the main suggestion of the present study, i.e., demonstrate that combining manual therapy with exercises can be highly beneficial.

The use of cervical exercises alone for chronic neck pain has been extensively demonstrated in the references cited in the study.[54-56] However, another trial suggested there are benefits in combining exercises and manual therapy for pain reduction, as opposed to manual therapy on its own.[57] The present study found that participants in the exercise group combined with OMT had less pain and disability and better function compared to the group that only performed the exercises. OMT was administered in a pragmatic way in accordance with osteopathic principles. The therapists treated all dysfunctions they considered relevant during the examinations. A pragmatic approach seeks to model real-life situations, and this approach was used to test how much it impacts improvement in individuals who receive osteopathic treatment. Through

the use of this model, results were obtained that confirm an important external validity.

Galindez et al. (2018) studied individuals with neck pain, comparing the immediate effects on pain of an osteopathic treatment versus one that uses exercise protocol. It was observed that both interventions were associated with immediate improvement in range of motion and pain after the treatment. There was also a significant change in upper trapezius Pressure Pain Threshold following both interventions.[58] The findings of Galindez et al. (2018) confirm certain results from the present study. However, these authors did not use osteopathic treatment in a pragmatic way. In their study, only high-velocity low-amplitude manipulation was used. In addition, osteopathy and exercise were used separately, and not combined, as in the present study.

In relation to Pressure Pain Threshold, there was no significant difference pre and post treatment in both groups. These results differ from another study on the short-term effects of manipulation.[59] However, that study reported immediate effects after treatment, whereas the measurements in the present study were taken 30 days after the start of treatment.

The strengths of the present study were the blinding of outcome assessors, randomization of participants and allocation concealment, which help reduce bias risk and preserve internal validity. Conversely, a limitation of the study was the impossibility of blinding participants and osteopaths. In addition, participants who received OMT had increased contact with an osteopath, and this interaction can lead to potential improvements and placebo effects. However, this study sought to treat participants in a pragmatic way and this type of interaction is part of osteopathic treatment. From a clinical

perspective, the changes observed in the study were statistically significant, the mean reductions in pain and disability were relatively modest and support to the use of combined OMT and exercises.

Conclusion

The results of this randomized controlled trial demonstrated that combining Osteopathic manipulative treatment with exercise is better than exercise alone for pain and disability and rotational mobility of the neck. The findings also provide some evidence that individuals with no specific chronic neck pain can be treated with osteopathic manipulative treatment along with exercises.

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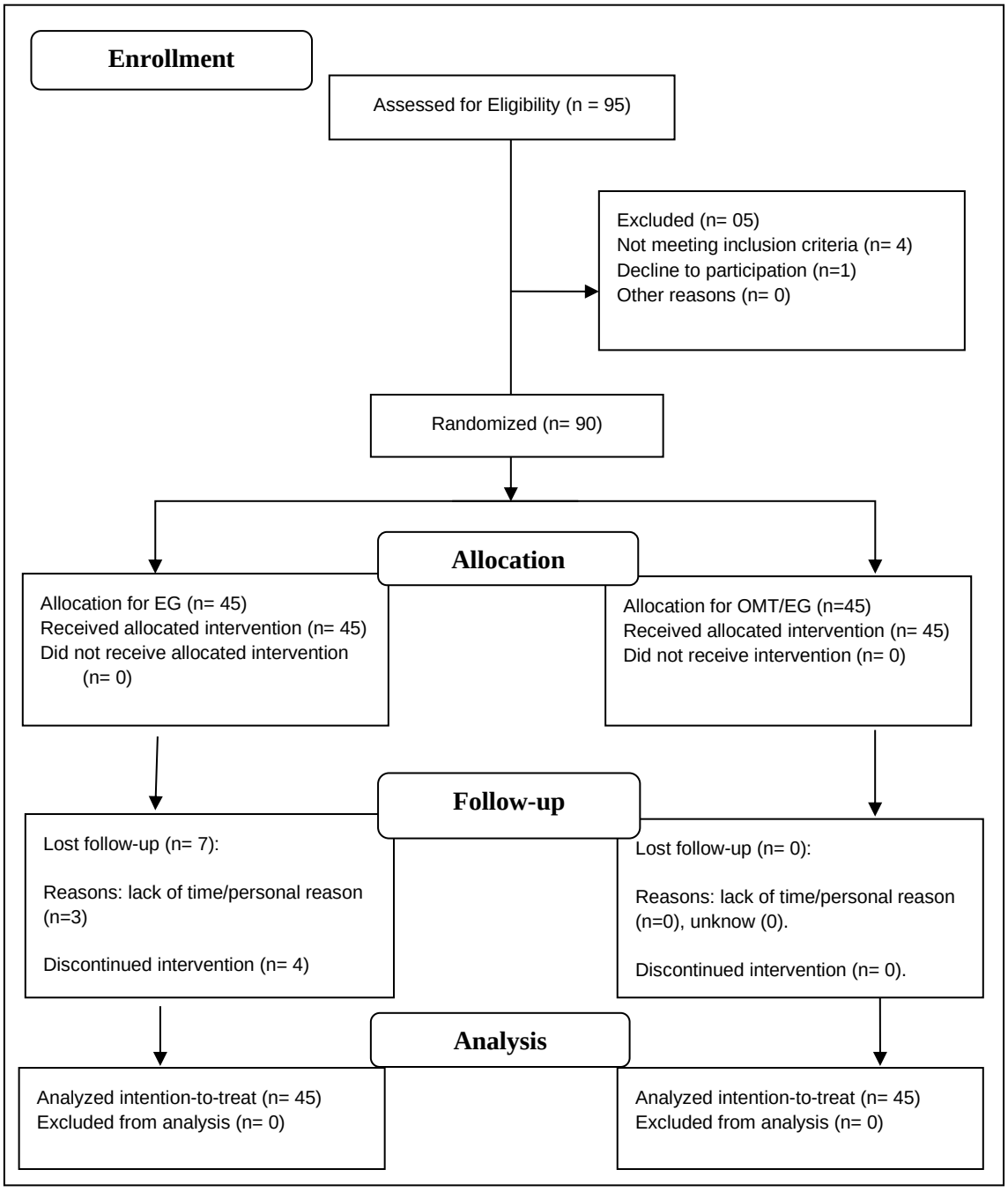

Figure 1. Design and flow of participants through the trial.

Table 1 – Comparison between baseline characteristics from patients with non-specific chronic neck pain in the exercise group (EG) and in the osteopathic manipulative treatment group (OMT/EG)

	EG (n=38)	**OMT/EG (n=45)**	**Difference between groups**	**p**
Women (%)	84,2% (n=32)	93,3% (n=42)	9.1	>0.05
Age (years)	42.8 ± 9.8	40.2 ± 12.3	2.5	0.3
Weight (kg)	70.4 ± 10.60	67.0 ± 11.4	3.4	0.1
Height (m)	1.65 ± 0.07	1.63 ± 0.07	0.02	0.5
NPRS	5.5 ± 1.6	5.7 ± 1.7	0.17	0.6
NDI	18.87 ± 6	18.87 ± 5.1	0	0.9
FABQ W	20.5 ± 11	20.0 ± 10	0.4	0.8
FABQ PA	9.8 ± 7.5	11.1 ± 7	1.2	0.4
HADS A > 10 (%)	65.8± 4	66.7± 4	0.9	0.9
HADS D > 8 (%)	28.9± 4	24.4± 4	4.5	0.8

Data expressed in percentage (%) and mean ± standard deviation; NPRS= Numeric Pain Rate Scale; NDI= Neck Disability Index; FABQ W = Fears Avoidance Believes Questionnaire Work; FABQ FA - Fears Avoidance Believes Questionnaire physical active; HADS A= Hospital Anxiety and Depression Scale - anxiety score; HADS D= Hospital Anxiety and Depression Scale – depression score.

Table 2 – Summary of primary outcomes results: Numeric Pain Rate Scale (NPRS), Pressure Pain Threshold (PPT) and neck disability index (NDI)

Outcome	Group	Pre Mean ±SD	Post Mean ±SD	Within-group Diference Mean ±SD CI (95%)	Within-group Cohen's effect size	Within-group p value	Between-group diference Mean ±SD CI (95%)	Between-group Cohen's effect size	Between-group p value
NPRS	OMT/EG	5.7±0.2	2.3±0.2*#	3.4±0.2 (2.9 to 3.9)	0.9	0.00	-1,4 ±0,5 (-2,4 to - 0,3)	0.8	0,007
	EG	5.5±0.2	3.6±0.4*	1.9±0.3 (1.1 to 2.6)	0.9	0.00			
PPT	OMT/EG	3.3±0,4	2,8 ±0,4	0.5±0.3 (-0.3 to 1.3)	_	0.2	-0,5 ±0,6 (-1,7 to 0,7)	_	0.4
	EG	2,9±0,3	3,3±0,4	-0.4±0.2 (-1.3 to 0.3)	_	0.2			
NDI	OMT/EG	18.9±6.2	11.2±6.8*#	7.7±0.8 (6.0 to 9.3)	0.5	0.00	-3,8 ±1,5 (-0,74 to -6,9)	0.2	0,01
	EG	18.8±8.0	15.0±8.8*	3.8±0.9 (1.9 to 5.7)	0.2	0.00			

Data expressed as mean±standard deviation (SD). Pre= baseline values; Post= values after 4 weeks treatment protocol; OMT/EG=osteopathic manipulative treatment group, EG =Exercise group, Threshold CI=confidence interval, * p<0.05 *vs* pre-values; # p<0.05 *vs* EG. Effect sizes were expressed as Cohen's *d*, and an effect size greater than 0.8 was considered large, an effect size of approximately 0.5 was considered moderate, and an effect size of less than 0.2 was considered small.

