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Eficácia do tratamento neurodinâmico em indivíduos com dor lombar irradiada para a perna: ensaio controlado randomizado.

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RESUMO

Introdução: A dor lombar é a condição musculoesquelética mais prevalente em países industrializados, sendo também a principal causa de anos vividos com incapacidade. Dentre as diversas apresentações clínicas da dor lombar, pacientes com dor lombar crônica irradiada para a perna (DLCIP) representam um subgrupo com maiores níveis de incapacidade e pior prognóstico comparados a pacientes com dor lombar isolada. Para pacientes com DLCIP e sinais de mecanosensibilidade neural, o tratamento neurodinâmico (TND) vem sendo proposto como uma alternativa para redução da dor, incapacidade e melhora da função. Entretanto, as diretrizes de prática clínica vigentes recomendam o uso de TND baseadas em evidências de baixa qualidade, devido ao número reduzido de estudos controlados randomizados (ECR). **Objetivos:** Verificar o efeito do TND sobre os níveis de dor na perna, dor lombar, incapacidade, função, auto-percepção de melhora e localização dos sintomas em pacientes com DLCIP. **Metodos:** 60 participantes com DLCIP recrutados da comunidade participaram deste estudo. Os participantes foram aleatoriamente alocados para receberem quatro sessões de tratamento neurodinâmico (TND) ou uma sessão de aconselhamento para se manter ativo (AMA). Pesquisadores cegados para a alocação avaliaram os participantes quanto à intensidade de dor na perna, intensidade de dor lombar, incapacidade, função, auto-percepção de melhora e localização dos sintomas em dois momentos distintos: duas semanas e um mês após a randomização. Modelos lineares mistos foram aplicados para a análise dos desfechos contínuos. A localização dos sintomas foi avaliada com o teste Chi-quadrado. Os dados foram analisados conforme princípios de intenção-de-tratamento. **Resultados:** Após duas semanas, não houve efeito significativo do TND na dor na perna (-0,9, IC 95% -0,27 até 2,14) e incapacidade (-2,04, IC 95% -8,43 até 4,34). Após um mês, os participantes que receberam TND experienciaram redução significativa na dor na perna (-2,28, IC 95% -3,51 até -1,04) mas não na incapacidade (-3,62, IC 95% -10,08 até 2,83). Houve também melhora significativa na função após duas semanas (4,75, IC 95% 1,78 até 7,73) e um mês (4,17, IC 95% 1,15 até 7,20), bem como para o desfecho auto-percepção de melhora após duas semanas (2,42, IC 95% 1,48 até 3,37) e um mês (2,77, IC 95% 1,81 até 3,73). Não houve diferença entre os grupos na intensidade de dor lombar após duas semanas (-0,66, IC 95% -1,94 até 0,61) e um mês (-1,24, IC 95% -2,53 até 0,49) e localização dos sintomas após duas semanas (RR 2,2, IC 95% 0,9 até 5,6) e um mês (RR 1,9, IC 95% 0,9 até 4,0).

Palavras-chave: Dor lombar; Ciática; Terapia manual; Tratamento neurodinâmico; Teste de slump.

ABSTRACT

Introduction: Low back pain is a highly prevalent and disabling condition that represents the major cause of years lived with disability in both developed and developing countries. Among the wide array of clinical presentations, patients with chronic nerve-related leg pain (NRLP) presents higher levels of work-related disability, lower levels of quality of life as well as poorer prognosis compared to patients with low back pain only. Patients with NRLP who present signs of nerve mechanosensitivity, neurodynamic treatment (NDT) has been proposed as an effective intervention to reduce pain, disability and improve function. However, current clinical practice guidelines recommend neurodynamic treatment for patients with chronic nerve-related leg pain based only on weak evidence due to the paucity of randomised controlled trials. **Objectives**: To verify the effects of NDT on leg pain, low back pain, disability, function, global perceived effect and location of symptoms in patients with BRLP at two weeks and one month after randomization. **Methods**: This is a parallel-group randomized controlled trial with allocation concealment and blinded to outcome assessment. Sixty participants with BRLP were recruited from the community to receive either four sessions of NDT for two weeks or one session of advice to remain active (ARA). Leg pain and low back pain, disability, function, global perceived effect and location of symptoms were measured at two weeks and one month after randomization. Continuous outcomes were analysed by linear mixed models. Location of symptoms was assessed by the Chi-square test. **Results:** At two weeks, there was no significant effect of treatment on leg pain (-0.9, 95% CI -0.27 to 2.14) and disability (-2.04, 95% CI -8.43 to 4.34). At four weeks, participants receiving neurodynamic treatment experienced significant reduction in leg pain (-2.28, 95% CI -3.51 to -1.04) but not in disability (-3,62, 95% CI -10.08 to 2.83). There was a significant effect of treatment on function improvement at two weeks (4.75, 95% CI 1.78 to 7.73) and four weeks (4.17, 95% CI 1.15 to 7.20), as well as global perceived effect at two weeks (2.42, 95% CI 1.48 to 3.37) and four weeks (2.77, 95% CI 1.81 to 3.73). No significant between-group differences were noted for low back pain at two weeks (-0.66, 95% CI -1.94 to 0.61) and four weeks (-1.24, 95% CI -2.53 to 0.49), and location of symptoms at two (RR 2.2, 95% CI 0.9 to 5.6) and four weeks (RR 1.9, 95% CI -0.9 to 4.0).

Key words: Low back pain; Sciatica; Manual Therapy; Neurodynamic treatment; Slump test.

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APM	Auto-percepção de melhora
DL	Dor lombar
DLCIP	Dor lombar crônica irradiada para a perna
DRP	Desfechos reportados pelo paciente
EEFP	Escala Específica Funcional do Paciente
GPE	*Global Perceived effect*
ODI	Oswestry Disability Index
TND	Tratamento neurodinâmico
IC 95%	Intervalo de confiança 95%
RR	Risco relativo

SUMÁRIO

1. INTRODUÇÃO

A dor lombar (DL) é uma condição musculoesquelética com alta prevalência pontual e de vida, sendo a doença mais incapacitante tanto em países desenvolvidos quanto naqueles em desenvolvimento, acarretando enormes custos diretos e indiretos. (GARCIA *et al.*, 2014; GLOBAL BURDEN OF DISEASE STUDY, 2015; NASCIMENTO e COSTA, 2015). Dentre as inúmeras apresentações clínicas possíveis, o subgrupo de pacientes com dor lombar crônica irradiada para a perna (DLCIP) apresenta considerável prevalência, seja na atenção primária, seja em níveis mais complexos de atenção. (HIDER *et al.*, 2015) Além disso, pacientes com DLCIP apresentam pior prognóstico, piores índices de qualidade de vida, incapacidade, além de utilizarem mais serviços de saúde comparados a pacientes com dor predominantemente lombar. (KONSTANTINOU *et al.*, 2013; KONSTANTINOU *et al.*, 2015)

Diversas estratégias de tratamento conservador são propostas para o tratamento da DLCIP, tais como acupuntura, manipulação vertebral, modalidades eletrotermofototerapêuticas, exercícios específicos de preferência direcional, fortalecimento e controle motor, bem como tração sustentada e intermitente. (CHOU, HUFFMAN*, et al.*, 2007; PETERSEN *et al.*, 2011; WEGNER *et al.*, 2013; BRONFORT *et al.*, 2014; LEWIS *et al.*, 2015; THACKERAY *et al.*, 2016) Entretanto, uma metanálise em rede recente demonstrou que muitas destas modalidades ou apresentam tamanhos de efeito pequenos a moderados, ou não são eficazes. Dessa forma, não existe consenso na literatura acerca da melhor intervenção, ou da melhor combinação de intervenções disponíveis para o tratamento da DLCIP.

Uma abordagem de tratamento fisioterapêutico para DLCIP ainda pouco investigada é o tratamento neurodinâmico (TND). O TND consiste em mobilizações passivas e ativas da coluna vertebral e segmentos corporais com o objetivo de mobilizar estruturas ao redor dos nervos periféricos, como também os nervos periféricos em si. (COPPIETERS *et al.*, 2015) Até o presente momento, poucos estudos investigaram o efeito do TND, e a evidência disponível advém, em sua maioria, de séries de casos (GEORGE, 2002; SCHAFER *et al.*, 2011), de estudos clínicos randomizados controlados

de baixa qualidade metodológica (GEORGE, 2002; CLELAND *et al.*, 2006) ou de ERC com intervenções múltiplas nas quais o TND é representado somente pela técnica de alongamento na posição de *slump*, não refletindo, portanto a prática clínica. (CLELAND et al., 2006; NAGRALE et al., 2012) Por isso, o TND é recomendado por uma recente diretriz de prática clínica (DELITTO et al., 2012) com grau de recomendação C – ou seja, recomendação baseada em evidência fraca.

Embora amplamente divulgado como uma estratégia efetiva de tratamento para condições que envolvem mecanismos de dor neuropática periférica, o TND ainda não possui um corpo de evidências de qualidade que possam verdadeiramente auxiliar fisioterapeutas no processo de tomada de decisão clínica. Considerando a crescente necessidade de pautar a prática fisioterapêutica de acordo com as melhores evidências disponíveis, a presente pesquisa se justifica pela necessidade de mais ensaios clínicos randomizados de alta qualidade metodológica que avaliem a eficácia do TND em desfechos clínicos em pacientes com DLCIP. Portanto, os objetivos deste estudo foram:

1. Verificar o efeito do TND, comparado a aconselhamento para se manter ativo, na intensidade de dor na perna de invidíduos com dor lombar crônica irradiada para a perna após duas semanas e um mês da randomização;
2. Verificar o efeito do TND, comparado a aconselhamento para se manter ativo, nos níveis de incapacidade de invidíduos com dor lombar crônica irradiada para a perna após duas semanas e um mês da randomização;
3. Verificar o efeito do TND, comparado a aconselhamento para se manter ativo, na intensidade de dor na coluna lombar de invidíduos com dor lombar crônica irradiada para a perna após duas semanas e um mês da randomização;
4. Verificar o efeito do TND, comparado a aconselhamento para se manter ativo, nos níveis de função de invidíduos com dor lombar crônica irradiada para a perna após duas semanas e um mês da randomização;
5. Verificar o efeito do TND, comparado a aconselhamento para se manter ativo, na auto-percepção de melhora de invidíduos com dor lombar crônica irradiada para a perna após duas semanas e um mês da randomização;

6. Verificar o efeito do TND, comparado à aconselhamento para se manter ativo, na intensidade de dor na perna de invidíduos com dor lombar crônica irradiada para a perna após duas semanas e um mês da randomização;
7. Verificar o efeito do TND, comparado à aconselhamento para se manter ativo, na localização de dor na perna de invidíduos com dor lombar crônica irradiada para a perna após duas semanas e um mês da randomização.

2. REVISÃO DE LITERATURA – CONTEXTUALIZAÇÃO

2.1 Epidemiologia

A DL é a desordem musculoesquelética mais prevalente na sociedade, sendo a principal causa de anos vividos com incapacidade em 90% dos países desenvolvidos, 68% dos países em desenvolvimento, bem como na população brasileira. (GLOBAL BURDEN OF DISEASE STUDY, 2015) Em cerca de 85% dos diagnósticos de dor lombar não é possível identificar, de forma acurada, a estrutura anatômica responsável pela geração dos sintomas. (CHOU, QASEEM*, et al.*, 2007) Isso se deve principalmente ao fato de achados degenerativos correlacionarem-se de maneira muito pobre à intensidade e comportamento dos sintomas reportados pelos pacientes. (CHOU, QASEEM*, et al.*, 2007) Dessa forma, nessa grande proporção de casos a DL é considerada inespecífica. (DELITTO *et al.*, 2012) Já quando a DL é acompanhada de radiculopatia (disfunção de raíz nervosa associada à dor radicular, alterações sensoriais ou motoras), estenose lombar associada à radiculopatia, ou outras causas potencialmente graves (fraturas, tumores, infecção, síndrome da cauda equina, etc), a DL passa a ser classificada como específica; (CHOU, QASEEM*, et al.*, 2007) Quanto ao tempo de duração dos sintomas, a DL pode ser classificada em aguda (dor por até 6 semanas), subaguda (dor por 6 a 12 semanas) e crônica (dor com duração superior a 12 semanas). (CHOU, QASEEM*, et al.*, 2007)

Mundialmente, estima-se que a prevalência pontual da DL seja de cerca de 11%, ao passo que a prevalência de vida é de aproximadamente 40%. (HOY et al., 2012) Na América Latina, as estimativas de prevalência de dor lombar crônica apontam para cerca de 10,5%. (GARCIA et al., 2014) Com relação à população brasileira, não existem até o momento estudos observacionais com adequado controle de viéses que possam representar de maneira acurada a real prevalência de DL. Uma recente revisão sistemática reportou prevalências entre 4,2% na população da cidade de Pelotas (RS) e 14,2% na população da cidade de Salvador (BA). (NASCIMENTO e COSTA, 2015)

Pacientes com dor DLCIP compõe um subgrupo de pacientes com DL com alta prevalência. Em um estudo conduzido na Inglaterra, 60% dos

pacientes que procuraram serviços de atenção primária com queixa de dor lombar apresentavam também dor irradiada para a perna, acima ou abaixo do joelho. (HIDER et al., 2015) Destes, 37% apresentavam sintomas crônicos; ou seja, com duração superior a 3 meses. Já a incidência reportada é bastante variável, entre 1% a 37%, e essa notável diferença se deve principalmente às diferentes definições operacionais adotadas pelos estudos. (COOK et al., 2014)

2.2 Fatores de risco

Embora o senso comum aponte os fatores biomecânicos como principais fatores de risco para DL, não existe consenso entre estudos prospectivos longitudinais a respeito de sua real contribuição. Bakker et al. (2009) revisaram sistematicamente 18 estudos prospectivos longitudinais de alta qualidade metodológica, totalizando 24.315 indivíduos, e encontraram evidências conflitantes para a associação entre trabalho físico pesado, atividades de lazer - tais como jardinagem -, flexão e rotação de tronco no trabalho, vibração de corpo inteiro e tarefas relacionadas ao cuidado de pacientes e risco para desenvolver DL. Esta mesma revisão apontou a existência de evidência forte para a ausência de associação entre prática de esportes em períodos de lazer, sentar, ortostase e caminhar prolongados e dor lombar. Roffey et al. (2010) demonstraram a existência de evidência forte para a ausência de associação entre posturas inadequadas no trabalho e dor lombar. Já a revisão sistemática conduzida por Wai et al. (2010) demonstrou a existência de evidências conflitantes para a associação entre flexão e rotações de tronco no ambiente de trabalho e dor lombar. Em contrapartida, o estudo prospectivo conduzido por Ramond-Roquin et al. (2013) demonstrou a existência de associação entre flexão por mais de duas horas por dia e dirigir veículos industriais e risco aumentado de desenvolver DL.

O reconhecimento de fatores psicossociais como potenciais causas de DL vem contribuindo para a transição do paradigma puramente centrado em aspectos patoanatômicos em direção a uma perspectiva de entendimento multidimensional do paciente, na qual os fatores biológicos interagem de forma complexa com determinantes sociais e psicológicos, aumentando o risco de desenvolvimento e perpetuação da DL. (HANCOCK *et al.*, 2011) Vargas-Prada

et al. (2013) conduziram um estudo prospectivo longitudinal em enfermeiras e trabalhadores de escritório e verificaram que a presença de má saúde mental e tendência à somatização aumentaram o risco de desenvolvimento de dor lombar após um ano em 1,5 e 1,8 vezes, respectivamente. Entretanto, há evidência moderada para a ausência de associação entre aspectos relacionados ao trabalho, como aspectos organizacionais e suporte social, e DL. (HARTVIGSEN *et al.*, 2004) Mais recentemente, a presença de sintomas depressivos foi associada a risco aumentado de desenvolver DL, e esta associação apresentou relação de dose-resposta, outro elemento importante para determinação da causalidade – além da temporalidade. (PINHEIRO, FERREIRA, REFSHAUGE, ORDONANA*, et al.*, 2015) Contudo, este mesmo grupo de autores também demonstraram que a associação significativa entre depressão e dor lombar desaparece quando há controle rígido de fatores genéticos, destacando a relevância destes fatores como potenciais confundidores em estudos longitudinais. (PINHEIRO, FERREIRA, REFSHAUGE, COLODRO-CONDE*, et al.*, 2015)

O alcoolismo é também considerado um fator de risco para DL (FERREIRA *et al.*, 2013). Já em indivíduos com dor lombar e ciática associada, fatores como o sobrepeso, a obesidade, e ser fumante ou ex fumante foram identificados como fator de risco para desenvolvimento da DLCIP. (COOK *et al.*, 2014)

Os achados patoanatômicos também são constantemente referidos como potenciais fatores de risco para desenvolvimento de DL. Isto é, distúrbios patoanatômicos predisporiam os indivíduos a desenvolverem dor. Embora estudos transversais reportem a existência de probabilidade três vezes maior de indivíduos com alterações anatômicas experienciarem dor lombar (LIVSHITS *et al.*, 2011), estudos prospectivos longitudinais falham em encontrar associação significativa entre alterações anatômicas como degeneração do disco intervertebral, Modic tipo I, osteoartrite facetária e lesões do ânulo fibroso com risco aumentado de desenvolver DL. (JARVIK *et al.*, 2005) Já em relação DLCIP, estima-se que cerca de 90% dos casos sejam relacionados à hérnia de disco e a consequente compressão das raízes nervosas. Fatores menos comuns, como estenose do canal vertebral e tumores também pode ser causadores desta sintomatologia. (KOES *et al.*, 2007)

Já em indivíduos previamente expostos à DL, a probabilidade de experienciar um novo episódio aumenta significativamente. (TAYLOR *et al.*, 2014) Além da história prévia, a existência de Modic tipo I (processo inflamatório inicial relacionado ao estágio inicial da doença degenerativa do disco intervertebral, caracterizada pela presença de hipersinal no platô vertebral), hérnia de disco, *High Intensity Zone* e degeneração do disco intervertebral (Pfirrmann ≥ 3) pareceram aumentar o risco de futuros episódios de DL. (STEFFENS *et al.*, 2014; HANCOCK *et al.*, 2015)

A ampla gama de fatores de risco propostos, diferenças entre as populações estudadas (ex: populações economicamente ativas em diferentes atividades ocupacionais, idosos, populações mistas), diferentes definições operacionais de episódio e recidiva, bem como a complexidade que envolve a condução de estudos prospectivos longitudinais com baixo risco de viés são fatores contribuintes para as inúmeras controvérsias sobre causalidade na literatura atual. É inegável também que uma importante proporção dos estudos longitudinais existentes sobre o tema considera apenas a magnitude da associação e a temporalidade para a determinação da relação causal. Entretanto, revisões sistemáticas de estudos longitudinais frequentemente demonstram inconsistência entre as estimativas descritas por estudos individuais e raramente avaliam a existência de relação de dose-resposta (isto é, se a magnitude da exposição afeta a magnitude do desfecho). Estes critérios são, em conjunto com a plausibilidade biológica, a especificidade e a coerência, fundamentais para determinação de causalidade real. (HOFLER, 2005)

2.3 Fatores prognósticos

Identificar o prognóstico de uma doença significa prever como será a sua evolução ao longo do tempo. A compreensão dos fatores prognósticos pode, por exemplo, auxiliar na tomada de decisão clínica, permitindo que pacientes com maiores chances de pior prognóstico recebam tratamentos mais eficazes, dessa forma reduzindo custos em saúde. (HILL *et al.*, 2011) Ao passo que algumas doenças apresentam maior probabilidade de mau prognóstico, tais como diversos tipos de câncer, o prognóstico da DL é favorável; isto é, os

indivíduos tendem a se recuperar, em alguma medida, com o passar do tempo. Porém, tanto indivíduos com DL aguda quanto indivíduos com DL crônica continuam a apresentar níveis baixos a moderados de dor e incapacidade mesmo após um ano do primeiro episódio. Já em relação à recuperação, grande parte dos pacientes com DL aguda recuperam-se, ao passo que menos da metade dos pacientes com DL crônica reportam recuperação plena (COSTA *et al.*, 2012)

Diversos fatores tem sido apontados como indicativos de mau prognóstico em pacientes com DL, tais como a presença de pensamentos catastróficos sobre dor, comportamentos de medo e evitação, alta intensidade de dor lombar, estar desempregado, ter a crença de que a dor persistirá, dor generalizada pelo corpo, incapacidade, medo, ansiedade e depressão (HILL *et al.*, 2008; DUNN *et al.*, 2011; CAMPBELL *et al.*, 2013; WERTLI, EUGSTER*, et al.*, 2014; WERTLI, RASMUSSEN-BARR*, et al.*, 2014; PINHEIRO *et al.*, 2016)

A literatura também demonstra a existência de fatores de bom prognóstico para pacientes com DL. Cook et al. (2013), ao avaliarem o auto-relato de recuperação de pacientes com dor lombar submetidos à terapia manual (mobilização com ou sem manipulação precoce) associada à exercícios de fortalecimento, identificaram que preencher os critérios do subgrupo manipulação validado por Childs et al. (2004) era um fator prognóstico independente da terapia recebida. Já a coorte prospectiva conduzida por de Schepper et al. (2016) demonstrou que pacientes mais jovens, com crenças e atitudes positivas em relação à DL e com sintomas neurológicos em uma das pernas foram fatores relacionados à melhora clínica após doze meses em pacientes com DL avaliados na atenção primária. O bom prognóstico associado à presença de sintomas neurológicos contrasta com os achados de uma recente revisão sistemática, na qual a presença de dor irradiada para a perna com sintomas neurológicos foi relacionada à pior prognóstico e maior utilização de serviços de saúde em comparação à indivíduos com dor lombar apenas. (KONSTANTINOU *et al.*, 2013)

A revisão sistemática de fatores prognósticos para DLCIP mais recente demonstrou que o único fator relacionado à mau prognóstico e subsequente indicação cirúrgica foi intensidade de dor na perna. (VERWOERD *et al.*, 2013) Em um estudo recente, a presença de compressão de raíz nervosa e hérnia

extrusa foram fatores prognósticos para menor intensidade de dor na perna após doze meses. Estas mesmas características associaram-se, embora não significativamente, à melhor percepção de recuperação após um ano. (EL BARZOUHI *et al.*, 2016).

Fatores como idade, gênero, índice de massa corporal elevado e ser fumante parecem não ser fatores prognósticos para pacientes com dor lombar. (VERKERK *et al.*, 2012) Em pacientes DLCIP, além dos fatores acima, história prévia de dor lombar e/ou irradiada para a perna abaixo do joelho, aumento dos sintomas ao tossir e/ou espirrar, teste de elevação da perna reta cruzado positivo, alterações sensoriais e motoras características de comprometimento de raíz nervosa, teste de Kemp positivo e presença de hérnia de disco não associaram-se a bom ou mau resultado. (VERWOERD *et al.*, 2013)

Aspectos de exame físico também têm sido investigados como potenciais fatores prognósticos, tais como exame neurológico completo (força, sensibilidade e reflexos), amplitude de movimento e palpação – tanto na busca de segmentos vertebrais com mobilidade reduzida, quanto na reprodução dos sintomas. Entretanto, uma recente revisão sistemática demonstrou não haver associação consistente entre achados de exame físico e desfecho clínico, à exceção da presença de centralização e de sinais não-orgânicos. (HARTVIGSEN *et al.*, 2015)

A capacidade preditiva de clínicos sobre o desfecho de pacientes com dor lombar foi recentemente comparada à habilidade preditiva do *StarT Back Screening Tool*, ferramenta de avaliação de prognóstico baseada na avaliação de fatores reconhecidamente prognósticos. Este estudo demonstrou que a habilidade preditiva de ambos foi comparável e pequena (KONGSTED *et al.*, 2016) Embora se tenha conhecimento sobre diversos fatores prognósticos de bom e mau desfecho clínico, faz-se necessário aprimorar as ferramentas de avaliação de prognóstico multidimensionais, dessa forma melhorando a capacidade de tomada de decisão clínica.

2.4 Medidas de avaliação de desfecho

Na intenção de promover serviços de saúde centrados no paciente, a avaliação de desfechos reportados pelo paciente (DRP) é imperativa. Os DRPs

caracterizam-se por desfechos que são advindos dos próprios pacientes sobre como eles se sentem e funcionam em relação à sua condição de saúde e em relação à eventuais tratamentos propostos. Estes desfechos não sofrem interferência e interpretação de profissionais de saúde responsáveis pelo cuidado, visando a registrar única e exclusivamente a percepção individual e intransferível do paciente. (NELSON *et al.*, 2015)

Uma barreira para a implementação de DRP é a crença de profissionais de saúde que o seu uso consome tempo e não confere benefícios adicionais ao cuidado do paciente. Além disso, a eventual subjetividade inerente às respostas é objeto de críticas por parte de clínicos e pesquisadores. Este último argumento ignora por completo a existência de estudos de clinimetria dos instrumentos. À despeito de críticas, o uso sistematizado de DRPs notoriamente leva à melhor comunicação entre pacientes e profissionais da saúde. Ademais, serviços de saúde podem ser treinados visando à melhorar a implementação de DRPs. (SANTANA *et al.*, 2015) Essa característica potencialmente melhora o processo de tomada de decisão e, aumenta a efetividade e a satisfação do paciente com o cuidado. (NELSON *et al.*, 2015)

Em pacientes com DL, enquanto o uso de DRP tem o potencial de informar sobre eficácia e efetividade de tratamentos, desfechos experimentais e substitutivos visam à determinar aspectos etiológicos e mecanismos de ação terapêuticos. Em um estudo *Delphi* recente, envolvendo pacientes, pesquisadores e clínicos, buscou-se determinar um consenso internacional sobre quais desfechos seriam centrais na avaliação de pacientes com DL. Os resultados deste estudo sugere que função física, intensidade de dor, qualidade de vida relacionada à saúde e número de mortes - devem ser utilizados em detrimento de desfechos substitutivos quando o objetivo é avaliar a eficácia e efetividade de intervenções de saúde. (CHIAROTTO *et al.*, 2015)

2.4.1 Dor

A avaliação da dor é extremamente complexa, dada a sua característica multidimensional, sendo o desfecho auto-reportado mais comumente adotado em estudos randomizados e controlados que visam a testar a eficácia de tratamentos fisioterapêuticos para DL. Atualmente, existem algumas opções de

instrumentos a serem utilizados, cada qual com vantagens e desvantagens. (FERREIRA-VALENTE *et al.*, 2011) Um dos atributos de validade mais importantes na avaliação da dor é a responsividade; ou seja, a habilidade da escala em captar mudanças clínicas, ainda que pequenas. (GABEL *et al.*, 2012) Ferreira-Valente et al. (2011) compararam quatro medidas de avaliação da dor, as escalas analógica visual, numérica, verbal e de faces. Todas apresentaram altos níveis de concordância e validade, sendo a escala numérica de dor a mais responsiva. Em pacientes com DL, a escala numérica de dor apresenta boa responsividade e considera-se como mudanças clinicamente importantes aquelas iguais ou superiores a 2 pontos. (CHILDS *et al.*, 2005)

2.4.2 Incapacidade

É imperativo avaliar o impacto de tratamentos para DL na incapacidade, dado os altíssimos níveis de anos vividos com incapacidade gerados por esta condição. Destacam-se como medidas de avaliação da incapacidade dois instrumentos, o *Oswestry Disability Index* (ODI) e o *Roland-Morris Questionnaire*, devidamente traduzidos e adaptados para o português brasileiro. (NUSBAUM *et al.*, 2001; VIGATTO *et al.*, 2007) Ambas as escalas apresentam adequados atributos de validade, sendo o ODI mais confiável que o RMQ; porém, perdem confiabilidade quando o reteste é realizado após muitos dias. (GEERE *et al.*, 2013) A versão brasileira do ODI apresenta boa consistência interna (Alfa de *Cronbach* = 0,87), moderada correlação com níveis de dor (r = 0,66) e alta correlação com a pontuação do RMQ (r = 0,81), indicando que esta escala pode ser utilizada em populações brasileiras com DL. (VIGATTO *et al.*, 2007) Considera-se como mudança clinicamente importante aquela igual ou maior a 10 pontos no ODI, considerando uma escala de 0 a 100. (OSTELO *et al.*, 2008)

2.4.3 Função

O entendimento de cada indivíduo sobre o que significa ser ou não funcional altamente variável e dependente de suas experiências, expectativas e

demandas do dia-a-dia, tornando-o “função” um constructo altamente complexo. A escala específica funcional do paciente (EEFP) visa à identificar atividades específicas que são importantes no dia-a-dia de cada paciente mas que, por conta de problemas musculoesqueléticos, estão prejudicadas. A EEFP tem sido utilizada em diversas condições musculoesqueléticas com adequadas propriedades clinimétricas. (HORN *et al.*, 2012) Este instrumento foi traduzido e adaptado para o português brasileiro em uma amostra de indivíduos com dor lombar por Costa et al. (2008) e demonstrou altos níveis de consistência interna, reprodutibilidade e adequados níveis de responsividade, sendo indicada para avaliação de função em brasileiros com DL.

2.4.4 Auto-percepção de melhora

Identificar se após um tratamento houve melhora ou deterioração do estado de saúde é fundamental para a adequada tomada de decisão clínica. Diversas escalas são reportadas na literatura, tais como a *Global Rating of Change* (GROC) e a *Global Perceived Effect* (GPE) e todas visam a quantificar a auto-percepção de melhora ao longo do tempo, geralmente após um tratamento. As escalas de auto-percepção de melhora (APM) necessitam que o indivíduo recorde o seu estado de saúde prévio, avalie o seu estado de saúde atual, e então calcule uma diferença entre ambos. Essa diferença é a medida real de melhora, piora ou ausência de efeito de um tratamento. (KAMPER *et al.*, 2010) A GPE apresenta excelentes níveis de reprodutibilidade, fornecendo medidas confiáveis a respeito da percepção de mudança em uma série de condições de saúde; entretanto, a pontuação reportada pelos indivíduos é altamente influenciável pelo atual estado de saúde. A GPE foi adaptada para o português brasileiro por Costa et al. (2008). Não existem valores de diferenças clinicamente importantes na literatura, mas sugere-se que uma mudança de dois pontos seja clinicalmente relevante. (KAMPER *et al.*, 2009)

2.4.5 Localização dos sintomas

Em pacientes com DLCIP, é importante verificar o efeito de um tratamento na localização dos sintomas, uma vez que a centralização dos

sintomas irradiados em direção à coluna lombar parece ser um fator prognóstico para bom desfecho clínico. (WERNEKE et al., 1999) A avaliação da localização é feita por meio de uma carta corpórea, em que os sintomas são ordinalmente categorizados de acordo com sua localização. A distribuição da queixa é classificada de 0 a 6, sendo 0 quando não houver sintoma identificável; 1 se a dor for isolada no centro da coluna; 2, se a dor for contida na coluna lombar, mas nas laterais; 3, se a dor for localizada nos glúteos; 4, se a dor for localizada na coxa; 5, se a dor for localizada na perna; e 6, se a dor for localizada no pé. É considerado o escore mais alto; isto é, o sintoma mais distal assinalado pelo paciente. Esse modelo de classificação apresenta excelente confiabilidade intra e inter-examinador (WERNEKE et al., 1999).

2.5 Neurobiologia e biomecânica do sistema nervoso periférico

Na ausência de ferramentas para identificação acurada de estruturas envolvidas na gênese e perpetuação da DL e DLCIP, as classificações de dor baseadas em mecanismos neurofisiológicos podem, potencialmente, explicar variações clínicas em termos de sinais e sintomas aparentemente inexplicáveis pelo modelo patoanatômico clássico. (SMART *et al.*, 2010) A combinação de diferentes padrões de sinais e sintomas para identificar pacientes com sintomas predominantemente nociceptivos, neuropático periféricos e centrais apresenta adequada validade discriminativa entre fisioterapeutas experientes. (SMART *et al.*, 2011) A nomenclatura “dor neuropática periférica” é utilizada para descrever situações nas quais raízes ou troncos nervosos são sujeitos à estímulos mecânicos ou químicos que excedem as capacidades físicas e biomecânicas do tecido nervoso periférico. (NEE e BUTLER, 2006) Na classificação de sintomas relacionados à mecanismos neuropáticos periféricos, os itens que melhor discriminam esta categoria são a presença de história de lesão nervosa prévia, padrão de dor irradiada dermatomal e testes neurodinâmicos provocativos visando à reprodução dos sintomas. (SMART *et al.*, 2011)

A dor neuropática periférica pode estar associada a sintomas positivos e negativos. Sintomas positivos são caracterizados pela presença de dor, parestesia, disestesia e espasmo muscular, os quais denotam

hiperexcitabilidade do sistema nervoso. Já sintomas negativos indicam redução da atividade condutora dos nervos periféricos e incluem hipoestesia, anestesia, hiporreflexia e fraqueza muscular.