Table 3 - Summary cervical range of motion (ROM), Fears Avoidance Believes Questionnaire (FABQ) and pain self-efficacy results

Outcome	Group	Pre Mean ±SD	Post Mean ±SD	Within-group Diference Mean ±SD CI (95%)	Within-group Cohen's effect size	Within-group p value	Between-group diference Mean ±SD CI (95%)	Between-group Cohen's effect size	Between-group p value
ROM left	OMT/EG	56.8±2.2	67.4±1.6*#	10.6±1.5 (13 to 7.4)	0.9	0.0	6.9 ±3.3 (0,4 a 13,4)	0.8	0,03
	EG	56.4±2.0	60.5±2.8	4.1±2.1 (-8.2 to 0.1)	_	0.6			
ROM right	OMT/EG	54.5±2.2	65.1±1.8*#	9.6±1.5 (12 to 6.4)	0.9	0.0	8±3.4 (0.3 a 13.6)	0.8	0.03
	EG	55.1±1.8	57.1±2.8	2.0±1.8 (-5.7 to 1.7)	_	0.3			
FABQ W	OMT/EG	20.0±11	18.2±12	1.8±1.5 (-1.1 to 4.9)	_	0.2	-1.3±3 (-7.2 to 4.5)	_	0.6
	EG	20.5±10	16.8±12	3.7±1.6 (-0.5 to 6.8)	_	0.2			
FABQ FA	OMT/EG	11.1±7	10.3±7	0.7±0.9 (-1 to 2.5)	_	0.4	1.8±1.7 (-5.2 to 1.6)	_	0.2
	EG	9.8±7.5	8.5±7	1.3±1.3 (-1.2 to3.9)	_	0.3			
Pain self-efficacy	OMT/EG	352.6±95	380.9±79*	-28.3±12 (-53 to -3)	0.1	0.0	-3,9 ±18,7 -32,8 a 40,8	_	0,8
	EG	319.7±100	377±81*	-57.2±10 (-78 to -36)	0.3	0.0			

Data expressed as mean ± standard deviation (SD). Pre= baseline values; Post= values after 4 weeks treatment protocol; OMT/EG=osteopathic manipulative treatment group, EG =Exercise group, Threshold CI=confidence interval. FABQ W = Fears Avoidance Believes Questionnaire Work; FABQ FA - Fears Avoidance Believes Questionnaire physical active. * $p<0.05$ *vs* pre-values; # $p<0.05$ *vs* EG. Effect sizes were expressed as Cohen's *d*, and an effect size greater than 0.8 was considered large, an effect size of approximately 0.5 was considered moderate, and an effect size of less than 0.2 was considered small.

6 ARTIGO 2

In the medium-term the Osteopathic manipulative treatment for one month combining with neck exercises, no added benefit in effectiveness of pain and functionality in individuals with non-specific chronic neck pain: a pragmatic randomized controlled trial chronic neck pain

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Abstract

OBJECTIVE: To determine the medium-term effectiveness of four sessions of the *O*steopathic manipulative treatment combined with stretching and strengthening neck exercise in pain and functionality in individuals with non-specific chronic neck pain.

DESIGN: Pragmatic randomized controlled trial

INTERVENTIONS: Ninety patients with non-specific chronic neck pain were randomized into two groups: (1) exercises group (EG, n=45) or (02) osteopathic manipulative treatment associated with exercises group (OMT/EG, n=45), participants received 4 weeks of treatment.

MAIN OUTCOME MEASUREMENTS: The clinical outcomes were recorded at baseline and at 3 and 6 months after the initiation of treatment. The primary outcome was pain an function: Numeric Pain-Rating Scale, Pressure Pain Threshold and Neck Disability Index. Secondary outcomes included range of motion for cervical spine rotation, Fear-Avoidance Beliefs Questionnaire Work/Physical Activity and Pain-self efficacy

RESULTS: In comparison with baseline values, after treatment, in both groups, there was a reduction of the values obtained in numeric pain rating scale ($p<0.05$) and neck pain disability index ($p<0.05$). However, no statistically significant differences in pain intensity or disability were found when OMT/EG was compared with EG at 3 months ($p = 0.1$ and $p = 0.2$, respectively) or 6 months ($p = 0.4$ and $p = 0.9$, respectively for pain or disability) and no difference was found between

OMT/EG and the EG in the secondary outcomes at the same follow-up period ($p > 0.05$).

CONCLUSIONS: In the medium-term the effectiveness of osteopathic manipulative treatment combined with neck exercise was the same of the only neck exercise in pain and functionality in individuals with non-specific chronic neck pain.

Keywords: Osteopathy. Osteopathic Manipulative Treatment. Musculoskeletal manipulation. Manual therapy. Neck Pain.

Introduction

Neck pain is a major health problem, with economic and social repercussions, affecting up to two thirds of adults at some point in their lives[1]. It is estimated that 4.5% of the population will present significant limitation of activities due to chronic neck pain. Studies show that up to 50% of people will have an episode of cervical pain at some point in their life, and may still have symptoms from 1 to 5 years after the first episode of pain[2; 3; 4]. As a result, cervical pain results in great health costs, mainly due to work absenteeism[5].

Most neck pain has no specific or identifiable cause and is therefore referred to as non-specific chronic cervical pain (NCNP)[6]. However, several factors may contribute to NCNP such as mechanical and biological aspects (age, gender, history of trauma, musculoskeletal disorders and physical activity), as well as other factors related to psychosocial aspects (beliefs, fears, expectations, job satisfaction, anxiety and depression). These factors are known to determine the transition from acute pain to chronic pain. [5; 7].

There are several options for management of NCNP, including manual therapy, conventional physical therapy, drug treatment, exercise, and pain education, among others[8; 9; 10; 11]. As a widely used approach, manual therapy has had a significant increase in the number of clinical trials investigating the effectiveness of this practice in recent years. [12; 13; 14; 15; 16]. However, there is only moderate quality evidence supporting the use of manipulative treatments for cervical pain, proving to be more useful than no intervention or placebo treatment [17;

[18; 19]. Manual therapy is a favorable treatment option for cervical pain compared to conventional physical therapy and drug treatment [20].

Another approach used in conservative treatment of NCNP is strengthening and stretching exercises. In a systematic review, Freitas et al. (2010) [21] describe improvement in pain and functionality in the exercise group when compared to the placebo group. An another systematic review, was concluded with moderate evidence that exercise impacts the improvement of pain, functionality, and satisfaction of the patient with NCNP [14]. Manual therapy combined with exercise also showed better levels of results when compared to only manual therapy or exercises applied alone. [22; 23]. The combination of different treatment modalities is called multimodal treatment. [23].

Osteopathic Manipulative Treatment (OMT) has been applied to treat cervical pain [6]. OMT consists of manual diagnostic techniques and manual treatments, following pre-established principles such as the interrelationship between structure and function, intrinsic capacity for self-regulation and homeostasis, as well as the concept of body unity[24]. The rational use of BMT in chronic pain patients cannot have a singular focus, it must integrate the body using an interrelation between structure and function, making sure the best conduct for each individual according to the somatic dysfunctions found. [13].

Current evidence has reported that OMT is more effective than placebo treatment or no treatment for pain and functionality in patients with NCNP. [6; 25; 26]. A recent systematic review of Franke et al. (2015) [6] examined the effectiveness of OMT in reducing pain and improving functionality in individuals with NCNP, concluding that OMT reduced pain when compared to other groups (physical therapy or placebo). Our previous study concluded that the association of OMT with exercise impacts pain and functionality improvement when these short-term (30

days) outcomes are evaluated [27]. Thus, there is a need to investigate the long-term impact of exercise-associated OMT in patients with NCNP, and other doses treatment. Thus, the aim of this study was to evaluate medium-term (3 and 6 months) effectiveness of the association of osteopathic manipulative treatment with isometric exercise and passive stretching in patients with chronic cervical pain of nonspecific origin.

Methods

Study Design

This study is characterized by as randomized, controlled, blinded, pragmatic clinical trial conducted from June 2017 to December 2018. Pragmatic studies are designed to evaluate the effectiveness of interventions in real-life conditions as interventions are applied on a day to day. After checking the eligibility criteria, each participant was randomly assigned to either the exercise group (EG) or the exercise combined with osteopathic manipulative treatment group (OMT/EG).

The study protocol was approved by the Ethics and Research Committee of the Federal University of Health Sciences of Porto Alegre (UFCSPA) with protocol number 1970517 and registered at ClinicalTrials.org under registration NCT02956863. This study was reported according to the guidelines from CONSORT [28; 29] for reporting randomized controlled clinical trials.

Prior to the study, an online software from RANDOM.ORG was used to generate a randomization list, and 90 participants were allocated into two treatment groups: EG or OMT/EG. These sequentially generated numbers were placed in 90 sealed opaque envelopes, informing which group each participant would belong to. The envelope was only opened after the participant had completed all the baseline assessment [30]. All the participants were told about the existence of the EG and OMT/EG groups. The therapists who performed the treatments could not be blinded. The evaluators who carried out the assessments were blinded in relation to the group that each participant belonged.

Participants

Adults with NCNP were recruited using advertisements and social media throughout the period of the study. NCNP was defined as the baseline for neck pain without any specific identifiable etiology (i.e. infection, trauma, inflammatory disease, tumor or radiculopathy)[31]. The eligibility criteria were assessed by evaluators who were blinded to the randomization list. The inclusion criteria were: age between 18 and 65, neck pain for at least three months, and a neck pain rate score (NPRS) of two or more at a scale from 0 to 10 and 10 out of 50 points at the Neck Disability Index (NDI) [32].

Participants who had gone through a neurological exam and presented at least one positive sign, altered sensation in one or more dermatomes, decreased muscle strength, or reflex alteration, were excluded. Besides these signs and symptoms, individuals who manifested three of the following four criteria from the clinical prediction rule for diagnosis of cervical radiculopathy were also excluded from the study [33]: positive Spurling test, positive distraction test, positive upper limb tension test A, and ipsilateral cervical rotation less than 60 degrees. Individuals that reported previous cervical surgery, previous history and medical diagnosis of spondylolisthesis, spinal stenosis, cancer or degenerative osteomioarticular diseases of the upper limbs, or pregnancy at the time of the study were also excluded. Participants who had received some form of manipulative treatment in the last three months and/or who engages in physical activity on a regular basis were likewise excluded.

Initial Evaluation

Eligibility criteria were collected during the initial assessment after the participant had read and signed the Informed Consent Form approved by the Research Ethics

Committee of the Federal University of Health Sciences of Porto Alegre (UFCSPA). Psychological factors are known to be highly related to neck pain [34]. Depression and anxiety were assessed by the Hospital Anxiety and Depression Scale (HADS) [35; 36]. The scale consists of two subscales with seven items each. Possible subscale scores range from 0 to 21, patients with depression scores> 8 were considered depressive, patients with anxiety scores> 10 were considered anxious.

Interventions

Exercise Group: The participants undertook supervised exercise program by an experienced physical therapist and consisted of one weekly session in addition to home exercise, over the course of four weeks. Each exercise session lasted approximately 40 - 45 minutes. It was composed of 10 min warm-up exercises, 30 min exercises focused on strengthening and stretching cervical for the neck muscle. This program included stabilization, flexion, extension and rotation exercises for the cervical region and self-mobilization targeting the deep neck muscles. The exercises had low isometric resistance and consisted of three sets of 10 repetitions in supine and sitting positions. Participants were instructed to perform the exercises at home 3 times a week in a way that did not cause pain.

OMT/ exercise Group: The exercise protocol of the OMT/ exercise group was the same as the one for the exercise group. Apart from the exercises, the participants in the OMT/ exercise group also received full osteopathic treatment, once a week over the course of four weeks, with each session lasting 50 to 60 minutes. Ten registered osteopaths performed all the treatments. At each visit, participants received a full-body osteopathic examination in accordance with osteopathic principles, which included clinical exams, observation, screening tests, palpation and motion testing. The osteopathic manipulative treatment entailed:

direct (high-velocity low-amplitude; muscle energy; and myofascial release), indirect (functional techniques and balanced ligamentous tension), visceral and cranial techniques. The osteopaths were free to assess the participants and decide which techniques were better to use.

Primary outcomes

Primary outcomes were pain and disability and these were evaluated by the Numeric Pain Rate Scale (NPRS) and Neck Disability Index (NDI). Secondary outcomes were Pressure Pain Threshold (PPT), Range of Motion (ROM) for cervical spine rotation, Fear-Avoidance Beliefs Questionnaire (FABQ) and Pain-self efficacy.

The Numeric Pain Rating Scale is an 11-point numeric pain intensity ranging from 0 ('no pain') to 10 ('as much pain as possible')[37]. A change of two points or more was identified as the minimal clinically important difference in patients with chronic neck pain [38; 39]. The question made in regards to pain was "what was the worst pain you felt within the last week?".

The Neck Disability Index is a self-administered questionnaire measuring the patients' limitations in managing everyday-life activities due to neck pain. Total score ranges between 0 and 50 points, with higher values indicating higher levels of disability[40]. It is a validated 10-item questionnaire where each item is rated on a 0 to 5-point scale,[40; 41] and has a report from 3.5 to 9.5 points represents a minimal clinically important change [39; 42; 43 44].

Pressure Pain Threshold was measured using a handheld electronic pressure algometer (model DD-2000, Instrutherm®) presented a probe of 1.0cm^2 (base tip) which was calibrated before testing begin. The measurements were taken in the suboccipital region, according to the trigger point map proposed by Dreyfuss et al.[45]:

one at a midpoint between the occipital bone and the region corresponding to the C2 vertebra. All the measurements were done with the participant laying prone on a table. Perpendicular pressure was applied with the algometer. Participants were instructed to say when they felt the sensation of pain, at this point no further force was applied, and the maximal pressure was recorded. Three measurements were taken, with a break of at least 30 seconds between each one, and the average of the three values represented the PPT for that participant [46].

A cervical range of motion instrument (CROM®) was used to assess cervical mobility. Range of Motion (ROM) for cervical rotation was obtained with the individual in the sitting position with movements from the left side to the right side. The CROM was placed on the subject's head. The measurements were repeated three times, and the final score was the arithmetic average of the three measurements. The CROM has good intratester and intertester reliability and validity[47].

FABQ was used to assess the patients' beliefs regarding the effect of physical activity and work on their pain. Fear-Avoidance Beliefs Questionnaire (FABQ) is a 16-item, self-reporting questionnaire. The FABQ contains 2 scales, a 7-item scale assessing fear-avoidance beliefs about work (FABQ work scale; score range, 0-42) and a 4-item scale assessing fear-avoidance beliefs about physical activity (FABQ physical activity scale; score range, 0-24). Higher scores on the FABQ work scale and FABQ physical activity scale indicates that the individual has elevated fear-avoidance beliefs. This test has good test-retest reliability[48; 49; 50; 51].

The Pain-self efficacy consists of 5 questions about the patient's confidence in carrying out various normal activities despite the pain. The questionnaire has 5

questions about pain management by the patient. Responses range from 10 percent sure to 100 percent sure[52].

Study participants were assessed by a blinded evaluator who did not know which group the participant belonged to. The main and secondary outcomes were collected in 3 moments (M) at 1, 3 and 6 months post-randomization:

(M1) = baseline;

(M2) = 3 months / 12 weeks after initiation of treatment;

(M3) = 6 months / 24 weeks after initiation of treatment.

Data Analysis

Sample size was determined in advance, based on the expected two-point difference for the main NPRS outcome, which was considered statistical significant, 70 participants were stipulated considering a standard deviation of the NPRS of ± 1.6. (Referencia 37 do primeiro artigo) A level of significance of 0.05 (0.5%) was stipulated, statistical power of 80%, and 20% of losses could occur.

The statistical analysis was performed by a statistician who was blinded to the randomization, measurement and intervention protocols according to intention-to-treat principle. Statistical analyses were conducted using SPSS Statistics 20 for Windows (IBM, Armonk, NY, USA). Demographic data and initial assessment results were compared using independent t-tests. The normality of the data was verified by visual inspection and the standard deviation size was also considered in relation to the mean and also considered if the skewness and kurtosis analysis of the values of the pre- and post-treatment variables. Mean values and standard deviation were calculated for each study variable. Generalized Estimating Equations was used to evaluate the effects of treatment. This test considers the missing data allowing for intent-to-treat analysis. Effects on time, group and time-by-group interaction were considered. Statistical analysis was conducted with a 95% confidence interval, an α value of 5%, thus representing a value of $p \leq 0.05$.

Results

Recruitment ran from June 2017 to December 2018 and the final 6-month follow-ups were completed in June 2019. Figure 1 shows the CONSORT flow diagram of participants through the trial. Of the 90 participants who were randomly assigned, 65 participants (72%) were followed up at 3 months and 55 participants (61%) were followed up at 6 months. No adverse events were reported, during the follow-up period, 13 participants from the OMT/EG were lost to follow-up (one moved to other city; twelve lost contact;), and 22 participants from the EG group (all due to loss of contact). Thus 55 participants (OMT/EG, n=32; EG, n=23) completed study.

. Participants were mainly female (88.7%), two study groups were homogeneous in terms of demographic variables at baseline, and had a mean age of 41.5 years (SD 11.5), the baseline anthropometric variables were similar between the 2 groups. Weight and height difference between groups were 3.4 kg $p>0.05$/ 0.02 m $p>0.05$ respectively.

There were no significant differences patient´s baseline characteristics between the two groups in terms of clinical variables numeric pain rating scale (NPRS), NDI, FABQ (W and FA) details presented in table 1 and 2.

There was a significant within group reduction of the values obtained in numeric pain rating scale (NPRS; $p<0.05$) and neck pain disability index (NDI; $p<0.05$; Tab 1).

Primary outcomes

The mean values at baseline, 3 months and 6 months post randomization are shown in the Table 1 and Table 2 that presents the results from the intention-to-treat analyses of treatment effects for disability and pain intensity at 3 and 6 months.

Pain

There were no significant between-group differences in pain intensity at either 3 months (mean difference, -0.9; 95% CI -2.0 to 0.1; p=0.1) or 6 months (mean difference, 0.6; 95% CI -0.8 to 1.9; p=0.4) (table 1).

Disability

There were no significant differences in disability between-group at either 3 months (mean difference, -2.2; 95% CI -6.2 to 1.5; p=0.2) or 6 months (mean difference, 0.1; 95% CI -4.0 to 2.2; p=0.9) (table 1).

Secondary outcomes

No significant differences were found for fear of physical activity or work and Pain-self efficacy at 3 months or 6 months (see tables 2).

Discussion

This study, to our knowledge, is the first pragmatic randomized controlled trial of Osteopathic Manipulative treatment and exercises and aimed to evaluate the medium-term effectiveness of the association of OMT with neck strengthening and stretching exercises in pain and functionality in participants with non-specific neck pain.

We found no statistically significant differences in the primary and secondary outcomes between the OMT / an EG group at 12 weeks and 24 weeks. However, our data analysis suggests significant reduction in pain intensity and improvement in functionality in both groups comparing baseline with 12 weeks and 24 weeks.

Both OMT/EG and EG made significant improvements in pain and functional outcomes measures. These results corroborate with the findings of several recent studies demonstrating limited evidence of no difference between groups on pain and functionality medium-term outcomes using manual therapy with exercises [7; 19; 56]. However, our results agree with the recommendation that for patients with chronic neck pain there was a benefit, in using Cervical stretching and strengthening for reducing pain and improving function. Furthermore, manual therapy, like TMO, combined with exercises demonstrated medium and long-term improvements in pain, function/disability, and global perceived effect compared to no treatment in patients with chronic neck pain [19].