O tecido nervoso periféfico é diariamente exposto a movimentos e posições que a ele imprimem forças compressivas, tênseis, friccionais ou vibratórias sem que isso acarrete dano estrutural. (DILLEY *et al.*, 2005) Quando a intensidade do estímulo atinge uma determinada intensidade, são evocados potenciais de ação em nociceptores específicos, o *nervi nervorum*, desencadeando respostas sintomáticas normalmente intermitentes, transitórias, e proporcionais à quantidade de estímulo periférico experienciada – as quais devem rapidamente ceder na medida em que o estímulo é cessado.

Entretanto, um estímulo periférico suficientemente intenso, ou sustentado por um período prolongado, pode dar início a uma cascata de eventos fisiopatológicos que culminam na lesão do nervo periférico. Os estímulos mecânicos inicialmente congestão venosa, comprometem o fluxo axoplasmático comprometendo a circulação intraneural. (LUNDBORG e DAHLIN, 1992) O comprometimento circulatório leva à hipóxia, gerando resposta inflamatória tanto nos troncos nervosos quanto ao nível do gânglio da raiz dorsal, gerando edema e, consequentemente, aumentando a pressão endoneural. Uma vez estimulados por agentes pró-inflamatórios, o nervi nervorum e os nervos sinovertebrais tornam-se sensibilizados a estímulos mecânicos antes inócuos; ou seja, o nervo periférico passa a apresentar mecanosensibilidade aumentada. O edema, ao persistir, compromete as propriedades viscoelásticas do tecido conectivo neural, gerando o aparecimento de fibrose do nervo nervoso periférico em seu leito. Nesta etapa do processo patológico, a produção de fibrose pode comprometer a excursão do nervo periférico em seu leito, aumentando ainda mais a intensidade de estímulos mecânicos entregues ao nervo já mecanossensível, dessa forma produzindo *input* nociceptivo ainda maior. Quanto à redução da excursão do nervo periférico, estudos *in vivo* demonstram que indivíduos com neuropatia diabética apresentam, de fato, redução da excursão do nervo tibial comparados a indivíduos saudáveis. (BOYD *et al.*, 2012) Este achado, porém, não se confirma em indivíduos com DLCIP, seja ela radicular ou somática.

Ainda que o padrão dermatomal da dor seja uma característica reconhecida por clínicos como discriminativa de dor neuropática periférica, a sua distribuição tende a ser bastante variável, e, provavelmente, o padrão dermatomal não seja um bom discriminador. Anatomicamente, fibras sensoriais e motoras apresentam conexões intra-durais entre níveis vertebrais adjacentes, e, portanto, lesões nervosas próximas ao forame intervertebral podem afetar fibras nervosas associadas a mais de um nível intervertebral. Já a sensibilização do sistema nervoso central após lesão periférica com a consequente expansão dos campos receptivos dos receptores periféricos também podem contribuir do ponto de vista neurofisiológicos para a explicar por que, na presença de dor neuropática periférica, os sintomas podem seguir distribuições inexatas e, eventualmente, altamente variáveis entre indivíduos com uma mesma condição musculoesquelética. (NEE e BUTLER, 2006)

O exame físico de pacientes com dor neuropática periférica frequentemente evidencia a presença de sensibilidade aumentada do sistema nervoso periférico à estímulos externos tênseis e compressivos, denominada mecanosensibilidade. A mecanosensibilidade é avaliada por meio de diversos testes provocativos, tais como os testes neurodinâmicos do membro superior, o teste de *Spurling* para radiculopatia cervical e os testes neurodinâmicos para condições da coluna lombar e do membro inferior, como os testes de elevação da perna reta e o teste de slump (SCHMID *et al.*, 2009). Como os testes neurodinâmicos costumam reproduzir sintomas neurogênicos também em indivíduos saudáveis (LAI *et al.*, 2012), a simples reprodução de dor ao tensionamento do nervo tem valor clínico questionável. Nesse sentido, o procedimento de diferenciação estrutural - que consiste em verificar se, ao movimentar um segmento corporal distante do local dos sintomas, há alteração da resposta sintomática – tem sido utilizado visando à aumentar a especificidade do teste neurodinâmico. Em um estudo recente, o teste de *slump* foi altamente sensível para detecção de dor neuropática periférica e, quando somado à avaliação da localização dos sintomas, apresentou alta especificidade para detecção de dor neuropática periférica. (URBAN e MACNEIL, 2015) A diferenciação estrutural é capaz de modificar significativamente a amplitude de movimento nos testes de elevação da perna reta e no teste de slump (HERRINGTON *et al.*, 2008) e vem sendo utilizada

como critério necessário durante a avaliação neurodinâmica em ensaios controlados randomizados (NEE *et al.*, 2012; FERREIRA *et al.*, 2016)

2.6 Evidências do tratamento conservador da DLCIP

Diversas são as abordagens terapêuticas conservadoras propostas como tratamentos para DLCIP. Os tratamentos farmacológicos, embora aceitos como estratégia conservadora de tratamento mandatória, não apresentam resultados animadores em pacientes com DLCIP. Em uma revisão sistemática, o uso de anti-inflamatórios não-esteroidais e antidepressivos não foi superior ao placebo. (PINTO, MAHER, FERREIRA, FERREIRA, et al., 2012) Uma revisão sistemática recente demonstrou que o uso de medicamentos derivados de opioides reduzem dor no curto e médio prazo para pacientes que os toleram. Entretanto, a magnitude do efeito de redução da dor é pequena, abaixo do ponto das estimativas clinicamente importantes, e comparável aos efeitos do exercício. (ABDEL SHAHEED et al., 2016)

A eficácia da administração de corticoesteroide epidural foi verificada em uma revisão sistemática. Existe evidência de alta qualidade metodológica de que as infiltrações epidurais reduzem significativamente a incapacidade e intensidade de dor na perna comparado ao placebo. No longo prazo, não há diferenças entre o tratamento com infiltrações ou infiltração placebo. O pequeno efeito detectado, embora estatisticamente significativo, não é clinicamente importante. Estes achados questionam a ampla prescrição de infiltrações para pacientes com DLCIP, considerando a relação entre eficácia, custos e potenciais efeitos adversos. (PINTO, MAHER, FERREIRA, HANCOCK, et al., 2012)

Em um ensaio controlado e randomizado, pacientes com DLCIP tratados por doze semanas com manipulação lombar associada a exercícios domiciliares e aconselhamento obtiveram, após três meses, redução clinicamente importante da dor na perna, dor lombar, redução da incapacidade, melhora da qualidade de vida, maiores níveis de impressão global de melhora e satisfação comparados a pacientes tratados com exercícios domiciliares apenas. Após um ano, os pacientes tratados com manipulação mantiveram maiores níveis de satisfação e impressão global de melhora, mas as diferenças

entre os grupos para dor na perna, dor lombar, incapacidade e qualidade de vida desapareceram após um ano. (BRONFORT et al., 2014)

O efeito de exercícios estruturados supervisionados comparados a aconselhamento para manter-se ativo foi investigado em uma recente revisão sistemática. (FERNANDEZ et al., 2015) O tratamento por meio de exercícios é amplamente utilizada na prática clínica, e a implementação de exercícios supervisionados permite ao fisioterapeuta estar em contato com o paciente, permitindo a prescrição individualizada de um programa de exercícios. Em contrapartida, o aconselhamento para se manter ativo objetiva agir sobretudo nos aspectos cognitivos, modificando as atitudes do paciente frente ao problema, possivelmente auxiliando na ressignificação da experiência dolorosa e sendo potencialmente eficaz com menores custos, já que pode ser implementado com menor necessidade de contato entre provedor de saúde e paciente. Os resultados desta revisão demonstram que a curto prazo exercício foi superior a aconselhamento para redução de dor na perna mas não de incapacidade. A médio e longo prazo não houve diferença entre as diferentes estratégias.

A tração é outro método de tratamento amplamente utilizado para o tratamento da DLCIP. A eficácia deste método, contudo, é altamente questionável, indicando a que a tração, seja ela contínua ou intermitente, isolada ou associada a outros tratamentos exerce pouco ou nenhum efeito sobre a dor, incapacidade, função, auto-percepção de melhora, e retorno ao trabalho em pacientes com DL e DLCIP. (WEGNER et al., 2013) Entretanto, os resultados desta revisão sistemática foram questionados por clínicos, considerando a qualidade baixa a moderada da evidência disponível, bem como a grande heterogeneidade clínica dos pacientes envolvidos nos estudos de tração. O argumento central da crítica é a inabilidade dos estudos em refletir a prática clínica, na qual, segundo muitos clínicos, apenas pacientes altamente selecionados seriam aptos a receber tração e nos quais a tração seria eficaz. Nesse sentido, Thackeray et al. (2016) conduziram um estudo prospectivo, controlado e randomizado em 120 pacientes com DLCIP e sinais de compressão de raiz nervosa. Estes pacientes foram tratados com exercícios de extensão lombar com ou sem a adição de tração lombar. Os pacientes foram ainda classificados como potenciais respondedores à tração lombar se

apresentassem periferilização dos sintomas durante movimentos de extensão lombar e teste de Lasègue cruzado positivo. Este subgrupo de pacientes fora previamente descrito por Fritz et al. (2007). Os resultados deste estudo demonstraram que a adição de tração a exercícios de extensão não resultou em redução da dor e incapacidade em pacientes com DLCIP e sinais de compressão nervosa nem em um subgrupo de pacientes pré-determinado. (THACKERAY et al., 2016)

Outra intervenção frequentemente utilizada para tratamento da DLCIP são os exercícios específicos de preferência direcional que fazem parte do sistema de Terapia e Diagnóstico Mecânico (MDT) descritos por Robin McKenzie. (MCKENZIE e MAY, 2003) A identificação da preferência direcional se dá quando posturas sustentadas ou movimentos repetidos no final da amplitude em uma direção (por exemplo, flexão ou extensão) diminuem, abolem ou centralizam os sintomas, sejam eles localizados na coluna lombar ou irradiados para a perna. (LONG et al., 2004). Os efeitos de exercícios de preferência direcional em indivíduos com DLCIP tem sido reportados como levemente superiores à manipulação vertebral (PETERSEN et al., 2011), superiores à exercícios na direção oposta à preferência direcional. (LONG et al., 2004) Boa parte dos estudos controlados e randomizados em MDT não fazem distinção quanto aos efeitos do método em diferentes populações, como indivíduos com DL e DLCIP com e sem comprometimento de raíz nervosa.

Considerando a baixa qualidade metodológica de diversos estudos, bem como os efeitos terapêuticos pequenos obtidos por diversas estratégias de tratamento conservador, faz-se necessário investigar o efeito de diferentes estratégias de tratamento nesta população, tais como o tratamento neurodinâmico (TND).

2.6.1 Evidências do tratamento neurodinâmico

O objetivo do TND é mobilizar o tecido nervoso ou as estruturas a ele adjacentes. (COPPIETERS *et al.*, 2015) Para mobilização do tecido nervoso são utilizadas técnicas de deslizamento ou tensionamento neural, sendo que exercícios de deslizamento produzem maior excursão do nervo ciático comparado a exercícios de tensionamento. (COPPIETERS *et al.*, 2015) A

maior excursão associada à menor tensão imposta ao nervo torna os exercícios de deslizamento neural teoricamente mais indicados em fases iniciais do tratamento, em que pode haver maiores níveis de irritabilidade. Já para mobilização de estruturas adjacentes ao tecido nervoso da coluna lombar e perna, técnicas que promovam abertura dos forames vertebrais podem reduzir a pressão sobre o sistema nervoso periférico. (FUJIWARA *et al.*, 2001)

Evidências recentes sugerem que técnicas de deslizamento e tensionamento são superiores ao alongamento estático de isquiotibiais no que diz respeito ao aumento da flexibilidade neste grupo muscular em indivíduos saudáveis. (SHARMA *et al.*, 2016) Recentemente, Ridehalgh et al. (2016) demonstraram que uma única sessão de técnicas de tensionamento neural não foi capaz de aumentar o limiar de dor à pressão e vibração de pacientes com DLCIP. Entretanto, a eficácia e a efetividade do tratamento neurodinâmico (TND) ainda não são amplamente conhecidos, devido principalmente à escassez de estudos prospectivos, randomizados e controlados. Dois estudos randomizados controlados conduzidos em pacientes com dor cervicobraquialgia demonstraram resultados promissores da técnica (ALLISON *et al*., 2002; NEE *et al*., 2012). Contudo, uma recente diretriz de prática clínica (DELITTO *et al.*, 2012) conferiu apenas grau de recomendação “C” para o uso de TND em pacientes com DLCIP, demonstrando a existência de evidência fraca. Até o presente momento, apenas dois ensaios controlados randomizados publicados em revista com revisão por pares avaliaram os efeitos do TND em indivíduos com DLCIP sem envolvimento radicular. Estes dois estudos avaliaram o efeito adicional de somente uma técnica de alongamento na posição de *slump long sitting* - uma técnica de tensionamento – a um programa de tratamento envolvendo mobilização da coluna lombar (CLELAND *et al.*, 2006) e mobilização da coluna lombar e associada a exercícios de estabilização. (NAGRALE *et al.*, 2012) Já a série de casos prospectiva Schäfer et al (2011) determinou que pacientes com DLCIP com mecanosensibilidade aumentada ao teste de elevação da perna reta e sem sinais de dor neuropática e radiculopatia obtiveram redução da dor e melhora da função clinicamente importantes.

Nas seções a seguir, serão apresentados o protocolo do estudo, publicado no *Journal of Bodywork & Movement Therapies*, bem como o artigo original, em processo de revisão no *Journal of Physiotherapy*.

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4. ARTIGO 1

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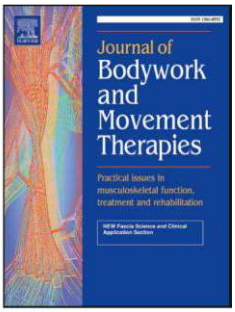

Neurodynamic treatment for patients with nerve-related leg pain: Protocol for a randomized controlled trial

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NEURODYNAMIC TREATMENT FOR PATIENTS WITH NERVE-RELATED LEG PAIN: PROTOCOL FOR A RANDOMIZED CONTROLLED TRIAL

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Abstract

Objectives: To investigate if neurodynamic treatment is more effective than advice to remain active in patients with nerve-related leg pain.

Design: Parallel-group randomized controlled trial blinded to the outcome assessor conducted in Porto Alegre, Brazil.

Participants: Sixty patients recruited from the community and private practices.

Intervention: Patients will be randomly assigned to receive four sessions of neurodynamic treatment over two weeks comprising passive lumbar foramen opening and neurodynamic sliders plus home exercises or advice to remain active.

Main outcome measures: Leg pain intensity, disability, low back pain intensity, functional ability, symptoms distribution and global impression of recovery will be assessed at two and four weeks after randomization.

Analysis: A linear mixed model will be employed for each outcome following intention to treat principles.

Word count: 123

Introduction

Individuals presenting with low back pain and concomitant leg pain represent a subgroup of patients with higher levels of pain and disability (Kongsted et al., 2012; Konstantinou et al., 2012) with a prevalence up to 43%, depending on the adopted operational definitions. (Cook et al., 2014) Among this heterogeneous population of patients with nerve-related leg pain (NRLP), increased nerve tissue mechanosensitivity may play a role in leg symptoms perpetuation and the use of neurodynamic treatment (NDT) has been advocated as an effective procedure for this condition. (Schäfer et al., 2011)

NDT involves the combination of active and passive movements in order to reduce nerve mechanosensitivity, thereby reducing pain and disability. (Nee et al., 2013) Experimental evidence shows that neurodynamic sliders can reduce intra-neural edema in unembalmed cadavers (Brown et al., 2011), as well as the expression of neuropathic pain biomarkers in rats. (Santos et al., 2012) However, the proposed mechanisms for therapeutic effects encompass a complex interaction of bottom-up and top-down pathways that still needs formal validation. (Nee et al., 2006)

NDT has been object of clinical research in the past few years, mainly in upper quarter conditions. Allison et al. (2002) demonstrated that NDT plus home exercises was slightly superior to thoracic and shoulder joint mobilization plus home exercises in patients with neck-related arm pain in an 8-week follow-up. Nee et al. (2012) investigated the effects of NDT versus advice to remain active in neck-related arm pain and showed statistically and clinically relevant differences in terms of pain reduction and improvement in daily-life activities favoring NDT. In contrast, patients treated with NDT in a randomized sham-controlled trial (Bialosky et al., 2009) did not

experience additional benefits on pain intensity and disability compared to sham-NDT.

The effects of NDT in conditions of the lower quadrant (Cleland et al., 2005; Nagrale et al., 2012; Scrimshaw et al., 2001) have been investigated by few studies, but evidence for the effect of NDT in patients with NRLP is lacking. A single-arm trial assessing the effects of NDT in patients with back-related leg pain (Schäfer et al., 2011) found significant improvements in pain and disability in those with clinical evidence of nerve mechanosensitivity. In this sense, there is a need for a randomized controlled trial that evaluates the effects of NDT in patients with NRLP. Hence, the primary aim of this trial is to verify the immediate effects (two weeks after randomization) and short-term effects (four weeks after randomization) of NDT versus advice to remain active on pain and disability. The secondary goal of this trial is to determine the immediate and short-term effects of NDT versus advice to remain active on low back pain intensity, functional ability, symptoms distribution and global perception of recovery.

Design

This study will be a parallel-group, superiority randomized controlled trial that will follow the Standard Protocol Items: Recommendations for Interventional Trials (SPIRIT). (Chan et al., 2013) The study flow diagram is depicted in Figure 1.

<<< Insert figure 1 around here>>>

Methods

Registry

This trial was prospectively registered (ClinicalTrials number: NCT01954199) and approved by the Ethics Research Committee of the Universidade Federal de Ciências da Saúde de Porto Alegre (registration number: 940.742).

Setting

Treatment will be provided in a physiotherapy clinic located in Porto Alegre, Rio Grande do Sul, Brazil.

Recruitment procedures

Patients will be recruited from the community and private practices located in the city of Porto Alegre.

Randomization and blinding procedures

Randomization will be performed by a researcher not involved in eligibility determination, baseline assessment and treatment provision. The procedure will adopt a 1:1 allocation ratio with blocks of six. Allocation will be stratified by baseline pain intensity in two strata (stratum 1: pain ranging from three to six; stratum 2: pain ranging seven to ten). Concealed allocation will be granted by using numbered, sequentially ordered, sealed opaque envelopes. Both randomization and allocation concealment will follow the procedures described by Doig et al. (2005).

The physiotherapist responsible for eligibility determination will be unaware of randomization and baseline assessments. Trained researchers that will assess outcomes will be blinded to treatment allocation. An assistant not involved in eligibility determination, randomization, outcome assessment and treatment will schedule appointments (treatment sessions and follow-up visits). Only this research assistant and the treating physiotherapist will have access to the appointment diary. Due to the nature of the intervention, therapist and patients will not be blind to treatment allocation.

Participants

To be included, patients must present the following characteristics: age between 18 and 80 years, chronic unilateral back-related leg pain (defined as pain distal to the buttocks for at least 12 weeks), leg pain intensity ≥ 3 points in the numeric pain rating scale, not receiving physiotherapy at the time of the baseline assessment and leg symptoms reproduced by the slump test and changed by structural differentiation (ankle dorsiflexion or neck flexion release). Those with inflammatory arthropathies, signs of cauda equine syndrome, bilateral leg pain, crossed straight leg raise test, previous lumbar and lower limb surgery, fractures, malignancy and with worker's compensation claims due to back or leg problem will be excluded.

A physiotherapist post-graduated in orthopedic manual therapy with seven years of clinical experience will screen patients for eligibility and will be blinded to treatment allocation. Eligible patients will be informed about the study objectives and will sign a consent form if they agree to enter the study. Treatment will initiate within three days from the baseline assessment.

Details of the intervention and control

The intervention will be delivered by a physiotherapist with two years of clinical experience in musculoskeletal physiotherapy that attended a 40-hour training course of neurodynamic techniques for the treatment of musculoskeletal conditions. All patients will be treated by the same physiotherapist. During the study period, patients will be able to maintain medication use prescribed by their clinician. The use of painkillers, nonsteroidal anti-inflammatory as well as opioids or drugs for chronic pain will not be monitored alongside the study period.

<<< Insert figure 2 and 3 around here>>>

Patients allocated to the control group (CG) will receive advice to remain active and to resume activities of daily living according to the best evidence available. The advice component will focus on two basic aspects: (1) demonstrating the harmful effects of prolonged rest, avoidance of daily-life activities and excessive muscle bracing during movement; (2) that light activities and movements will be beneficial for their pain. A booklet containing such information will be provided to each patient. Patients in this group will be advised not to seek any form of additional treatment during the study period. However, no restriction will be made for those who seek. Additional treatment modalities sought by the participants will be recorded and patients will not be excluded.

Subjects allocated to the NDT group (NDTG) will be treated for two weeks, twice a week, totaling four treatment visits. The first treatment session will comprise a brief explanation of why NDT is suitable for the patient's condition, an educational approach in accordance with previous studies. (Nee et al., 2012) In each treatment session, patients will receive lumbar foramen opening techniques (figure 2) following a standardized algorithm of progression (figure 3). Upon completion of lumbar foramen opening techniques, neurodynamic sliders will be performed in two different positions, side-lying and slump sitting (figure 4), following a standardized algorithm of progression (figure 5). Both techniques will be discontinued in patients who report increase in symptoms (NPRS ≥ 2 points and increase in numbness or tingling). Patients in the NDTG will also receive two exercises (a slider and a tensioner technique) to be performed at home, twice a day, ten repetitions each (figure 6). On each treatment session, patients will receive orientation regarding the execution of

home exercises. Home exercises compliance will be monitored. All treatment techniques will be delivered in the absence of pain (i.e., in an amplitude range before the first onset of pain). (Maitland et al., 2007) The individuals allocated to the treatment group will also receive the booklet. Treatment will be discontinued if a patient does not tolerate any technique during any treatment session. They will not be excluded from the final analysis.

<<< Insert figure 4 and 5 around here>>>

Baseline assessments

Patients will undergo a thorough history taking and physical examination in the baseline assessment. Besides the outcome measures collection, validated instruments will be employed to further characterize included patients in relation to presence of neuropathic mechanisms of pain, which will be assessed by the Leeds Assessment of Neuropathic Symptoms and Signs (LANSS) (Bennet et al., 2001; Schestatsky et al., 2011); fear-avoidance beliefs, measured by the Fear-avoidance Beliefs Questionnaire (FABQ) (Abreu et al., 2008; Waddell et al., 1993); and catastrophic thoughts, assessed by the Pain Catastrophizing Scale (Sehn et al., 2012; Sullivan et al., 1995). A neurological assessment comprising manual muscle force of the entire lower limb, patellar and Achilles tendon reflex and sensation (pin prick and light touch) will be carried out. Patients with one or more neurological signs (muscle weakness, decreased reflex or sensation) will be classified as having nerve root compromise.

Primary and secondary outcome measures and assessment points

Leg pain intensity and disability after treatment (i.e., two weeks after the

randomization) will be the primary outcomes. Secondary outcomes will be leg pain intensity and disability measured four weeks after randomization and low back pain intensity, distribution of symptoms, functional ability, and global impression of recovery measured after treatment and four weeks after randomization. Each outcome measure is described below.

Numeric Pain Rating Scale. Leg pain and low back pain intensities will be measured by the Brazilian version of the Numeric Pain Rating Scale (NPRS) a 11-point scale which ranges from 0 (no pain) to 10 (worst possible pain). (Costa et al., 2008) This scale has adequate responsiveness for both clinical and research settings (Childs et al., 2005) and its minimally important clinical difference (MICD) is two points. (Ostelo et al., 2008) This outcome will be measured at all time-points.

Oswestry Disbility Index. Disability will be measured by the Brazilian version of the Oswestry Disability Index 2.0 (ODI). (Fairbank et al., 1980; Vigatto et al., 2007) The ODI comprises ten six-point scales (ranging from 0 to 5). The score is expressed as a percentage of the maximum scores. The total ODI score ranges from 0 (no disability) to 100 (maximum disability). The translated version of the ODI has high internal consistency ($\alpha = 0.87$), correlates moderately with the numeric pain scale and has adequate reliability. Its MICD is ten points. (Ostelo et al., 2008) This outcome will be measured at all time-points.

Body diagram. Distribution of symptoms will be assessed by a body diagram (BD). (Werneke et al., 1999) A researcher not involved with randomization and treatment will determine the most distal location of pain using a clear overlay template. Pain location will be coded from 1 (proximal) to 6 (distal). This method has showed excellent reliability. (Werneke et al., 1999) This outcome will be measured at all time-points.

Patient-Specific Functional Scale (PSFS). This scale was translated and cross-culturally adapted to Brazilian Portuguese by Costa et al. (2008) and has shown high levels of internal consistency and reproducibility in the translated version, as well as excellent reliability for chronic and mechanical low back pain and good reliability for acute low back pain in the English version. This outcome will be measured at all time-points.

Global Perceived Effect Scale. The Global Perceived Effect Scale is an 11-point scale ranging from -5 ("vastly worse") to +5 (completely recovered). (Fischer et al., 1999) This scale, translated to Brazilian Portuguese (Costa et al., 2008), measures patient's perception of recovery. Clinimetric testing showed high test-retest reliability in several musculoskeletal conditions. (Kamper et al., 2010) This outcome will be measured at two and four weeks after randomization.

Anticipated dates of trial commencement and completion

The trial is scheduled to commence in April, 2015. Completion is scheduled to April, 2016.

Statistical analysis including sample size calculations

Data will be analyzed following intention-to-treat principles for all outcomes. The significance level will be set at $p < 0.05$. Normality of data will be checked with the Shapiro-Wilk test. Descriptive statistics with point (mean or median) and variability measures (standard deviation and 95% confidence intervals or interquartile range) will be reported for continuous variables, whereas frequencies and percentages will be provided for categorical variables.

A linear mixed model with group (CG or NDTG) versus time (baseline, two

weeks and four weeks) interaction terms will be employed. Between-group differences and their respective 95% confidence intervals will be calculated for each outcome. In order to enhance transparency by avoiding *post-hoc* adjustment and reducing the likelihood of type I error increase(RAAB *et al.*, 2000; POCOCK *et al.*, 2002), the LANSS score (continuous variable), baseline low back pain intensity (continuous variable), time of onset of symptoms (continuous variable), FABQ score (continuous variable), PCS score (continuous score) and the presence of radiculopathy (dummy coded dichotomous variable) will be defined *a priori* as potential covariates. These covariates were determined based on clinical expertise of the trial team as well as on available evidence showing that patients with signs of nerve root compromise and with higher LANSS scores may not benefit from NDT (Schäfer et al., 2011). To test whether these variables are related to the outcomes, a stepwise multiple regression approach will be conducted, and only variables strongly or very strongly correlated ($r \geq 0.5$) with the primary outcomes will be included in the final model. Only variables assessed before randomization will enter the model. All analysis will be performed on SPSS version 20.0 (IBM Corporation, Armonk, USA).

Sample size was calculated on Stata 12 (StataCorp, LP, USA) and was based on the paper by Nee et al. (2012), a parallel-group, randomized controlled trial that found a mean difference between groups of 1.6 point in the NPRS (with standard deviations of 2.4 and 2.1 for the treatment and control arms of the trial, respectively). Considering a statistical power of 80%, a two-tailed test, 5% as the significance level, an independent samples design and an allocation ration of 1:1, 50 patients would be necessary to detect a statistically significant difference. Assuming 20% of sample loss, ten additional subjects will be included. Therefore, 60 patients will be enrolled in this study.

Discussion

Although widely used by physiotherapists to treat nerve-related symptoms, few trials have evaluated the effects of NDT on patient-important outcomes. (Bialosky et al., 2009; Cleland et al., 2005; Nagrale et al., 2012) Moreover, trials assessing the effects of NDT in patients with NRLP have not been conducted yet. The only study with similar inclusion criteria performed so far is a single-arm trial with a pre-posttest design that evinced that patients with NRLP without nerve root compromise or signs of neuropathic pain may benefit from NDT (Schäfer et al., 2011). This study demonstrated that not all patients with NRLP are likely to benefit from NDT and that the absence of the aforementioned conditions as well as evidence of nerve mechanosensitivity seems to be important clinical features that ensure a good prognosis with the technique.

The methods of this trial will grant adequate internal validity, increasing the confidence in the effect estimates. Furthermore, the proposed statistical analysis will control for potential prognostic factors, enhancing the statistical power of the trial. Another strength of this trial is that all potential covariates that will enter the adjusted analysis were described a priori. This approach will prevent post-hoc adjustment, a procedure that artificially inflates the statistical power and may yield spurious associations between outcomes and prognostic variables. (Raab et al., 2000)

There are two main limitations inherent to the trial's design. It is important to note that the presence of a control group will not enable readers to infer about the true and isolated effect of NDT on NRLP. Instead, this study design will indicate whether NDT can alter the natural history of the studied condition. Unspecific effects such as spontaneous remission, regression to the mean, detection ambiguity,

unidentified co-interventions, and psychosocial factors, such as expectation and learning - or a combination of them – may explain the observed effects. (Benedetti et al., 2011) The second limitation is that since only patients with evidence of nerve mechanosensitivity will be enrolled, we acknowledge that the results of this trial cannot be generalized to the entire population of individuals with back-related leg pain. It is expected that this trial will fill a gap in the current literature, contributing to both clinical and scientific communities, enhancing the clinical decision-making process in the management of NRLP.

Word count: 2735

Ethical approval: Universidade Federal de Ciências da Saúde de Porto Alegre Human Research Ethics Committee (approval number: 940.742)

Trial registration: ClinicalTrials identifier: NCT01954199

Was this trial prospectively registered? Yes

- Date of trial registration: September 24, 2013
- Anticipated completion date: April, 2016

Conflict of interest declaration: The authors declare that there is no conflict of interest.