The treatment adherence was 71% in OMT/EG and 51% in EG. Adherence was higher in the OMT/EG group which may have been motivated by contact with the osteopath, many studies indicate that patient-provider interaction is potent a

potent factor in outcomes and treatments adherence [56]. This compares with previous estimates of adherence in treatment programs for neck and low back pain, converging around 50% [56; 57].

We must consider two important aspects that may have influenced the results. First, the lower adherence in the EG may have impacted the results because it is known that the groups with the greatest loss of follow-up tend to be a group with lower morbidity. Another aspect to consider is regarding the OMT dose, future studies should consider a higher dose and frequency of treatment so that we can observe the medium-term and long-term effects of OMT.

Study strengths and limitations.

Strengths: it was prospectively registered, and incorporated design features known to minimize bias such as concealed allocation and intention-to-treat analysis. This pragmatic trial represented clinical practice as we allowed the osteopaths in the individualized intervention the freedom to deliver the treatment in line with their clinical judgment and available resources.

Limitations: thirty-eight per cent of randomized participants did not complete treatment, only 72% completed the 3-month follow-up, and only 61% of participants completed the 6-month follow-up. Although, this loss of follow-up was not significantly different between interventions, we acknowledge that non-adherence can lead to unmeasured bias in intention-to-treat results.

Future research needs to explore an analysis of the influence of a higher frequency of treatment and include a subgroup analysis to determine those most will probably benefit from osteopathy.

In conclusion, in medium-term both treatments improve pain and functionality however, the results do not support the hypothesis that the addition of Osteopathic Manipulative Treatment with neck strengthening and stretching exercises would result in greater functionality and less pain in patients with nonspecific chronic neck pain in medium-term.

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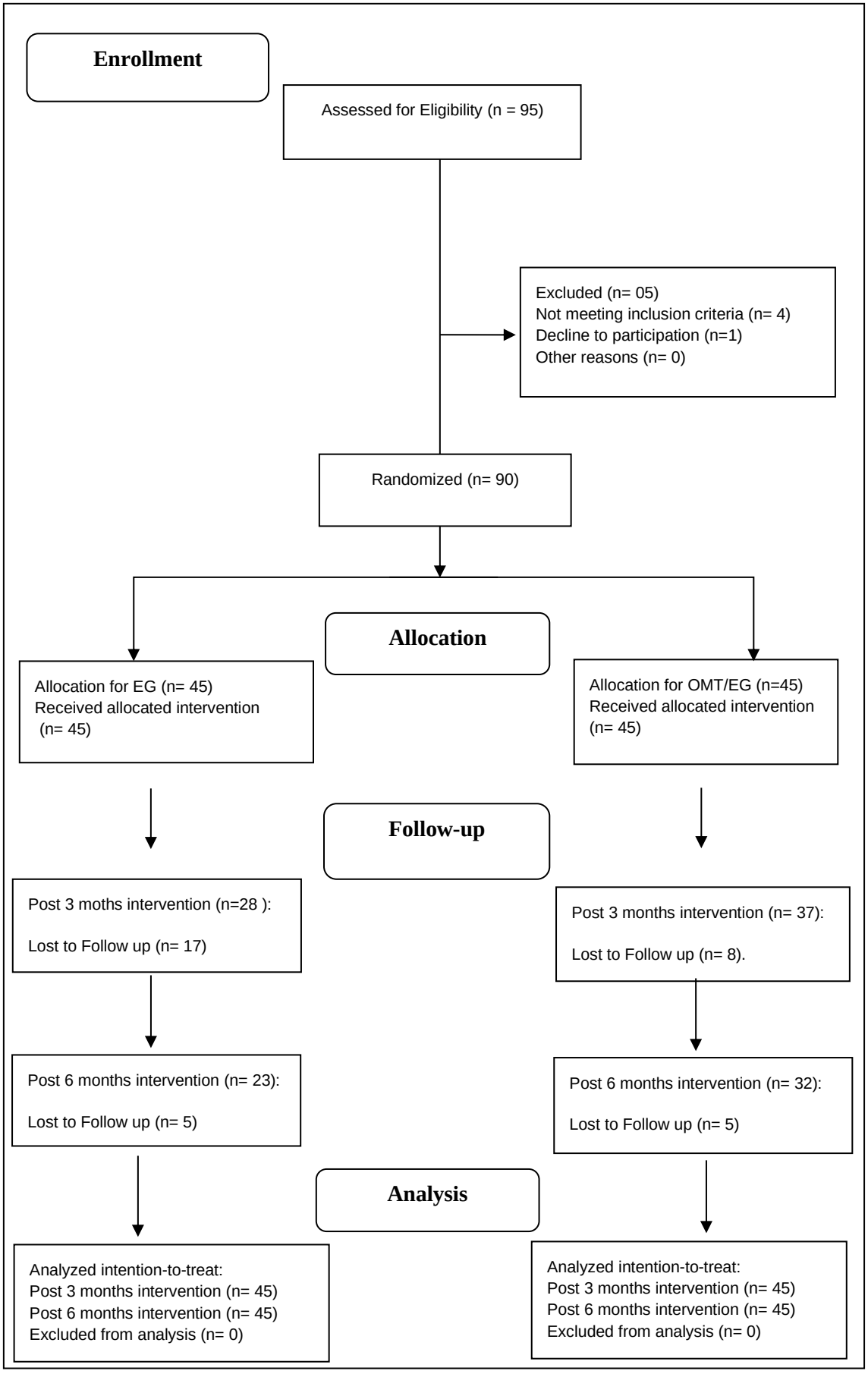
Enrollment
Assessed for Eligibility (n = 95)
Excluded (n= 05)
Not meeting inclusion criteria (n= 4)
Decline to participation (n=1)
Other reasons (n= 0)
Randomized (n= 90)
Allocation
Allocation for EG (n= 45)
Received allocated intervention
(n= 45)
Allocation for OMT/EG (n=45)
Received allocated intervention
(n= 45)
Follow-up
Post 3 moths intervention (n=28):
Lost to Follow up (n= 17)
Post 3 months intervention (n= 37):
Lost to Follow up (n= 8).
Post 6 months intervention (n= 23):
Lost to Follow up (n= 5)
Post 6 months intervention (n= 32):
Lost to Follow up (n= 5)
Analysis
Analyzed intention-to-treat:
Post 3 months intervention (n= 45)
Post 6 months intervention (n= 45)
Excluded from analysis (n= 0)
Analyzed intention-to-treat:
Post 3 months intervention (n= 45)
Post 6 months intervention (n= 45)
Excluded from analysis (n= 0)

Figure 1. Design and flow of participants through the trial.

Table 1 – Summary of primary outcomes results: Numeric Pain Rate Scale (NPRS), Pressure Pain Threshold (PPT)

Primary Outcome measures	OMT/EG Mean ±SE	EG Mean ±SE	Between-group difference Mean ±SE CI (95%)	Between-group p value
NPRS				
Baseline	5.7±0.2	5.5±0.2	0.2±0.3 (-0.5 to 0.9)	0.6
3 months	2.7±0.3	3.6±0.4	-0.9±0.5 (-2.0 to 0.1)	0.1
6 months	3.6±0.4	3,0±0.5	0.6±0.7 (-0.8 to 1.9)	0.4

and neck disability index (NDI)

Baseline/12 weeks Within-group Difference-Mean ±SE CI (95%)	3.0±0.4 (2.2 to 3.8) P<0.001*	1.9±0.4 (1.0 to 2.7) P<0.001*		
Baseline/24 weeks Within-group Difference-Mean ±SE CI (95%)	2.1±0.5 (1.1 to 3.1) P<0.001*	2.5±0.4 (1.5 to 3.4) P<0.001*		
PPT				
Baseline	3.3±0.4	2.7±0.3	0.4±0.5 (0.6 to 1.5)	0.4
3 months	3.1±0.4	3.2±0.5	-0.1±0.6 (-1.4 to 1.2)	0.8
6 months	3.9±0.5	3.5±0.6	0.4±0.8 (-1.2 to 2.1)	0.6
Baseline/12 weeks Within-group Difference-Mean ±SE CI (95%)	0.7±0.3 (-0.6 to 0.8) P=0.8	-0.5±0.4 (-1.64 to 0.4) P=0.2		
Baseline/24 weeks Within-group Difference-Mean ±SE CI (95%)	-0.6±0.4 (-1.6 to 0.05) P=0.06	-0.8±0.7 (-2.2 to 0.6) P=0.2		
NDI				
Baseline	18.9±7	18.9±9	0.0±1.2 (-2.4 to 2.4)	0.9
3 months	10.7±1.1	12.9±1.5	-2.2±1.9 (-6.2 to 1.5)	0.2
6 months	10.9±1.4	10.8±1.5	0.1±2.1 (-4.0 to 2.2)	0.9
Baseline/12 weeks Within-group Difference-Mean ±SE CI (95%)	8.1±1.1 (6.0 to 10.3) P<0.001	5.9±1.5 (2.9 to 8.8) P<0.001		
Baseline/24 weeks Within-group - Difference Mean ±SE CI (95%)	7.9±1.3 (5.3 to 10.5) P<0.001	8.0±1.7 (4.5 to 11.5) P<0.001		

Data expressed as mean±standard Error (SE). Baseline = baseline values; 3 months = values after 12 weeks treatment protocol; 6 months = values after 24 weeks treatment protocol; OMT/EG=osteopathic manipulative treatment group, EG =Exercise group, PPT= Pressure Pain Threshold CI=confidence interval. * statistically significant.

Secundary Outcome measures	OMT/EG Mean ±SE	EG Mean ±SE	Between-group difference Mean ±SE CI (95%)	Between-group p value
FABQ W				
Baseline	20.0±1.5	20.5±1.82	-0.5±2.4 (-5.2 to 4.3)	0.8

Table 2 - Fears Avoidance Believes Questionnaire (FABQ), pain self-efficacy and CROM results.