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Figure 1

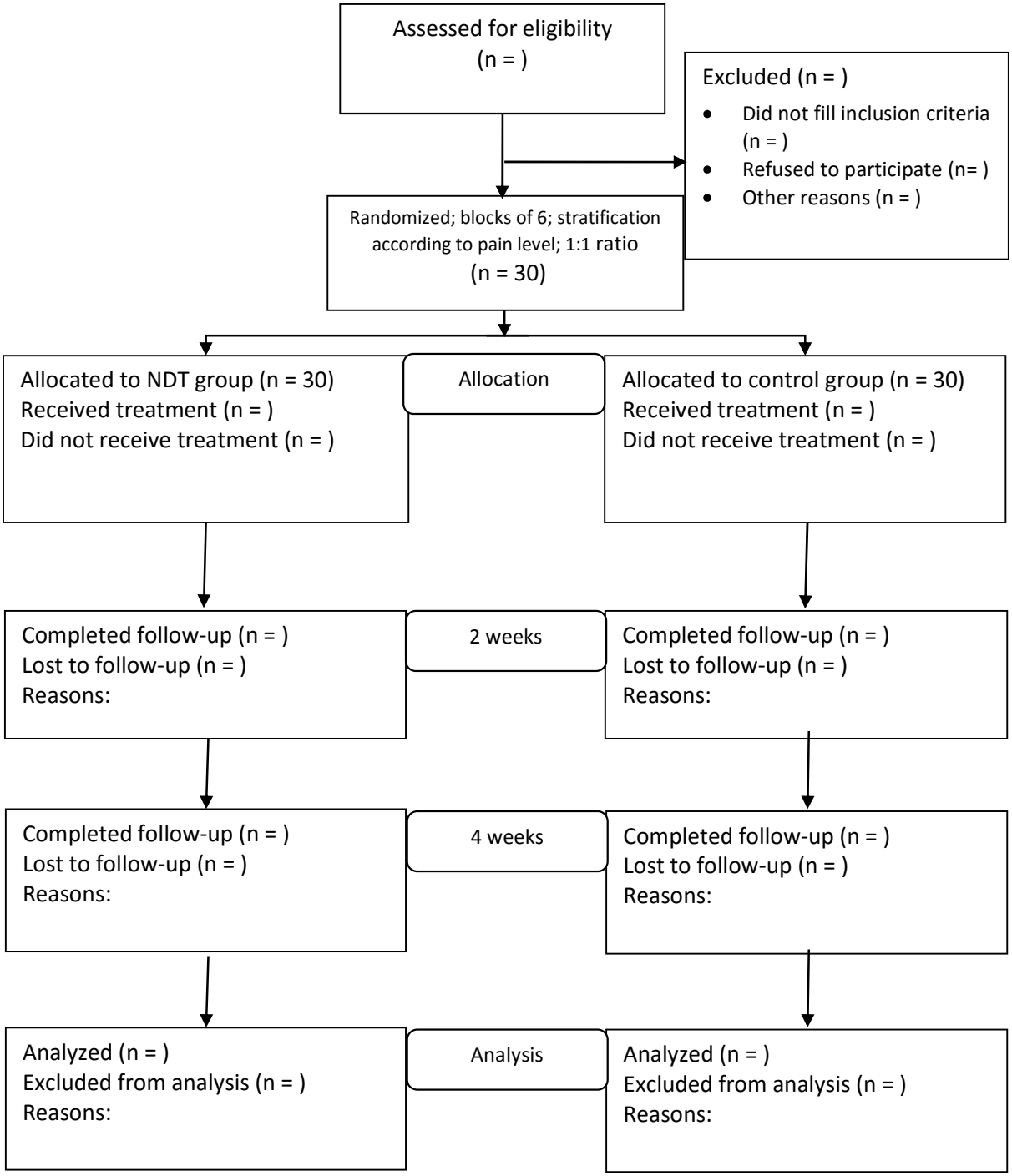


Figure 2

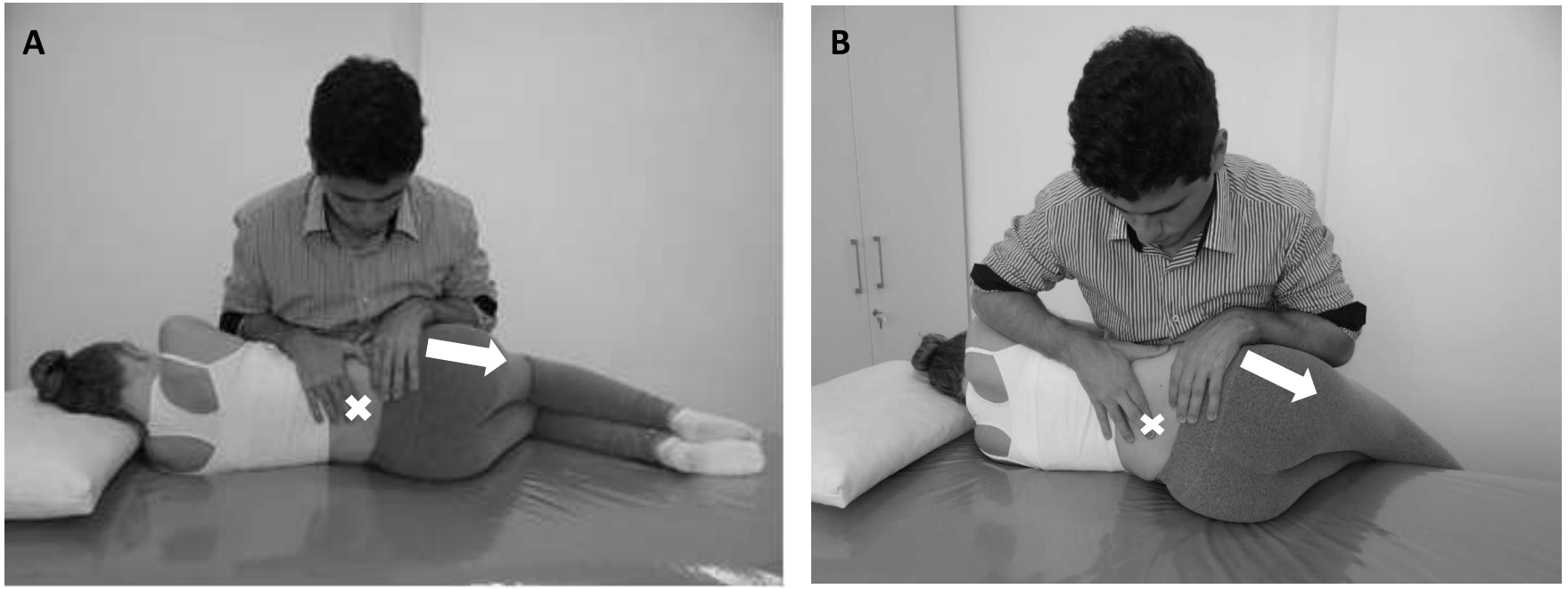


Figure 3

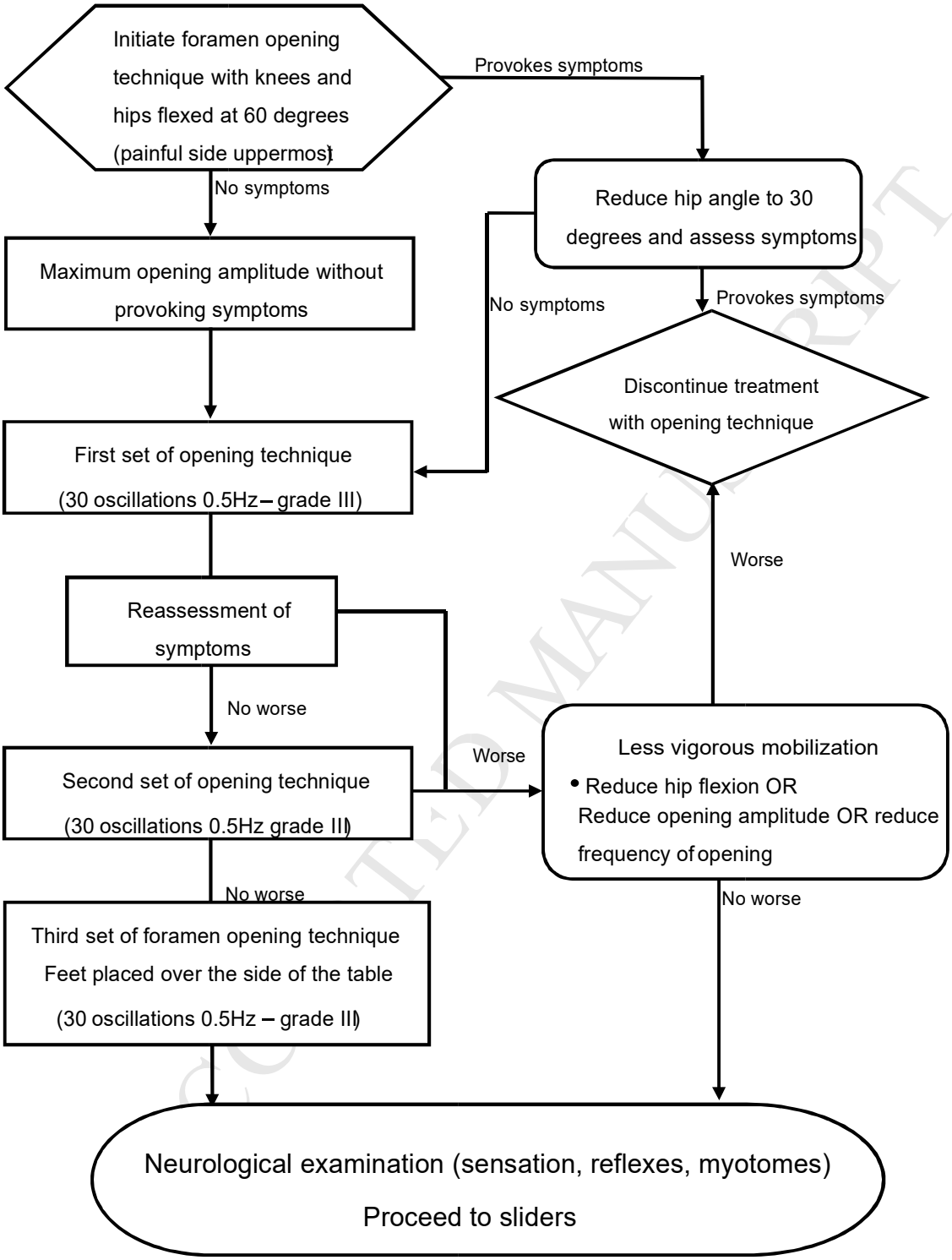


Figure 4

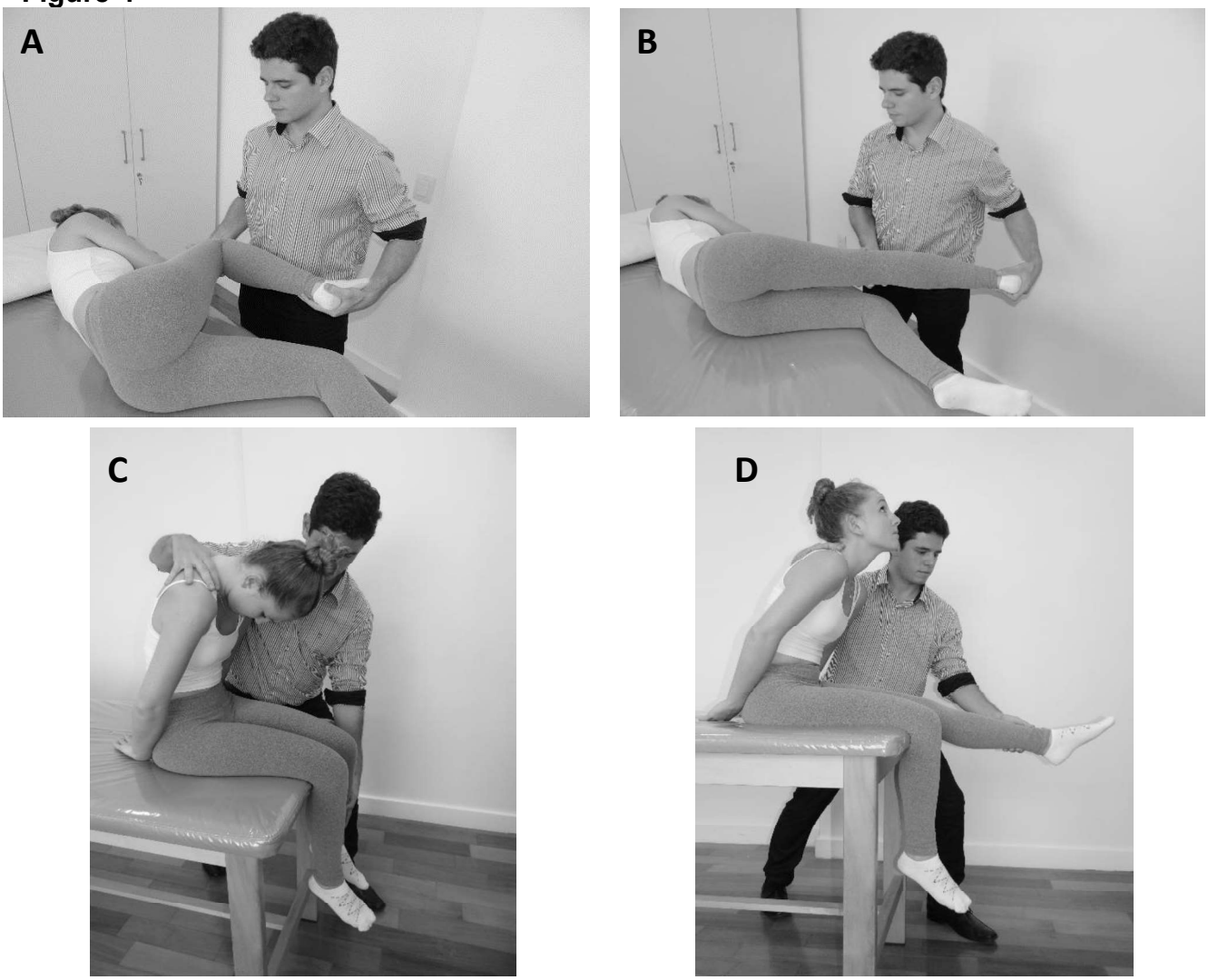


Figure 5

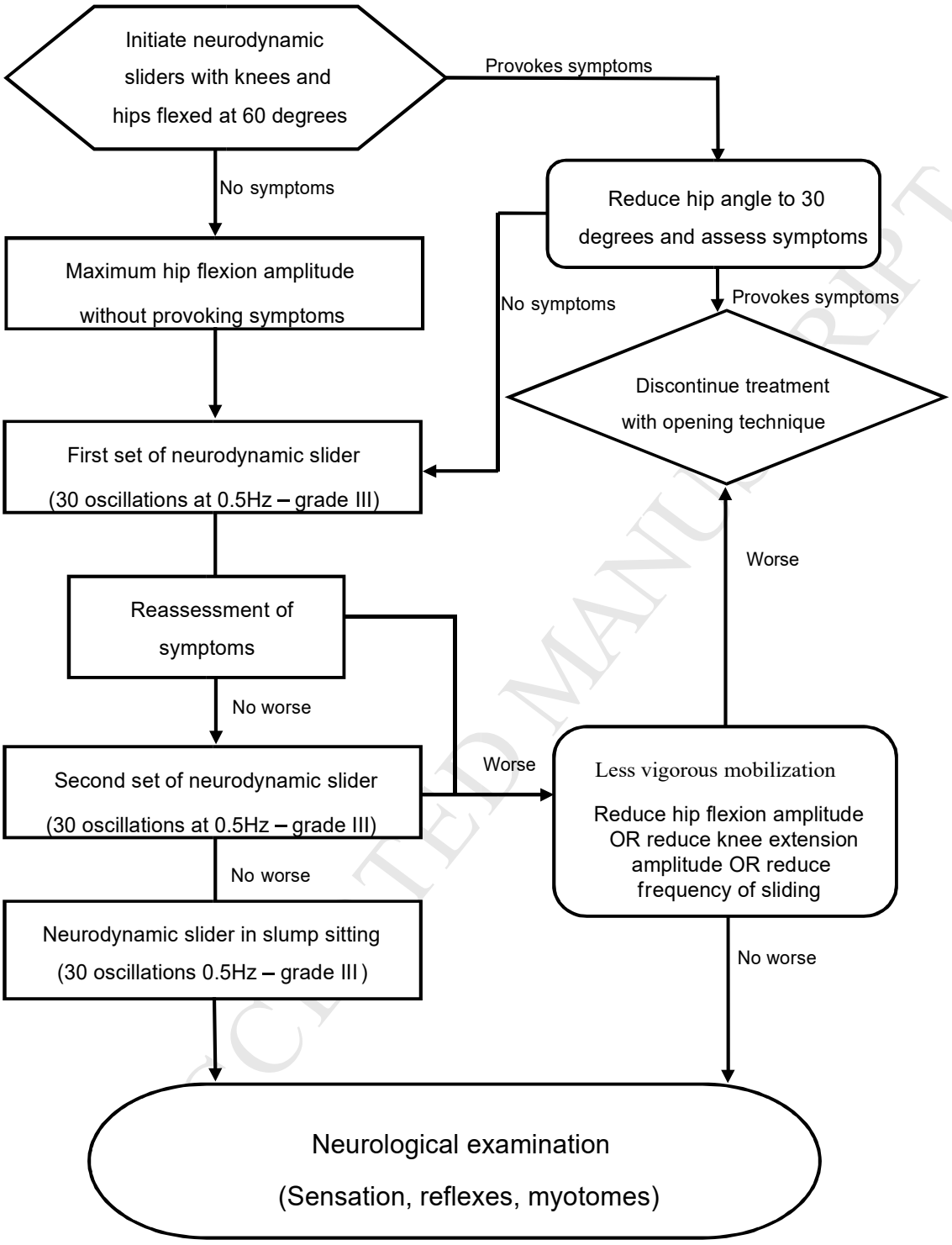
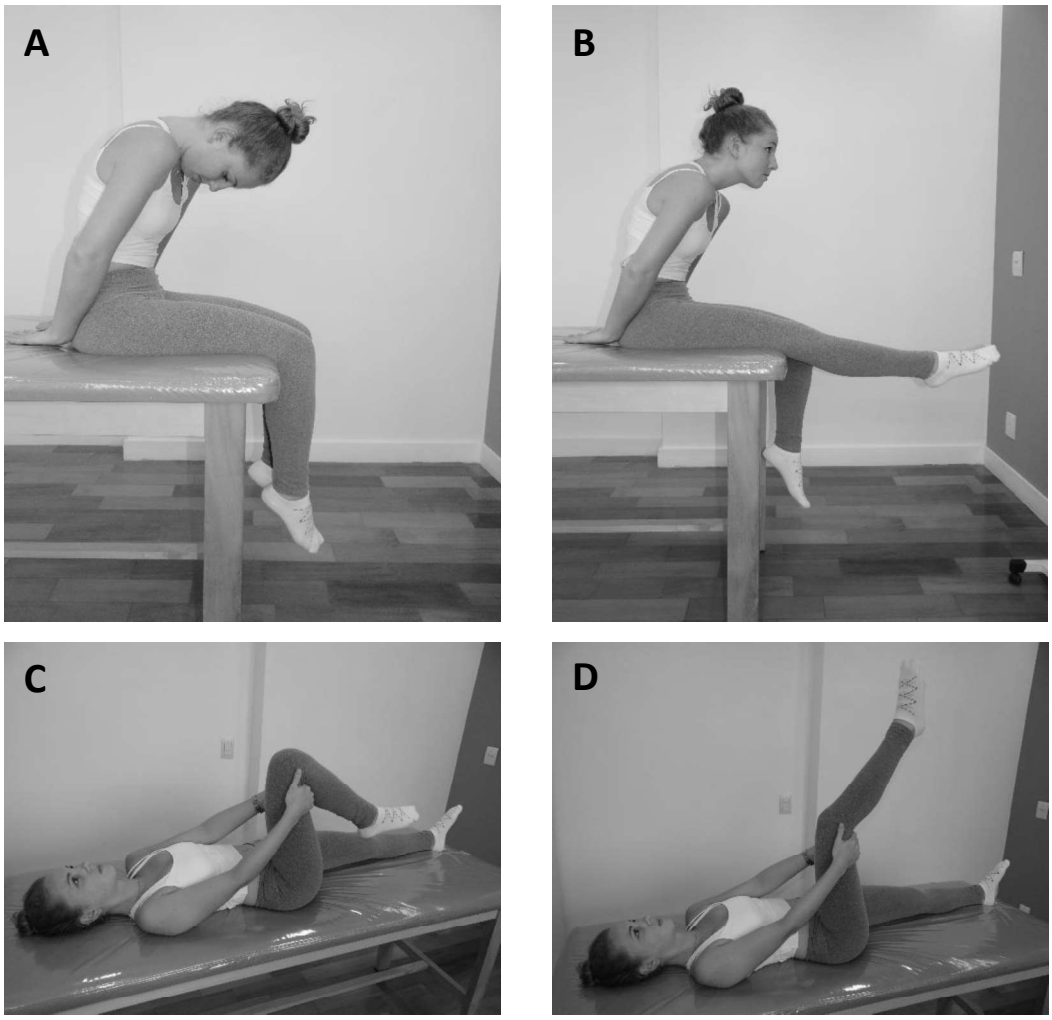