3 months	16.1±2.1	19.7±2.3	-3.5±3.1 (-9.8 to 2.7)	0.2
6 months	16.4±2.4	18.0±2.4	-1.6±3.4 (-8.3 to 5.1)	0.6
Baseline/12 weeks Within-group Difference-Mean ±SE CI (95%)	3.9±1.5 (0.7 to 7.0) P=0.1	0.8±1.9 (-2.9 to 4.5) P=0.6		
Baseline/24 weeks Within-group Difference - Mean ±SE CI (95%)	3.6±1.8 (-.11 to 7.3) P = 0.9	2.4±2.1 (-1.6 to 6.6) P = 0.2		
FABQ FA				
Baseline	11.1±1.0	9.9±1.2	1.2±1.5 (-1.8 to 4.3)	0.4
3 months	9.6±1.24	8.5±1.4	1.1±1.8 (-2.5 to 4.7)	0.5
6 months	10.7±1.3	7.0±1.3	3.7±1.9 (-.12 to 7.2)	0.6
Baseline/12 weeks Within-group Difference-Mean ±SE CI (95%)	1.5±1.2 (-0.8 to 3.9) P=0.2	1.3±1.5 (-3 to 3.6) P=0.1		
Baseline/24 weeks Within-group Difference - Mean ±SE CI (95%)	0.4±1.3 (-2.2 to 3.1) P=0.7	2.8±1.5 (-.08 to 5.8) P=0.5		
Pain-self efficacy				
Baseline	352.6±14.1	319.7±16	32.9±2.1 (-9.0 to 74.8)	0.1
3 months	405.7±18.7	351.9±35.8	54.7±40.4 (-24.5 to 134.05)	0.1
6 months	415.0±19.3	440.0±16.1	-25.0±25.2 (-74.4 to 24.4)	0.3
Baseline/12 weeks Within-group Difference-Mean ±SE CI (95%)	-53±18 (-90 to -16) P=0.005	-31±34 (-99 to36) P=0.3		
Baseline/24 weeks Within-group Difference - Mean ±SE CI (95%)	-62.±.21 (-10 to -20) P=0.004*	-120±21 (-161 to 79) P=0.000*		

CROM Right				
Baseline	54±2	55±1	-0.6±2.9 (-6.3 to 5.1)	P=0.8
3 months	60.7±1	59.1±2	1.5±3 (-4 to 7.5)	P=0.6
6 months	59±2	57±2	2.0±3.7 (-9 to 5)	P= 0.5
Baseline/12 weeks Within-group Difference-Mean ±SE CI (95%)	6±2 (10 to 2) P=0.004*	3±1 (7to -0.8) P=0.1		
Baseline/24 weeks Within-group Difference - Mean ±SE CI (95%)	4±2 (-8 to -0.1) P=0.04	1.8±2 (-5 to 2) P= 0.3		
CROM Left				
Baseline	56.8±1	56.4±2	0.3±3 (-5.3 to 6.3)	P=0.9
3 months	61.6±1	60.1±2	0.7±2 (-4 to 6)	P=0.7
6 months	61±2	61±2	0±3 (-6 to 6)	P= 0.9
Baseline/12 weeks Within-group Difference-Mean ±SE CI (95%)	4±1 (-8 to 0.9) P=0.1	5±2 (-10 to 0.4) P=0.07		
Baseline/24 weeks Within-group Difference - Mean ±SE CI (95%)	4±3 (-11 to 2) P=0.1	5±2 (-9 to 0.9) P= 0.1		

Data expressed as mean ± standard Error (SE). **Baseline** = baseline values; **3 months** = values after 12 weeks treatment protocol; **6 months =** values after 24 weeks treatment protocol; OMT/EG=osteopathic manipulative treatment group, EG =Exercise group, Threshold CI=confidence interval. FABQ W = Fears Avoidance Believes Questionnaire Work; FABQ FA - Fears Avoidance Believes Questionnaire physical active, CROM = Cervical Range of Motion. *statistically significant.

CONCLUSÃO

Os estudos provenientes desta tese foram elaborados com o objetivo de avaliar os efeitos da associação do tratamento manipulativo osteopático com exercícios de fortalecimento e alongamentos, a curto e médio prazo.

O estudo 1, um ensaio clínico controlado randomizado, demonstrou que a combinação de tratamento manipulativo osteopático com exercícios de fortalecimento e alongamentos a curto prazo é melhor que exercícios usados de forma isolada para dor, incapacidade e mobilidade rotacional do pescoço. Os resultados fornecem evidências de que indivíduos com dor crônica cervical de origem inespecífica podem ser tratados com Tratamento Manipulativo Osteopático junto com exercícios.

Entretanto, no segundo estudo, quando os dados são analisados no período de 3 e 6 meses respectivamente, os resultados não sustentam a hipótese de que a adição de Tratamento Manipulativo Osteopático com exercícios de fortalecimento e alongamento do pescoço resultaria em maior funcionalidade e menos dor em pacientes com dor cervical crônica inespecífica.

Estudos futuros são necessários para esclarecer se o aumento da dose tanto na frequência quanto no tempo em ambos tratamentos impacta na melhora da função e da dor. Da mesma forma, outros desfechos devem ser estudados para a maior compreensão dos efeitos clínicos e da capacidade de modulação da dor na associação destas abordagens.

7. ANEXOS

8.1 Publicação de artigo

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Original Research

Osteopathic manipulative treatment combined with exercise improves pain and disability in individuals with non-specific chronic neck pain: A pragmatic randomized controlled trial

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ABSTRACT

Purpose: To determine effectiveness of osteopathic manipulative treatment combined with stretching and strengthening exercises in the cervical region on pain and disability in individuals with non-specific chronic neck pain.
Methods: 90 adults with non-specific chronic neck pain were randomized to either exercises group (EG, n = 45) or osteopathic manipulative treatment associated with exercises group (OMT/EG, n = 45). The primary outcomes were obtained by the use of Numeric Pain-Rating Scale (NPRS), Pressure Pain Threshold (PPT) and Neck Disability Index (NDI). Secondary outcomes included range of motion (ROM) for cervical spine rotation, Fear-Avoidance Beliefs Questionnaire Work/Physical Activity (FABQ-W/PA) and Pain-self efficacy at two different moments: baseline and 4 weeks after the first treatment. Techniques and dosages of OMT were selected pragmatically by a registered osteopath. Generalized Estimating Equations model (GEE), complemented by the Least Significant Difference (LSD) and the intention-to-treat analysis, was used to assess the clinical outcomes.
Results: Analysis with GEE indicated that OMT/EG reduced pain and disability more than the EG alone after 4 weeks of treatment with statistically significant difference ($p < 0,05$), as well as cervical active rotation was significantly improved ($p = 0.03$). There were no between-group differences observed in Pressure Pain Threshold (PPT) measure, Fear-Avoidance Beliefs Questionnaire and Pain-self efficacy.
Conclusion: The association between OMT and exercises reduces pain and improves functional disability more than only exercise for individuals with non-specific chronic neck pain.

1. Introduction

Neck pain is a common condition with a reported prevalence ranging from 22% to 70% among the general population, and it is more common in women than in men (Blanpied et al., 2017). Neck pain, as well as low back pain, is the leading cause of disability measured in years lived with disability (L. Carroll, 2000; Hogg-Johnson et al., 2008; Palmer et al., 2001; Vos et al., 2016). Studies show that up to 54% of people will suffer from cervical pain at some point in their lives, and almost all of them will still have symptoms during the first five years after the first episode of pain (L. J. Carroll et al., 2009; Côté et al., 2004; Wright et al., 1999). Consequently, neck pain results in major health costs, mainly due to absenteeism from work (Blanpied et al., 2017; Bronfort et al., 2001).

Since the cause of pain is unknown in most cases, neck pain is labeled as non-specific chronic neck pain (NCNP) (Hidalgo et al.,

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2017). However, several factors may contribute to NCNP, such as mechanical and biological aspects (age, gender, history of trauma and musculoskeletal diseases), and other factors related to psychosocial characteristics (physical activity, beliefs, expectations and job satisfaction). These factors are known as having an influence on the transition from acute to chronic pain (Bronfort et al., 2001; Curatolo et al., 2011; Hidalgo et al., 2017).

There are several NCNP management options, including manual therapy, conventional physiotherapy, drug treatment, exercise, pain education, among others (Borghouts et al., 1999; Cleland et al., 2005; Gross et al., 2015; Lau et al., 2011). Manual therapy is a widely used approach, and there has been a significant increase in the number of clinical trials investigating this practice in recent years (Cross et al., 2011; Miller et al., 2010; Vincent et al., 2013). Although there is moderate evidence to support the use of manipulative treatments for cervical pain, the literature shows it is more effective than no intervention or placebo treatment (González-Iglesias et al., 2009; Gross et al., 2010; Schwerla et al., 2008).

A combination of several treatment modalities is referred as multimodal care. Combined manual therapy and exercises have also led to the improvement of patient outcomes when compared to manual therapy or exercises alone (Walker et al., 2008).

Osteopathic manipulative treatment (OMT) is a noninvasive approach that incorporates manual diagnostic and treatment techniques in accordance to pre-established principles, such as interrelation between structure and function, intrinsic self-regulation and homeostasis, and concept of body unity (Kuchera, 2007).

Current evidence indicates that OMT is more effective than placebo treatment or no treatment for pain and function (Franke et al., 2015; Hamilton et al., 2007; Mandara et al., 2010). A recent systematic review (Franke et al., 2015) demonstrated clinically relevant effects of OMT for reducing pain in patients with NCNP. However, these studies have not investigated the effectiveness and impact of OMT combined with exercises on NCNP patients.

Therefore, the objective of this clinical trial was to assess the effectiveness of osteopathic manipulative treatment combined with stretching and strengthening exercises on the cervical region for conservative treatment of individuals with NCNP.