Initiate neurodynamic sliders with knees and hips flexed at 60 degrees
Provokes symptoms
No symptoms
Reduce hip angle to 30 degrees and assess symptoms
Maximum hip flexion amplitude without provoking symptoms
No symptoms
Provokes symptoms
Discontinue treatment with opening technique
First set of neurodynamic slider (30 oscillations at 0.5Hz – grade III)
Worse
Reassessment of symptoms
No worse
Second set of neurodynamic slider (30 oscillations at 0.5Hz – grade III)
Worse
Less vigorous mobilization
Reduce hip flexion amplitude OR reduce knee extension amplitude OR reduce frequency of sliding
No worse
Neurodynamic slider in slump sitting (30 oscillations 0.5Hz – grade III)
Neurological examination
(Sensation, reflexes, myotomes)

Figure 6



Captions

Figure 1. Study flow diagram

Figure 2. Intervertebral foramen opening technique. **A** indicates the first progression of the technique. The symptomatic side is uppermost. The cephalad hand stabilizes the lumbar spine (marked with an "x"), while the caudal hand delivers the force to open the lumbar foramen (white arrow). **B** progression of the foramen opening technique. The patient's feet is positioned over the side of the table to enhance the intervertebral foramen opening. Care is taken to avoid excessive lumbar flexion or extension. The cephalad hand stabilizes the lumbar spine (marked with an "x"), while the caudal hand delivers the opening force, whose vector is represented by the white arrow.

Figure 3. Protocol for the lumbar foramen opening technique. Patients will receive up to three sets of the technique in each session (approximately three minutes). Progression will occur according to patient's toleration, and parameters like opening amplitude, hip range of motion and feet on or over the side of the couch will be used to control the intensity of mobilization. The Lumbar foramen opening techniques will be discontinued to patients who report increase in symptoms (NPRS ≥ 2 points and increase in numbness or tingling).

Figure 4. Neurodynamic sliders. **A, B** neurodynamic slider for the sciatic nerve. The patient is in side-lying with the painful side uppermost. **A**, hip flexion combined with knee flexion. **B**, hip extension combined with knee extension. **C**, **D** sliding technique in slump sitting. This technique provides the largest excursion to the sciatic nerve. **C**, neck and knee flexion. **D**, neck and knee extension.

Figure 5. Protocol for the neurodyamic sliders techniques. Patients will receive up to three sets of neurodynamic sliders in each session (approximately three minutes).

Progression will occur according to the toleration of the patient, and parameters like frequency of sliding, hip flexion and knee extension range of motion will be used to control the intensity of mobilization. The neurodynamic sliders will be discontinued to patients who report increase in symptoms (NPRS ≥ 2 points and increase in numbness or tingling).

Figure 6. Home exercises. **A, B**, sliding technique in slump sitting. The patient will be instructed to perform the technique alternating neck and knee flexion (**A**) with neck and knee extension (**B**). **C, D,** tensioner technique. The patient will be instructed to avoid symptoms provocation, but a mild pull sensation will be tolerated. **A**, knee flexion. **B**, knee extension.

5. ARTIGO 2

Title: Neurodynamic treatment provides no benefit on pain and disability in patients with chronic nerve-related leg pain: a randomised controlled trial

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Provenance: Brazil

ABSTRACT

Question: Does neurodynamic treatment for patients with nerve-related leg pain improves leg pain, low back pain, disability, function, global perceived effect and location of symptoms compared to advice to remain active?
Design: Randomised controlled trial with allocation concealment, blinded outcome assessor and analysis following intention-to-treat principles.
Participants: 60 participants with nerve-related leg pain recruited from the community.
Intervention: Four sessions of neurodynamic treatment or advice to remain active.
Outcome measures: Leg pain and low back pain, disability, function, global perceived effect and location of symptoms were measured at two and four weeks after randomisation. Continuous outcomes were analysed by linear mixed models. Location of symptoms was assessed by the Chi-square test.
Results: At two weeks, there was no significant effect of treatment on leg pain (-0.9, 95% CI -0.27 to 2.14) and disability (-2.04, 95% CI -8.43 to 4.34). At four weeks, participants receiving neurodynamic treatment experienced significant and clinically important reduction in leg pain (-2.28, 95% CI -3.51 to -1.04). There was a significant effect of treatment on function improvement at two weeks (4.75, 95% CI 1.78 to 7.73) and four weeks (4.17, 95% CI 1.15 to 7.20), as well as global perceived effect at two weeks (2.42, 95% CI 1.48 to 3.37) and four weeks (2.77, 95% CI 1.81 to 3.73). No significant between-group differences were noted for low back pain and location of symptoms.
Conclusion: Neurodynamic treatment did not improve leg pain and disability compared to advice to remain active.
Trial registration: NCT01954199.

INTRODUCTION

Low back pain is a highly prevalent and disabling condition that represents the major cause of years lived with disability in both developed and developing countries.[1] Among the wide array of clinical presentations, the prevalence of radiating leg pain either above or below the knee can be up to 60% in primary care.[2] Besides, this subgroup of patients presents higher levels of work-related disability, lower levels of quality of life as well as poorer prognosis compared to patients with low back pain only.[3]

To date, there is no consensus on the most appropriate management strategy patients with nerve-related leg pain. A recent network meta-analysis[4] found that a range of widely used conservative treatments, such as acupuncture, exercise therapy, traction, passive physiotherapy modalities such as ultrasound and TENS, and advice/education alone were not effective in reducing leg pain compared to inactive control. Despite the high risk of bias of several included studies and moderate to high levels of between-study heterogeneity, this study provided evidence that commonly used conservative interventions were not capable of altering the natural history of leg pain. Therefore, the investigation of different conservative treatment strategies addressed to this population should be a research priority, given the cost-effectiveness of stepped-care approaches compared to direct referral for surgery.[4]

One conservative treatment that warrants further investigation is neurodynamic treatment. This approach has been considered to be effective[5] for patients with signs of nerve mechanosensitivity, which can be clinically assessed by provocative tests that challenge the ability of the nerve tissue to tolerate tension.[6] In neurodynamic treatment, specific positions, as well as active and passive movements of the lumbar spine and legs, are used to mobilise structures around the nervous system and the nervous system itself.[7]

Despite the plausible biological rationale of this treatment approach[8-10], little is known about its effects on patient-important outcomes. To date, two case series[5,11] and two randomised trials[12,13] demonstrated that neurodynamic treatment could be effective for nerve-related leg pain. However, whilst case series are at high risk of

bias, both trials enrolled participants likely to represent a mixed sample of acute, subacute and chronic pain, which may have exerted direct influence on outcomes due to differences in the expected prognosis of leg pain and disability. The paucity of high-quality studies assessing the effects of this treatment approach was highlighted by a clinical practice guideline that recommended[14] neurodynamic treatment for patients with chronic nerve-related leg pain based only on weak evidence. As such, there is a need for a randomised controlled trial to assess the effects of neurodynamic treatment in patients with chronic nerve-related leg pain. Therefore, the specific research questions for this study were:

1. In participants with nerve-related leg pain, does neurodynamic treatment improves leg pain, low back pain, disability, function, and global perceived effect compared to advice to remain active?

2. Is the proportion of participants whose leg pain symptoms centralise, or remain unchanged different between those receiving neurodynamic treatment or advice to remain active?

METHOD

Design

This study was a prospectively registered, parallel-group randomised controlled trial with a blinded assessor. This trial's report followed the recommendations of the Consolidated Standards of Reporting Trials (CONSORT) statement[15]. The study protocol was published previously.[16]

At baseline, the presence of neuropathic pain was assessed by the *Leeds Assessment of Neuropathic Symptoms and Signs* (LANSS) score, in which a score ≥ 12 indicated the presence of neuropathic pain[17]. A neurological examination, comprising manual muscle strength testing of the lower limbs, patellar and Achilles reflexes and sensation was carried out and participants with at least one positive neurological finding were classified as having nerve root compromise. Fear-avoidance beliefs was assessed by the *Fear-avoidance beliefs questionnaire* (FABQ), and pain catastrophising was evaluated by the *Pain Catastrophising Scale* (PCS).

Following baseline assessment, participants were randomly assigned to neurodynamic treatment or advice to remain active. Randomisation followed a 1:1 ratio and was stratified by current leg pain intensity in two strata (pain ranging from three to six and pain ranging from seven to ten on a 0-10 scale) and in blocks of six. Sequentially numbered, opaque and sealed envelopes containing the treatment allocation were shuffled prior to enrolment by a researcher not involved assessment or treatment provision. The envelope was opened only after the enrolled participants completed all baseline assessments.[18]

Participants, therapists, centres

Participants were recruited from the community through advertisements in local newspapers and social media between March 2015 and March 2016. Albeit recruitment from private practices (i.e., secondary health care facilities) was planned and described in the study protocol[13], no participant was referred from such facilities due to lack of referrals. Adults aged 18-80 years presenting with chronic unilateral nerve-related leg pain (i.e., leg pain for at least 12 weeks) radiating below the gluteal fold were included. Participants had to report a leg pain intensity of at least three on the 11-point numeric pain rating scale and their leg symptoms had to be reproduced by the slump test and changed by structural differentiation (releasing of cervical flexion or ankle dorsiflexion).[19] Current low back pain was not a necessary criterion for an individual to be included. Participants were excluded if they had signs of *cauda equina* syndrome, bilateral leg pain, positive crossed Lasègue sign, previous surgery in the lumbar spine or in the symptomatic leg, inflammatory arthropathies, fractures or malignancy. Those with workers compensation claims or on physiotherapy treatment at the time of baseline assessment were also excluded. Participants who met all eligibility criteria provided informed consent and entered the trial.

A physiotherapist with two years of clinical experience who attended a 40-hour course of management of neuromusculoskeletal disorders with neurodynamic techniques provided treatment to all participants enrolled in the neurodynamic treatment group. All treatment sessions were provided in a private physiotherapy practive located in Porto Alegre, Brazil.

Intervention

Participants in both groups received advice to remain active, an educational approach that focused on two aspects: (1) demonstrating the harmful effects of prolonged rest, avoidance of daily-life activities and excessive muscle bracing during movement and (2) that light activities and movements would be beneficial for their pain. At baseline assessment, participants were advised to maintain their usual activities and medication intake was recorded.

Neurodynamic treatment consisted of passive or active movements aiming to desensitise the overly sensitised nervous system by restoring its ability to tolerate external forces, such as movement and compression.[20] Participants received four treatment sessions over two weeks (two times per week) with each treatment session lasting up to 25 minutes. On the first appointment, they were informed that nerve sensitisation was playing a role in their leg symptoms and that the treatment goal was to desensitise it. This educational component related to neurodynamic treatment was applied in a previous trial.[21]

Participants received a grade III (i.e. large amplitude movement performed into firm resistance or up to the limit of the available range) lumbar foramen opening mobilisation and neurodynamic sliders. Reproduction of patients' symptoms were not allowed during the treatment, but a mild pull sensation was tolerated. The lumbar foramen opening mobilisation was performed for two sets of 30 oscillations at 0.5 Hz with the participants in side-lying (painful side uppermost) with hip flexion to induce flexion of the lumbar segments. If the participant's symptoms did not worsen after two sets of mobilisations, both legs were draped over the side of the table in order to increase the foramen size and one additional set of 30 oscillations was performed.

For the neurodynamic slider technique, the participants were initially positioned in side-lying (painful side uppermost) and a combination of hip and knee flexion followed by hip and knee extension was performed for two sets of 30 repetitions. In the absence of symptoms worsening, a progression was added and the participants executed one set of 30 repetitions of an active sliding technique in slump sitting, which combined neck flexion and knee flexion with neck extension and knee extension, an exercise that produce a great amount of nerve excursion.[6] During the active slider technique, the participant was instructed to move up to the onset of

symptoms.

The lumbar foramen opening technique was designed to reduce pressure over the sensitised nervous system[22] by increasing the size of the lumbar foramen. The sliding techniques were implemented aiming to induce painless nerve excursion, which occurs when elongation of the nerve bed at one joint (e.g knee extension) is simultaneously counterbalanced by a reduction in the length of the nerve bed at an adjacent joint (e.g. neck extension). The nerve excursion promoted by neurodynamic sliders may reduce intraneural oedema and venous congestion.[5] Apart from the proposed mechanical effects, neurophysiological effects of neurodynamic treatment have been described, such as the ability to inhibit temporal summation in patients with carpal tunnel syndrome, which reflects decreased hyper excitability of the dorsal horn.[23]

The intervention was applied following standardized algorithms of progression[16], which implies that the intervention was not tailored to participants' symptoms presentation (e.g. the neurodynamic sliders were not biased to the tibial or peroneal nerves). Nevertheless, a similar treatment protocol was shown to be effective for patients with back-related leg pain with peripheral nerve sensitization[5]. A treatment session was discontinued if a participant reported increase in leg pain (≥ 2 points on pain rating scale), numbness or tingling.

The home exercise program involved one sliding (active sliding in slump sitting) and one tensioning technique (active knee extension in supine). Each technique was performed for one set of 10 repetitions twice a day during the treatment period and was standardised across participants. Participants were advised to do the home exercises in a painless way. A self-reported exercise log verified home exercises compliance. At the end of the treatment, home exercises were no longer monitored, and the decision of whether to continue or not was at the discretion of the participants. Due to the nature of the interventions, neither participants nor therapists were blinded to allocation.