2. Materials and methods

2.1. Study design

This study was a pragmatic single-blinded randomized controlled trial conducted from June 2017 to December 2018. Pragmatic studies are designed to evaluate the effectiveness of interventions in real-life practice conditions and to test interventions in the full spectrum of everyday clinical settings in order to maximize clinical applicability (Harper et al., 2019; Patsopoulos, 2011; Treweek and Zwarenstein, 2009).

The study protocol was approved by the local human research ethics committee and registered at ClinicalTrials.org under registration No. NCT03085355. The general study design is presented in a flowchart (Fig. 1). This paper was reported according to the CONSORT statement (Schulz et al., 2010).

After verifying eligibility, each participant was randomly assigned to either the exercise group (EG) or the exercise group combined with osteopathic manipulative treatment (OMT/EG). The protocol for each group took four weeks, with four exercise sessions for the EG and four exercise sessions combined with osteopathic manipulative treatment for the OMT/EG.

Prior to the study, an online software from RANDOM.ORG was used to generate a randomization list, and 90 participants were allocated into two treatments groups: EG or OMT/EG. These sequentially generated numbers were placed in 90 sealed opaque envelopes, informing which group each participant would belong. The envelope was only opened after the participant had completed all the baseline assessments (Doig and Simpson, 2005). All the participants were told about the existence of the EG and OMT/EG groups. The therapists who performed the treatments could not be blinded. The evaluators who carried out the assessments were blinded in relation to the group that each participant belonged.

2.2. Participants

Adults with NCNP were recruited using advertisements and social media throughout the period of the study. NCNP was defined as the baseline for neck pain without any specific identifiable etiology (i.e. infection, trauma, inflammatory disease, tumor or radiculopathy) (Cohen, 2015). The eligibility criteria were assessed by evaluators who were blinded to the randomization list. The inclusion criteria were: age between 18 and 65, neck pain for at least three months, and a neck pain rate score (NPRS) of two or more at a scale from 0 to 10 and 10 out of 50 points at the Neck Disability Index (NDI) (Vernon, 2008).

Participants who had gone through a neurological exam and presented at least one positive sign, including pain, altered sensation in one or more dermatomes, decreased muscle strength, or reflex alteration, were excluded. Besides these signs and symptoms, individuals who manifested three of the following four criteria from the clinical prediction rule for diagnosis of cervical radiculopathy were also excluded from the study (Wainner et al., 2003): positive Spurling test, positive distraction test, positive upper limb tension test A, and ipsilateral cervical rotation less than 60°. Individuals that reported previous cervical surgery, previous history and medical diagnosis of spondylolisthesis, spinal stenosis, cancer or degenerative osteomioarticular diseases of the upper limbs, or pregnancy at the time of the study were also excluded. Participants who had received some form of manipulative treatment in the last three months and/or who engaged in physical activity on a regular basis were likewise excluded.

2.3. Initial assessment

The eligibility criteria data were collected during the initial assessment after the participant had read and signed the Informed Consent Form and the protocol had been approved by the university's research ethics committee. Psychological factors are known to be highly linked with neck pain (Blozik et al., 2009). Depressive mood and anxiety, were measured by the Hospital Anxiety and Depression Scale (HADS) (Marcolino et al., 2007; Pais-Ribeiro et al., 2007; Zigmond and Snaith, 1983). It consists of two subscales with seven items each. Possible subscale scores range from 0 to 21. According to the German Test Manual, patients with a depression score >8 were considered depressive, patients with an anxiety score >10 were considered anxious.

2.4. Outcome measurements

The outcomes of the participants were collected at baseline (pre-treatment) and after 4 weeks of treatment (post-treatment). Primary outcomes were pain and disability and these were evaluated by the Numeric Pain Rate Scale (NPRS) and Neck Disability Index (NDI). Secondary outcomes were Pressure Pain Threshold (PPT), Range of Motion (ROM) for cervical spine rotation, Fear-Avoidance Beliefs Questionnaire (FABQ) and Pain-self efficacy. Each group followed the same measurement protocol.

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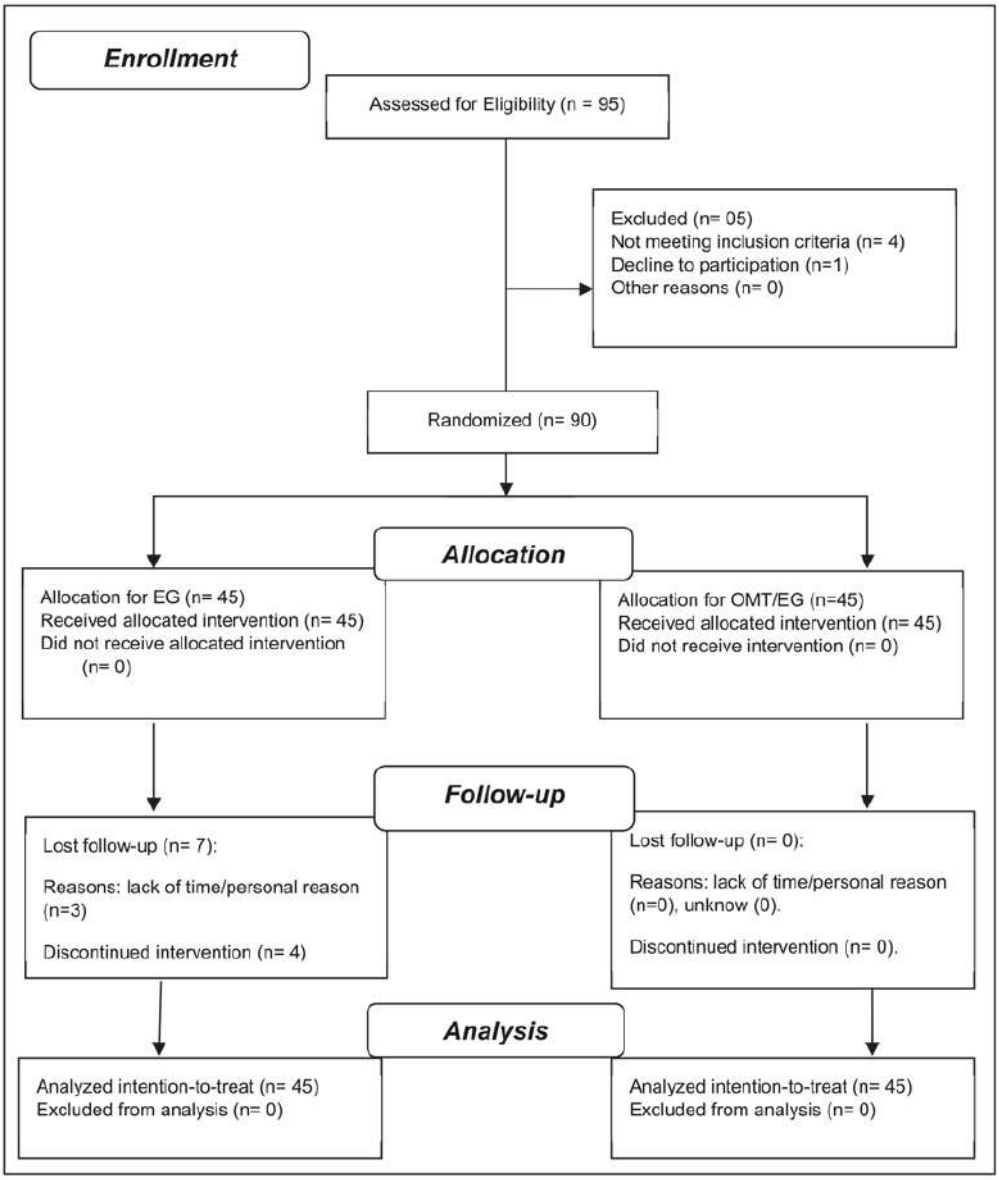

Fig. 1. Design and flow of participants through the trial.

- NPRS: cervical pain was assessed using the 11-point Numeric Pain Rating Scale (0 = no pain, 10 = worst possible pain) for the previous week; The Minimum Clinically Important Change (MCIC) of the NPRS has been reported as 1.3 points for patients with neck pain (Barry and Jenner, 1995; Cleland et al., 2008). The question made in regards to pain was "what was the worst pain you felt within the last week?".
- NDI: The Neck Disability Index score was used for the disability assessment. The NDI is widely used for assessing disability caused by neck pain, and has high test-retest reliability (Vernon and Mior, 1991). It is a validated 10-item questionnaire where each item is rated on a 0 to 5-point scale (Cook et al., 2006; Vernon and Mior, 1991), and has a report from 3.5 to 9.5 points represents a minimal clinically important change MCIC (Cleland et al., 2008; Pereira, 2012; Pool et al., 2007) (Stratford, 1999).
- PPT: Pressure Pain Threshold was measured using a handheld electronic pressure algometer (model DD-2000, Instrutherm®) presented a probe of 1.0 cm^2 (base tip) which was calibrated before testing begin. The measurements were taken in the suboccipital region, according to the trigger point map proposed by Dreyfuss et al. (Dreyfuss et al., 1994): one at a midpoint between the occipital bone and the region corresponding to the C2

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vertebra. All the measurements were done with the participant laying prone on a table. Perpendicular pressure was applied with the algometer. Participants were instructed to say when they felt the sensation of pain, at this point no further force was applied, and the maximal pressure was recorded. Three measurements were taken, with a break of at least 30 s between each one, and the average of the three values represented the PPT for that participant (Hamilton et al., 2007).