Outcome measures

Baseline assessment was performed before randomisation and investigators blinded to treatment allocation collected the follow-up measures. When the participant could not attend the follow-up sessions, data were collected over the

telephone or a standardized form was sent by e-mail.

The primary outcomes were leg pain and disability measured two weeks after randomisation. The numerical pain rating scale (NPRS), a 0-10 scale in which 0 represents “no pain” and 10 represents “worst possible pain”, was used to assess leg pain. Participants were asked to rate their average leg pain intensity over the last 24 hours. A 2-point reduction in NPRS was considered clinically relevant.[24] Disability was assessed by the Brazilian version of the Oswestry Disability Index 2.0 whose minimal clinically important difference is 10 points on a 0-100 scale.[24]

Secondary outcomes were leg pain intensity and disability measured at four weeks after randomisation and low back pain intensity (measured by the NPRS), function (measured by the Patient-Specific Functional Scale)[25], location of symptoms[26] and global perceived effect[27]. All secondary outcomes were measured at two and four weeks after randomization.

Data analysis

Sample size was determined *a priori*.[16] Enrolment of 60 participants ensured that this trial was powered to detect a difference of 1.6 points on leg pain (with standard deviations of 2.4 and 2.1 for the neurodynamic treatment and advice to remain active groups, respectively) with 80% power, a two-tailed alpha of 5% and an expected dropout rate of 20%. This sample size has also 80% power to detect a difference of 9 points (standard deviation of 12) on the 100-point Oswestry Disability Index.

Data normality was checked by visual inspection of histograms, which revealed a normal distribution for all data, except for duration of symptoms. Descriptive statistics were presented by treatment group. Normally distributed continuous variables were summarised as mean and standard deviations, whereas duration of symptoms was reported with median and interquartile range. Categorical or dichotomous data were summarised by frequencies.

A repeated measures linear mixed model including terms for participant, group, time and group by time interaction was used to assess the effect of treatment

on leg pain, disability, low back pain, function and global perceived effect at two and four weeks. Repeated measures were modelled using a Toeplitz covariance structure. For each outcome, LANSS, FABQ (physical activity and work subscales), PCS, baseline leg pain intensity, and baseline low back pain intensity were tested as potential covariates following a backward elimination approach. These covariates were determined *a priori* on the study protocol.[16] As no covariate improved the overall fit of the model it was not necessary to adjust the model. Mean scores, standard errors (SE) and between-group mean differences (95% CIs) were calculated for all outcomes across all time points. The linear mixed model analysis accounts for the dependency of the repeated measures taken from each participant through time and handles missing data without the need for imputation procedures. This ensured that data were analysed following intention to treat principles; that is, participants were analysed according to group allocation, regardless of treatment received after randomisation. For location of symptoms, scores at each follow-up were compared against baseline values and coded as “centralised” if the most distal location of the pain moved towards the lumbar spine (e.g, if pain moved from 5 [leg] to 4 [thigh]), or “non-centralised” if the most distal location of the pain moved towards the feet or did not change. Missing values were imputed using logistic regression and the relative risk of pain centralisation was calculated. All statistical tests were two-tailed and a P value of < 0.05 was considered significant.

RESULTS

Flow of participants, therapists, centres through the study

From March 2015 to March 2016, 158 patients were recruited and 60 were eligible to be included in the study. All participants received the intervention for which they were initially allocated. In the neurodynamic treatment group, two participants could not be followed up at the two weeks follow-up (93% follow-up) and three could not be followed-up at the four weeks follow-up (90% follow-up). In the advice to remain active group, two and three participants were lost to follow up at the 2 weeks (93% follow-up) and four weeks follow-up (90% follow-up), respectively. The flow of participants, reasons for ineligibility and reasons to drop-out are detailed in Figure 1.

Participants in the neurodynamic treatment group received a mean of 3.7 (1.0) sessions along two weeks. Home exercise compliance was 85%. No adverse effects

were observed during sessions, and only one participant (2%) reported an adverse effect following home exercises that subsided within 24 hours. This participant performed a vigorous hamstring stretching instead of the oriented sliding and tensioning techniques. Two participants (3%) reported co-interventions (one participant in the treatment group sought for chiropractic treatment and one participant in the advice to remain active group reported having consulted a physiotherapist). Overall, most of participants were woman with moderate levels of disability, low back pain and leg pain. Leg pain was more intense than back pain in most of the participants. Baseline demographic and clinical characteristics of enrolled participants are displayed in Table 1.

There was no effect of neurodynamic treatment on leg pain intensity at two weeks (-0.9 point, 95% CI -0.2 to 2.1), but a significant and clinically important effect on leg pain intensity was observed at four weeks (-2.2 points, 95% CI -3.5 to -1.0). There was no significant effect of treatment on disability at two weeks (-2.0 points, 95% CI -8.4 to 4.3) and four weeks (-3.6 points, 95% CI -10 to 2.8) (Table 2).

Neurodynamic treatment did not exert significant influence on low back pain intensity at two weeks (-0.6 point, 95% CI -1.9 to 0.6) and four weeks (1.2, 95% CI -2.5 to 0.4). Conversely, there was a significant effect of treatment on function at two weeks (4.7 points, 95% CI 1.7 to 7.7) and four weeks (4.1 points, 95% CI 1.1 to 7.2). Likewise, global perceived effect improved in favour of neurodynamic treatment at two weeks (-2.4 points, 95% CI 1.4 to 3.3) and four weeks (2.7 points, 95% CI 1.8 to 3.7) (Table 2).

There was no effect of treatment on location of symptoms. At two weeks, 11 (37%) participants in the treatment group and 5 (17%) participants in the advice to remain active group reported centralisation of the most distal leg pain and this difference was not statistically significant (RR 2.2, 95% CI 0.9 to 5.6). At four weeks, 13 (43%) participants in the treatment group and 7 (23%) of participants in the advice to remain active group reported centralisation of the most distal leg pain (RR 1.9, 95% CI 0.9 to 4.0).

DISCUSSION

This is the first randomised controlled trial of neurodynamic treatment for chronic nerve-related leg pain. Neurodynamic treatment provided no benefit compared to advice to remain active on primary outcomes; i.e., pain and disability two weeks after randomisation. However, a significant and ~~clinically important effect~~ of treatment was found for leg pain intensity at four weeks, function and global perceived effect at both two weeks and four weeks but not for leg pain intensity at two weeks, low back pain intensity, disability and location of symptoms at two and four weeks.

Some findings of this trial are in accordance with previous studies. Cleland et al.[12] showed that patients with non-radicular low back pain treated with spinal mobilisation plus slump stretching displayed a significant, although not clinically important, reduction in pain, disability and centralisation of symptoms compared to mobilisation only. Nagrale et al.[13] conducted a similar trial adding lumbar stabilisation exercises to mobilisation or mobilisation plus slump stretching and also found significant reduction in pain, which was clinically important at six weeks. In the case series by Schafer et al.[5] participants with peripheral nerve sensitisation without signs of neuropathic pain, nerve root compromise and somatic pain achieved a clinically important reduction on pain following neurodynamic treatment.

It has been suggested that participants with neuropathic pain or signs of nerve root compromise would not benefit from neurodynamic treatment and that treatment effects would be diluted in trials with more relaxed inclusion criteria.[5,21] To overcome the inappropriateness of one-size-fits-all approaches to treat nerve-related leg pain, Schäfer et al.[5] proposed a mutually exclusive classification system, in which only patients presenting signs of nerve mechanosensitivity without nerve root compromise and neuropathic pain features would benefit from neurodynamic treatment. In contrast, even with a broader inclusion criteria, which enabled the enrollment of participants with neuropathic pain features and nerve root compromise, clinically important effects favouring neurodynamic treatment were found in our trial for leg pain intensity, function and global perceived effect. These findings appear to challenge the current understanding on which clinical characteristics would increase the likelihood of achieving better outcomes with neurodynamic treatment. However, any inferences about the magnitude and direction of the relationship between the

presence of neuropathic pain, nerve root compromise, and outcomes following neurodynamic treatment would be premature and statistically inaccurate. Future studies with a rigorous pre-planned subgroup analysis[28] and adequate sample size to conduct such analysis should clarify whether the presence (or absence) of neuropathic pain and nerve root compromise are treatment effect modifiers for patients receiving neurodynamic treatment.

Participants receiving neurodynamic treatment displayed a consistent pattern of leg pain reduction at each follow-up, achieving a reduction of 2.4 points at four weeks, as opposed to participants enrolled to receive advice to remain active, who improved by 1 point at two weeks, but returned to baseline levels of leg pain intensity at four weeks. The observed difference in symptoms' behavior along the study period may reflect that neurodynamic treatment altered the natural history of leg pain in the short-term, while participants in the advice to remain active group displayed a natural fluctuation in leg pain. Whilst recent evidence shows that only a small proportion of patients with chronic low back pain have fluctuating symptoms[29], it is currently unknown whether this finding also applies to individuals with predominant leg pain with or without signs of nerve root compromise and neuropathic pain.

The strengths of this trial were the implementation of true randomisation, allocation concealment, blinding of outcome assessors as well as the conduction of analysis based on intention-to-treat principles, which ensured adequate internal validity reducing the likelihood of bias[15]. Furthermore, the broader inclusion criteria adopted increased the generalisation capacity of the findings.

Some limitations must be highlighted. As this trial only assessed short-term outcomes, it is currently unknown the whether the results would be sustained in/on longer follow-up assessments. Outcome measures such as disability and function displayed wide 95% CI, which reflects imprecision in data. Moreover, participants enrolled to neurodynamic treatment were seen by the therapist four times during the treatment period, while participants allocated to the advice to remain active group had face-to-face contact with the study staff only once. The difference in the quantity of visits between groups may have created attention bias, which may justify why participants in the advice to remain active improved in some outcomes measures in

the first follow-up, but returned to the baseline level at the four weeks follow-up. Apart from attention bias, placebo effects might explain some degree of the observed treatment effects. Participants receiving neurodynamic treatment were exposed to a therapeutic context, in which the interaction with the therapist as well as to a therapeutic setting may have potentialised improvement compared to those who did not receive treatment[30]. Since, to date, there is no validated sham-neurodynamic treatment for conditions of the lower quadrant, the true therapeutic effect of this approach needs to be determined by future placebo-controlled studies[31].

In conclusion, neurodynamic treatment was not capable of reducing leg pain and disability compared to advice to remain active. Based on the findings of the primary outcomes of this trial, neurodynamic treatment should not be recommended for the treatment of nerve-related leg pain. However, given the beneficial effects on function and global perceived effect, trials with larger samples and longer follow-up assessments should be conducted in order to determine the extent to which the results of these secondary outcomes are relevant to patients with nerve-related leg pain.

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Table 1. Baseline characteristics

	Neurodynamic treatment (n = 30)	Advice to remain active (n = 30)
Age (*yr*) mean (SD)	43.9 (14.5)	40.3 (12.9)
Gender, n female (%)	22 (76.7)	23 (73.3)
BMI (*kg/m²*) mean (SD)	26.8 (4.2)	27.3 (4.6)
Education, n (%)		
Elementary degree	2 (6.7)	3 (10)
High school	12 (40)	14 (46.7)
University	16 (53.3)	13 (43.3)
Smoker, n (%)	5 (16.7)	3 (10)
Duration of leg symptoms *(yr)*, median [IQR]	5.8 [5.4]	2 [4.4]
Use of medication, n (%)		
NSAID	9 (30)	12 (40)
Muscle relaxants	8 (26.7)	6 (20)
Opioid	2 (6.7)	0 (0)
Gapabentin	1 (3.3)	0 (0)
Antidepressants	1 (3.3)	0 (0)
Nerve root compromise, n (%)	19 (63)	14 (46.7)
LANSS score (0 – 24), mean (SD)	11.4 (5.3)	12 (3.6)
Neuropathic pain, n (%)	11 (36.7)	15 (50)
FABQ, mean (SD)		
Physical Activity (0-24)	15.2 (5.8)	14.3 (4.6)
Work (0-24)	15.1 (8.6)	18.6 (10)
PCS (0-52), mean (SD)	26.5 (9.9)	28.6 (9.8)
Low back pain 24h (0-10), mean (SD)	5.5 (2.3)	5.1 (2.5)
Leg pain 24h (0-10), mean (SD)	6.1 (1.6)	6.1 (1.9)
ODI (0-100), mean (SD)	26.9 (8.1)	28.7 (15.1)
PSFS (0-30), mean (SD)	13.8 (5.2)	14.6 (6.1)
Location of symptoms, n (%)		
Thigh	10 (33.3)	10 (33.3)
Leg	12 (40)	10 (33.3)
Foot	8 (26.7)	10 (33.3)

NSAID, non-steroidal anti-inflammatory drugs; LANSS, Leeds Assessment of Neuropathic Symptoms and Signs; FABQ, Fear-avoidance Beliefs Questionnaire; PCS, Pain Catastrophising Scale; ODI, Oswestry Disability Index; PSFS, Patient-specific Functional Scale

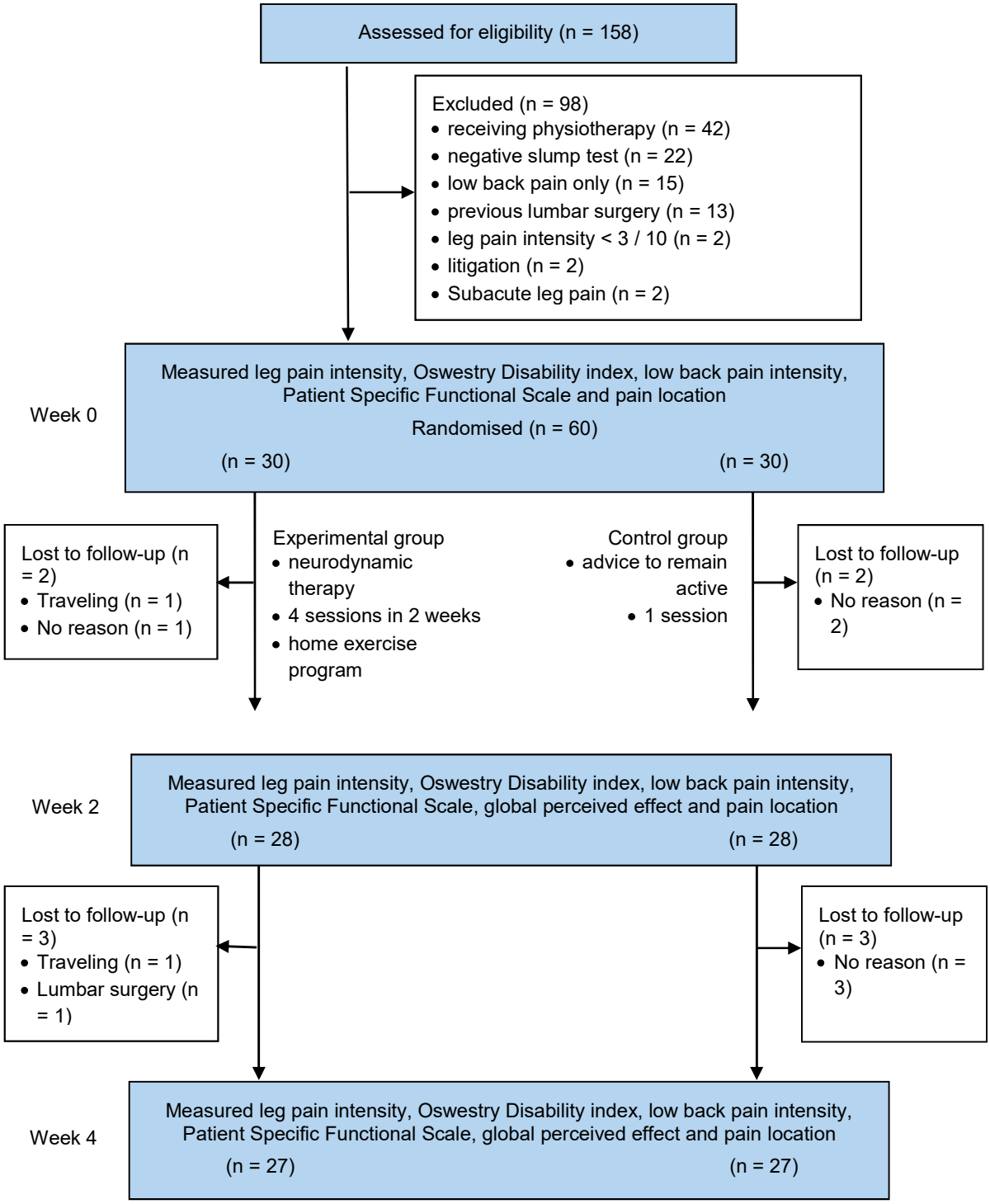

Figure 1. Design and flow of participants through the trial.