- Cervical Spine ROM: a cervical range of motion instrument (CROM®) was used to assess cervical mobility. Range of Motion (ROM) for cervical rotation was obtained with the individual in the sitting position with movements from the left side to the right side. The CROM was placed on the subject's head. The measurements were repeated three times, and the final score was the arithmetic average of the three measurements. The CROM has good intratester and intertester reliability and validity (M. A. Williams, McCarthy, Chorti, Cooke and Gates, 2010).
- FABQ was used to assess the patients' beliefs regarding the effect of physical activity and work on their pain. Fear-Avoidance Beliefs Questionnaire (FABQ) is a 16-item, self-reporting questionnaire. The FABQ contains 2 scales, a 7-item scale assessing fear-avoidance beliefs about work (FABQ work scale; score range, 0–42) and a 4-item scale assessing fear-avoidance beliefs about physical activity (FABQ physical activity scale; score range, 0–24). Higher scores on the FABQ work scale and FABQ physical activity scale indicates that the individual has elevated fear-avoidance beliefs This test has good test-retest reliability (Abreu et al., 2008; de Souza, da Silva Marinho, Siqueira, Maher and Costa, 2008; Landers et al., 2008; Waddell et al., 1993).
- Pain-self efficacy: this outcome consists of 5 questions about the patient's confidence in carrying out various normal activities despite the pain. The questionnaire has 5 questions about pain management by the patient. Responses range from 10 percent sure to 100 percent sure (Salvetti and Pimenta, 2005).

2.5. Interventions

Exercise Group (EG): The participants undertook supervised exercise programs by an experienced physical therapist and consisted of one weekly session in addition to home exercise, over the course of four weeks. Each exercise session lasted approximately 40–45 min. It was composed of 10 min warm-up exercises and about 30 min exercises focused on strengthening and stretching cervical for the neck muscles. This program included stabilization, flexing, extension and rotation exercises for the cervical region and self-mobilization targeting the deep neck muscles (Blanpied et al., 2017). The exercises had low isometric resistance and consisted of three sets of 10 repetitions in supine and sitting positions. Participants were instructed to perform the exercises at home 3 times a week in a way that did not cause pain.

OMT/Exercise Group: The exercise protocol of the OMT/EG was the same as the one for the exercise group. Apart from the exercises, the participants in the OMT/EG also received full osteopathic treatments, once a week over the course of four weeks, with each session lasting 50–60 min. Ten registered osteopaths performed all the treatments. At each visit, participants received a full-body osteopathic examination in accordance with osteopathic principles, which included clinical exams, observation, screening tests, palpation and motion testing. The osteopathic manipulative treatment entailed: direct (high-velocity low-amplitude; muscle energy; and myofascial release), indirect (functional techniques and balanced ligamentous tension), visceral and cranial techniques (Glossary of Osteopathic Terminology). The osteopaths were free to assess the participants and decide which techniques were best to use.

2.6. Data analysis

Sample size was determined in advance, based on the expected two-point difference for the main NPRS outcome, which was considered statistically significant (Cleland et al., 2008). 70 participants were stipulated considering a standard deviation of the NPRS of ±1.6. A level of significance of 0.05 (0.5%) was stipulated, statistical power of 80%, and 20% of losses could occur.

The statistical analysis was performed by a statistician who was blinded to the randomization, measurement and intervention protocols according to intention-to-treat principle. Statistical analyses were conducted using SPSS Statistics 20 for Windows (IBM, Armonk, NY, USA). Demographic data and initial assessment results were compared using independent t-tests. The normality of the data was verified by visual inspection and the standard deviation size was also considered in relation to the mean and also considered if the skewness and kurtosis analysis of the values of the pre- and post-treatment variables. Mean values and standard deviation were calculated for each study variable. Generalized estimating equations model (GEE) complemented by the least significant difference (LSD) were used to evaluate the effects of treatment. This test considers the missing data allowing for intent-to-treat analysis. Effects on time, group and time-by-group interaction were considered. Statistical analysis was conducted with a 95% confidence interval, an α value of 5%, thus representing a value of $p \leq 0.05$.

Finally, Cohen's d was used to calculate effect size. A Cohen's d score of approximately 0.2 was considered a small effect; a moderate effect was defined as a Cohen's d score of approximately 0.5; and a score of approximately 0.8 identified a large effect. The alpha level was set at 0.05.

3. Results

In total, 90 individuals were assessed for eligibility criteria, from June 2017 to December 2018, and then randomly assigned to the exercise (n = 45) and OMT/EG (n = 45) groups (Fig. 1). The subjects of the both groups showed similar baseline characteristics. There were no statistically significant differences between-groups at baseline characteristics (gender, age, weight, height and body mass index, NPRS, NDI, FABQ, HADS) ($p > 0.05$; Table 1). No adverse events were reported during study.

There was within-group difference in pain ($p < 0.05$) and disability ($p < 0.05$) (Table 2). In addition, patients of the OMT/EG showed an increase in cervical rotation range of motion to both sides (ROM; $p < 0.05$; Table 3). This increase in the range of motion did not occur in EG ($p > 0.05$; Table 3).

Osteopathic Manipulative Treatment combining with exercise led to greater reductions in disability and pain compared with the EG. OMT/EG showed lower NPRS (mean difference, −1,4; 95% CI -2,4 to - 0,3; p = 0,007), NDI (mean difference, −3,8; 95% CI -0,74 to −6,9; p = 0,01) and higher cervical rotational range of motion values when compared to patients of the exercise group ($p < 0.05$; Tables 2 and 3).

There were no significant between-group differences at either 4 weeks in Pain-self efficacy (mean difference, −3,9; 95% CI -32,8 to 40,8; p = 0,8), PPT (mean difference, −0,5; 95% CI -1,7 to 0,7; p = 0,4) and FABQ outcomes ($p > 0.05$) (Tables 2 and 3).

4. Discussion

The main purpose of the present study was to assess the combination of OMT and strengthening and stretching exercises in

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Table 1
Comparison between baseline characteristics from patients with non-specific chronic neck pain in the exercise group (EG) and in the osteopathic manipulative treatment group (OMT/EG).

	EG (n = 38)	OMT/EG (n = 45)	Difference between groups	p
Women (%)	84,2% (n = 32)	93.3% (n = 42)	9.1	>0.05
Age (years)	42.8 ± 9.8	40.2 ± 12.3	2.5	0.3
Weight (kg)	70.4 ± 10.60	67.0 ± 11.4	3.4	0.1
Height (m)	1.65 ± 0.07	1.63 ± 0.07	0.02	0.5
NPRS	5.5 ± 1.6	5.7 ± 1.7	0.17	0.6
NDI	18.87 ± 6	18.87 ± 5.1	0	0.9
FABQ W	20.5 ± 11	20.0 ± 10	0.4	0.8
FABQ PA	9.8 ± 7.5	11.1 ± 7	1.2	0.4
HADS A > 10 (%)	65.8 ± 4	66.7 ± 4	0.9	0.9
HADS D > 8 (%)	28.9 ± 4	24.4 ± 4	4.5	0.8

Data expressed in percentage (%) and mean ± standard deviation; NPRS= Numeric Pain Rate Scale; NDI= Neck Disability Index; FABQ W = Fears Avoidance Believes Questionnaire Work; FABQ FA - Fears Avoidance Believes Questionnaire physical active; HADS A = Hospital Anxiety and Depression Scale - anxiety score; HADS D = Hospital Anxiety and Depression Scale – depression score.

Table 2
Summary of primary outcomes results: Numeric Pain Rate Scale (NPRS), Pressure Pain Threshold (PPT) and neck disability index (NDI).

Outcome	Group	Pre Mean ± SD	Post Mean ± SD	Within-group Diference Mean ± SD CI (95%)	Within-group Cohen's effect size	Within-group p value	Between-group diference Mean ± SD CI (95%)	Between-group Cohen's effect size	Between-group p value
NPRS	OMT/EG	5.7 ± 0.2	2.3 ± 0.2*#	3.4 ± 0.2 (2.9–3.9)	0.9	0.00	−1.4 ± 0.5 (−2,4 to - 0,3)	0.8	0,007
	EG	5.5 ± 0.2	3.6 ± 0.4*	1.9 ± 0.3 (1.1–2.6)	0.9	0.00			
PPT	OMT/EG	3.3 ± 0.4	2.8 ± 0.4	0.5 ± 0.3 (−0.3 to 1.3)	_	0.2	−0.5 ± 0.6 (−1.7 to 0.7)	_	0.4
	EG	2,9 ± 0,3	3,3 ± 0,4	−0.4 ± 0.2 (−1.3 to 0.3)	_	0.2			
NDI	OMT/EG	18.9 ± 6.2	11.2 ± 6.8*#	7.7 ± 0.8 (6.0–9.3)	0.5	0.00	−3.8 ± 1.5 (−0,74 to −6,9)	0.2	0,01
	EG	18.8 ± 8.0	15.0 ± 8.8*	3.8 ± 0.9 (1.9–5.7)	0.2	0.00			

Data expressed as mean ± standard deviation (SD). Pre = baseline values; Post = values after 4 weeks treatment protocol; OMT/EG = osteopathic manipulative treatment group, EG = Exercise group, PPT= Pressure Pain Threshold CI = confidence interval, *p < 0.05 *vs* pre-values; #p < 0.05 *vs* EG. Effect sizes were expressed as Cohen's *d*, and an effect size greater than 0.8 was considered large, an effect size of approximately 0.5 was considered moderate, and an effect size of less than 0.2 was considered small.

Table 3
Summary cervical range of motion (ROM), Fears Avoidance Believes Questionnaire (FABQ) and pain self-efficacy results.

Outcome	Group	Pre Mean ± SD	Post Mean ± SD	Within-group Diference Mean ± SD CI (95%)	Within-group Cohen's effect size	Within-group p value	Between-group diference Mean ± SD CI (95%)	Between-group Cohen's effect size	Between-group p value
ROM left	OMT/EG	56.8 ± 2.2	67.4 ± 1.6*#	10.6 ± 1.5 (13–7.4)	0.9	0.0	6.9 ± 3.3 (0,4 to 13,4)	0.8	0,03
	EG	56.4 ± 2.0	60.5 ± 2.8	4.1 ± 2.1 (−8.2 to 0.1)	_	0.6			
ROM right	OMT/EG	54.5 ± 2.2	65.1 ± 1.8*#	9.6 ± 1.5 (12–6.4)	0.9	0.0	8 ± 3.4 (0.3–13.6)	0.8	0.03
	EG	55.1 ± 1.8	57.1 ± 2.8	2.0 ± 1.8 (−5.7 to 1.7)	_	0.3			
FABQ W	OMT/EG	20.0 ± 11	18.2 ± 12	1.8 ± 1.5 (−1.1 to 4.9)	_	0.2	−1.3 ± 3 (−7.2 to 4.5)	_	0.6
	EG	20.5 ± 10	16.8 ± 12	3.7 ± 1.6 (−0.5 to 6.8)	_	0.2			
FABQ FA	OMT/EG	11.1 ± 7	10.3 ± 7	0.7 ± 0.9 (−1 to 2.5)	_	0.4	1.8 ± 1.7 (−5.2 to 1.6)	_	0.2
	EG	9.8 ± 7.5	8.5 ± 7	1.3 ± 1.3 (−1.2 to3.9)	_	0.3			
Pain-self efficacy	OMT/EG	352.6 ± 95	380.9 ± 79*	−28.3 ± 12 (−53 to −3)	0.1	0.0	−3,9 ± 18,7 (−32,8 to 40,8)	_	0,8
	EG	319.7 ± 100	377 ± 81*	−57.2 ± 10 (−78 to −36)	0.3	0.0			

Data expressed as mean ± standard deviation (SD). Pre = baseline values; Post = values after 4 weeks treatment protocol; OMT/EG = osteopathic manipulative treatment group, EG = Exercise group, Threshold CI = confidence interval. FABQ W = Fears Avoidance Believes Questionnaire Work; FABQ FA - Fears Avoidance Believes Questionnaire physical active. *p < 0.05 *vs* pre-values; #p < 0.05 *vs* EG. Effect sizes were expressed as Cohen's *d*, and an effect size greater than 0.8 was considered large, an effect size of approximately 0.5 was considered moderate, and an effect size of less than 0.2 was considered small.

subjects with non-specific chronic neck pain and disability. The results demonstrated that combining both treatments led to reduction of pain and improvements of function disability. Multiple factors may have contributed to the improvement in the functioning and pain levels in individuals with chronic neck pain after osteopathic manipulative treatment in combination with exercise, such as mechanical, neurophysiological, and psychosocial effects (Hidalgo et al., 2017).

Several studies have shown that manual therapy combined with exercises is more effective for patients with neck pain than manipulation or exercises alone (Bronfort et al., 2001; Evans et al., 2002). As far as we know, this is the first study to investigate the effects of OMT combined with exercises on individuals with non-specific chronic neck pain. The findings showed a reduction of pain and an improvement in function in both groups, what supports the use of combined OMT and exercises in achieving clinically important pain reduction and functional improve.

In previous clinical trials, patients with neck pain treated with OMT experienced a reduction in pain of at least 1.5 points (Mandara et al., 2010; Schwerla et al., 2008; N. H. Williams et al., 2003). However, these studies compared osteopathic treatment with placebo treatment. Similarly, another randomized trial, which included participants with neck pain, found that OMT improved quality of life compared with placebo treatment (Schwerla et al.,

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2008). In contrast to those trials, the present study compared exercises on its own and OMT combined with exercises, and found that neck pain was significantly reduced in both groups.

When comparing the two groups, statistically significant difference was noted for pain. The difference in pain between the groups was significant in the study. Moreover, the effect size for the NPRS score was larger in the OMT/exercise group ($r = 0.50$), demonstrating a 3-point reduction, which constitutes a clinically significant difference. This result suggests that people suffering from neck pain can have benefits from OMT.

In a recent systematic review, it was suggested that OMT improves functionality. This coincides with the findings of the present study where improvement in functionality only occurred in the OMT/EG (Franke et al., 2015). The authors of this review suggested that future studies should consider adding exercises to enhance OMT effectiveness (Franke et al., 2015). This was exactly the main goal of the present study, i.e., to demonstrate that combining OMT with exercises can be highly effective.

The use of cervical exercises alone for chronic neck pain has been extensively demonstrated in the references cited in this study (Celenay et al., 2016; Rendant et al., 2011; Ylinen et al., 2003). However, another trial suggested that there are benefits in combining exercises and manual therapy for pain reduction, as opposed to manual therapy on its own (Martel et al., 2011). The present study found that participants in the exercise group combined with OMT had less pain and disability and functioned better as compared to the group that only performed the exercises. OMT was administered in a pragmatic way in accordance with osteopathic principles. The therapists treated all dysfunctions they considered as relevant during the examinations. A pragmatic approach is a real-life situation model, and this approach was used to test how it impacts on the improvement in individuals who received osteopathic treatment. Through the use of this model, the obtained results could confirm an important external validity.

Galindez-Ibarbengoetxea et al. (2017) studied individuals with neck pain, analyzing the immediate effects on pain from an osteopathic treatment compared to exercise protocol use. It was observed that both interventions were associated with immediate improvement in range of motion and pain after the treatment. There was also a significant change in upper trapezius Pressure Pain Threshold following both interventions (Galindez-Ibarbengoetxea et al., 2017). The findings of Galindez-Ibarbengoetxea et al. (2017) confirm some results found by the present study. However, these authors did not use osteopathic treatment in a pragmatic way. In their study, only high-velocity low-amplitude manipulation was used. In addition, osteopathy and exercises were used separately, in contrast to the present study, which used both treatments in a combined way.

In relation to Pressure Pain Threshold, there was no significant difference pre- and post- treatment in both groups, in opposite to other studies which have found this difference (O'Leary et al., 2007).

4.1. Limitations

There are some limitations in this study. First, methodologically blinding of the patients and osteopaths is difficult. Second, participants who received OMT had increased contact with an osteopath, and this interaction can lead to potential improvements and placebo effects. We consider that it may be more useful to carry out long-term follow-up studies to confirm our findings and show longer-lasting effects. However, this is the first prospective study in the literature to evaluate the efficacy of OMT and exercise in patients with NCNP. This study sought to treat participants in a pragmatic way and this type of interaction is part of the osteopathic treatment. From a clinical perspective, the changes observed in the study were statistically significant, the reductions in pain and disability were moderate and support the use of combined OMT and exercises.

5. Conclusion

The results of this randomized controlled trial demonstrated that combining Osteopathic Manipulative Treatment with exercise is better than exercise alone for pain, disability and rotational mobility of the neck. The findings also provide some evidence that individuals with no specific chronic neck pain can be treated with osteopathic manipulative treatment along with exercises.

Clinical relevance

Osteopathic manipulative treatment combined with exercise applied 4 times led to clinically relevant positive changes in pain intensity and functional disability in individuals with chronic non-specific neck pain. In a short-term, it is a safe and an additional option of treatment.

Financial disclosure

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Declaration of competing interest

None.

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8.2 Aprovação do Comitê de Ética UFCSPA

UNIVERSIDADE FEDERAL DE CIÊNCIAS DA SAÚDE DE PORTO ALEGRE

PARECER CONSUBSTANCIADO DO CEP

DADOS DO PROJETO DE PESQUISA

Título da Pesquisa: AVALIAÇÃO DOS EFEITOS DA ASSOCIAÇÃO DO TRATAMENTO MANIPULATIVO OSTEOPÁTICO À EXERCÍCIOS NA DOR E FUNCIONALIDADE DE PARTICIPANTES COM DOR CERVICAL DE ORIGEM INESPECÍFICA ¿ ENSAIO CLÍNICO RANDOMIZADO PRAGMÁTICO

Pesquisador: Geraldo Pereira Jotz

Área Temática:

Versão: 2

CAAE: 63216616.2.0000.5345

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

Patrocinador Principal: Financiamento Próprio

DADOS DO PARECER

Número do Parecer: 1.970.517

Apresentação do Projeto:

O presente projeto de pesquisa é sobre o efeito da associação do tratamento manipulativo osteopático à exercícios cervicais na diminuição da dor e na melhora da funcionalidade de participantes com dor cervical crônica inespecífica.

Objetivo da Pesquisa:

O objetivo geral da pesquisa é avaliar os efeitos do tratamento manipulativo osteopático associados à exercícios cervicais na dor e na funcionalidade de participantes com dor cervical.

Avaliação dos Riscos e Benefícios:

Riscos e benefiicos foram bem documentados.

Comentários e Considerações sobre a Pesquisa:

A pesquisa parece estar bem conduzida. Apresentação critérios adequados de inclusão, exclusão, bem como cálculo de amostra. O cartaz convite foi apresentado e está adequado. O tema da pesquisa é pertinente.

Considerações sobre os Termos de apresentação obrigatória:

O TCLE e o termo de anuência para realização da pesquisa foram adequados.

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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_INFORMAÇÕES_BÁSICAS_DO_PROJETO_823234.pdf	09/02/2017 14:30:05		Aceito
Outros	RESPOSTA_PARECER_CONSUBSTANCIADO.docx	09/02/2017 14:28:44	Sandro Groisman	Aceito
Outros	termo_de_anuencia.pdf	09/02/2017 14:27:47	Sandro Groisman	Aceito
TCLE / Termos de Assentimento / Justificativa de Ausência	TCLE_Reformulado.pdf	09/02/2017 14:25:49	Sandro Groisman	Aceito
Outros	Termoentrega.pdf	06/12/2016 14:10:34	Sandro Groisman	Aceito
Folha de Rosto	FolhadeRosto.pdf	17/11/2016 19:08:40	Sandro Groisman	Aceito
Projeto Detalhado / Brochura Investigador	Projeto.pdf	17/11/2016 19:03:50	Sandro Groisman	Aceito

Situação do Parecer:

Aprovado

Necessita Apreciação da CONEP:

Não

PORTO ALEGRE, 17 de Março de 2017

Assinado por:
Julia Fernanda Semmelmann Pereira Lima
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