Table 2
Mean (SD) for continuous outcomes at each assessment point for each group, mean (SD) difference within groups, and mean (95% CI) difference between groups.

Outcomes	Groups						Within-group difference				Between-group difference	
	Week 0		Week 2		Week 4		Week 2 minus Week 0		Week 4 minus Week 0		Week 2 minus Week 0	Week 4 minus Week 0
	Exp (n = 30)	Con (n = 30)	Exp (n = 28)	Con (n = 28)	Exp (n = 27)	Con (n = 27)	Exp	Con	Exp	Con	Exp minus Con	Exp minus Con
Leg pain *(0 to 10)* [a]	6.1 (1.6)	6.1 (1.9)	4.1 (2.3)	5.1 (2.3)	3.7 (2.6)	6.1 (2.4)	-1.9 (2.6)	-1.0 (2.4)	-2.2 (2.4)	0 (2.1)	-0.9 (-0.2 to 2.1)	-2.2 (-3.5 to -1.0)
Oswestry Disability Index *(0 to 100)*	29 (8.1)	27 (15)	21 (12)	23 (12)	20 (12)	23 (12)	-7.4 (13)	-3.6 (9.5)	-8.7 (15)	-3.3 (8.1)	-2.0 (-8.4 to 4.3)	-3.6 (-10 to 2.8)
Low back pain *(0 to 10)* [a]	5.5 (2.3)	5.1 (2.5)	4.2 (2.4)	4.9 (2.4)	4.2 (2.5)	5.4 (2.5)	-1.2 (2.5)	-0.1 (1.5)	-1.2 (2.1)	0.3 (2.1)	-0.6 (-1.9 to 0.6)	-1.2 (-2.5 to 0.4)
PSFS *(0 to 30)*[b]	14 (5.2)	15 (6.1)	20 (5.8)	15 (5.8)	19 (5.9)	15 (5.9)	6.2 (6.9)	0.6 (6.3)	5.2 (6.3)	0.2 (7.5)	4.7 (1.7 to 7.7)	4.1 (1.1 to 7.2)
Global perceived effect *(–5 to 5)*[b]			2.2 (1.2)	-0.2 (2.1)	2.0 (1.5)	-0.7 (1.9)					2.4 (1.8 to 3.7)	2.7 (1.8 to 3.7)

Con = Control group, Exp = Experimental group, PSFS = Patient Specific Functional Scale. Shaded cells = primary outcome.
[a] Average intensity during past 24 hours

Table 3
Number of participants (%) in each group whose pain had centralised by each assessment point, and relative risk (95% CI) between groups.

Outcome	Groups				Relative risk between groups (95% CI)	
	Week 2		Week 4		Week 2	Week 4
	Exp (n = 30)	Con (n = 30)	Exp (n = 30)	Con (n = 30)	Exp relative to Con	Exp relative to Con
Pain centralised	11 (37)	5 (17)	13 (43)	7 (23)	2.2 (0.9 to 5.6)	1.9 (0.9 to 4.0)

Exp = experimental group, Con = control group

6. CONCLUSÃO

O manejo da DL se impõe como um grande desafio mundial na atualidade, considerando sua alta prevalência e os altos custos gerados. Para o subgrupo de pacientes com DLCIP, os questionáveis efeitos de diversas estratégias de tratamento conservador amplamente utilizadas diariamente no tratamento deste problema, bem como a escassez de estudos clínicos sobre a eficácia do tratamento neurodinâmico nesta população motivou a realização deste trabalho.

O presente estudo demonstrou que não o TND não foi superior ao AMA em reduzir a intensidade de dor na perna e incapacidade duas semanas após a randomização. O TND também não foi superior ao AMA em relação à intensidade de dor lombar e localização dos sintomas. Entretanto, o TND foi superior ao AMA em termos de aumento de função e auto-percepção de melhora após duas semanas e um mês após a randomização. Além disso, o TND reduziu significativamente a dor na perna comparado ao AMA um mês após a randomização.

Os critérios de inclusão amplos adotados pelo presente estudo possibilitaram a inclusão de indivíduos com comprometimento de raíz nervosa e sintomas relacionados à dor neuropática, características estas descritas por estudos prévios como relacionadas a maus resultados com TND. (NEE *et al*., 2012; SCHAFER et al., 2011) Ainda assim, foi possível observar que o tratamento experimental modificou, de maneira significativa a auto-percepção de melhora, a intensidade de dor na perna após um mês e a função, embora o último desfecho tenha apresentado intervalos de confiança amplos, caracterizando imprecisão das estimativas.

Os participantes recrutados para o grupo TND experienciaram redução progressiva na intensidade de dor na perna, enquanto os pacientes do grupo AMA inicialmente reportaram melhora, mas retornaram aos níveis da linha de base após um mês. A diferença entre o comportamento da dor intensidade de dor na perna entre os grupos pode indicar que o TND foi capaz de alterar eventuais oscilações nos sintomas – dessa forma sugerindo que o TND foi modificou a história natural da dor na perna. Resultados semelhantes foram

descritos para pacientes com dor cervical irradiada para o braço submetidos a TND. (NEE *et al*., 2012)

Em conclusão, este ensaio clínico randomizado demonstrou que o TND não foi capaz de modificar a intensidade de dor na perna e a incapacidade, mas apresentou efeitos positivos na função e a auto-percepção de melhora. Estudos futuros devem verificar os efeitos do TND a longo prazo, bem como seu efeito comparado a estratégias de manejo comumente utilizadas para o tratamento da DLCIP.

7. ANEXOS

7.1 Registro prospectivo – ClinicalTrials

ClinicalTrials.gov PRS
Protocol Registration and Results System

ClinicalTrials.gov Protocol Registration and Results System (PRS) Receipt Release Date: 06/01/2016

ClinicalTrials.gov ID: NCT01954199

Study Identification

Unique Protocol ID: UFCSPA
Brief Title: The Effectiveness of Neurodynamic Techniques in Patients With Nerve-Related Leg Pain
Official Title: The Effectiveness of Neurodynamic Techniques in Patients With Nerve-Related Leg Pain
Secondary IDs:

Study Status

Record Verification: June 2016
Overall Status: Completed
Study Start: March 2015
Primary Completion: April 2016 [Actual] Study
Completion: April 2016 [Actual]

Sponsor/Collaborators

Sponsor: Federal University of Health Science of Porto Alegre
Responsible Party: Principal Investigator
Investigator: Giovanni Esteves Ferreira [gferreira]
Official Title: Mr
Affiliation: Federal University of Health Science of Porto Alegre

Oversight

FDA Regulated?: No
IND/IDE Protocol?: No
Review Board: Approval Status: Approved
Approval Number: 940.742 Board Name: CEP-UFCSPA
Board Affiliation: UFCSPA Phone: +5133038810 Email:
Data Monitoring?: Yes
Plan to Share Data?: Yes

Study Description

Brief Summary: This study aims to verify if patients with nerve-related leg pain benefits from neurodynamic treatment over two weeks.

Detailed Description: Nerve-related leg pain (NRLP) although less prevalent than low back pain itself, is associated with higher economic and social burden, and has been considered a predictor of chronicity and disability among subjects with low back pain.

Numerous approaches are proposed for its management; however, evidence regarding the best therapeutic approach is lacking. Neurodynamic techniques are proposed to be effective to manage NRLP.

Thus, this study aims to verify, through a randomized controlled trial, the effectiveness of a two-week program of neurodynamic techniques on pain and disability in individuals with NRLP.

Conditions

Conditions: Nerve Pain
Peripheral Nerve Injuries
Peripheral Nervous System Diseases
Sciatica
Low Back Pain
Low Back Ache
Signs and Symptoms
Keywords: Sciatica
Nerve pain
Low back pain

Study Design

Study Type: Interventional
Primary Purpose: Treatment
Study Phase: N/A
Intervention Model: Parallel Assignment
Number of Arms: 2
Masking: Single Blind (Outcomes Assessor) Allocation: Randomized
Endpoint Classification: Efficacy Study
Enrollment: 60 [Actual]

Arms and Interventions

Arms	Assigned Interventions
Experimental: Neurodynamic group Patients allocated to this group will receive three different neurodynamic techniques: a lumbar foramen dynamic opener; a side-lying slider and a slider in the slump position. Patients will be asked to perform home exercises (a slider and a tensioner technique). Patients wiill receive four treatments during two weeks (two sessions/week).	Procedure/Surgery: Neurodynamic Group All techniques will be executed in a pain-free way (grade III). Mild discomfort will be accepted, but it must subside as soon as the technique ends. * In the dynamic opener technique, patient will be positioned in side-lying, with the affected side upwards. The therapist will then perform grade III oscillations aiming to open the lumbar foramen; * In the side-lying slider, the patient will be in side-lying with the affected side upwards. A combination of knee and hip flexion and extension movements will produce sliding in the neural structures; * In the slump slider, the patient will be seated in slump position. Combinations between neck and knee movements will produce greater nerve excursion than the side-lying slider. Patients will perform the slump slider in a pain-free manner. Other Names: • Neural mobilization • Sliders • Tensioners • Nerve tissue management

Arms	Assigned Interventions

No Intervention: Control Group Patients allocated to Control Group (CG) will receive no intervention and will be advised according to the best evidence available; i.e, advice to remain active and to resume activities of daily living Upon trial completion, treatment will be offered.	

Outcome Measures

Primary Outcome Measure:

1. Leg Pain Intensity
   [Time Frame: Two weeks after randomization] [Safety Issue: No]
   Leg Pain will be measured by a 0-10 Numeric Rating Scale (Pain NRS)
2. Disability
   [Time Frame: Two weeks after randomization] [Safety Issue: No]
   Disability will be measured by the Oswestry Disability Index (ODI)

Secondary Outcome Measure:

3. Leg pain Intensity
   [Time Frame: Four weeks after randomization] [Safety Issue: No] Leg Pain will me measured by a 0-10 Pain NRS
4. Disability
   [Time Frame: Four weeks after randomization] [Safety Issue: No]
   Disability will be measured by the Oswestry Disability Index (ODI)
5. Back pain intensity
   [Time Frame: Two weeks after randomization] [Safety Issue: No] Back Pain will me measured by an 0-10 Pain NRS
6. Back pain intensity
   [Time Frame: Four weeks after randomization] [Safety Issue: No] Back Pain will me measured by an 0-10 Pain NRS
7. Distribution of Symptoms
   [Time Frame: Two weeks, Four weeks after randomization] [Safety Issue: No] Distribution of symptoms will me measured by a body diagram 8. Function

[Time Frame: Two weeks, Four weeks after randomization] [Safety Issue: No] Function will be measured by the Patient-Specific Functional Scale (PSFS)

9. Global Perceived Effect
   [Time Frame: Two weeks, Four weeks after randomization] [Safety Issue: No]
   Global Perceived Effect will be measured by an 11-point (-5 to +5) Global Perceived Effect Scale

Eligibility

Minimum Age: 18 Years
Maximum Age: 80 Years
Gender: Both
Accepts Healthy Volunteers?: No
Criteria: Inclusion criteria:

- unilateral leg pain (Intensity ≥ 3)
- Pain distal to the buttocks
- Reproduction of symptoms and change in symptoms with structural differentiation (cervical return to neutral position or ankle dorsiflexion) with slump test; Exclusion criteria:
- cauda equina syndrome;
- bilateral leg pain;
- crossed Lasègue sign;
- previous surgery in the lumbar spine;
- inflammatory arthropathies;
- malignancy
- being in litigation or in work-compensation due to back and/or leg pain
- being receiving physiotherapy treatment at the time of baseline assessment

Contacts/Locations

Study Officials: Marcelo F Silva, PhD
Study Chair
Federal University of Health Sciences of Porto Alegre

Locations: Brazil
Federal University of Health Sciences of Porto Alegre
Porto Alegre, Rio Grande do sul, Brazil, 90050-170

References

Citations:
Links:
Study Data/Documents:

7.2 Normas de formatação do período

Journal of Physiotherapy (JoP) is the first Open Access core physiotherapy journal; it welcomes contributions that are relevant to the science or practice of physiotherapy.

CONTENT

Original Research
The Editorial Board is committed to publishing excellent research and will consider the following types of papers:

• Systematic reviews
Systematic reviews are strongly preferred over narrative (non-systematic) reviews. High quality systematic reviews with firm conclusions are a publication priority. However, systematic reviews are unlikely to be published if they find there is not enough good quality evidence to review or if the literature is inconclusive. Note that this journal gives priority to systematic reviews that are prospectively registered in a publicly available register (e.g., PROSPERO at http://www.crd.york.ac.uk/PROSPERO). Authors should submit evidence of registration when submitting a manuscript for consideration. There are specific guidelines available for this type of study at the end of the Presentation section of these Author Guidelines.
• Clinical trials
All clinical trials submitted to JoP must have been registered in a publicly-accessible trials register. We will accept any register that satisfies the International Committee of Medical Journal Editors requirements (such as The Australian New Zealand Clinical Trial Registry at http://www.anzctr.org.au). Authors must provide the name and website address of the register and the trial registration number on submission. The journal will only accept trials that have been registered prospectively unless data collection began before 2006, in which case retrospective registration is acceptable. There are specific guidelines available for this type of study at the end of the Presentation section.
• Economic analyses
• Experimental studies
• Qualitative studies
Qualitative research refers to research where the analysis of data involves qualitative judgements. Commonly qualitative research explores aspects of the human, social world. Qualitative research methodologies include narrative inquiry, case studies, naturalistic inquiry, ethnography, hermeneutics, phenomenology, and survey research using open-ended questions. There are specific guidelines available for this type of study at the end of the Presentation section.
• Epidemiological studies
• Observational studies
• Narrative reviews
Narrative reviews critically appraise and summarise literature on a common topic area but do not set specific criteria for selecting literature to be included or a specific review protocol. A narrative review draws together major arguments in a field of discourse or provides a significant historical review of an important aspect of physiotherapy. Narrative reviews should be on topics that do not lend themselves to systematic reviews, e.g., examination of the mechanisms underlying a clinical phenomenon. Narrative reviews will almost always be invited and will be considered only if they are written by authors with extensive research experience in the field, usually reflected in multiple significant publications. Authors considering submission of a narrative review should first consult the Journal Editor regarding potential suitability of the review for publication. Narrative reviews of intervention, diagnosis, and prognosis will generally not be accepted.

The following types of studies are a low priority:
• Studies of the reliability or validity of clinical measurement procedures
• Surveys of physiotherapy students
• Surveys of physiotherapy practice
• Any survey with a low response rate (less than 70%)

Submission of these types of studies should be accompanied by a short (less than 100 words) explanation of why the study would be of particular interest to readers of JoP. The Editorial Board will decide, on the basis of this explanation and the abstract, whether the manuscript should be considered for publication. If accepted, such studies will be published as papers of less than 2000 words with no more than one table or

figure.

The following types of studies are not accepted:

• Clinical practice guidelines
Although the journal is particularly interested in presenting the recommendations of clinical practice guidelines to its readers, clinical practice guidelines are often developed by consensus and may be endorsed by a professional body. This can make it difficult to apply the Journal's normal process of peer review. Therefore, particularly relevant guidelines that have been developed using a rigorous process and endorsed by a high quality professional body, such as NHMRC, will be summarised in the Appraisal section of the journal, but will not be republished. Details of the location where hard or electronic copies of the full guidelines are available will be given in the summary.
• Pilot studies
Pilot clinical trials are those that are not designed to have adequate statistical power. Their purpose is to test the feasibility of an intervention in terms of recruitment and delivery of the intervention, as well as to examine the rate of dropouts. They usually provide information to power a future trial and do not therefore reach firm conclusions.

Manuscript length (not including title page, abstract, references, tables or figure legends) depends on the type of study:
• Systematic reviews: up to 5000 words
• Clinical trials, experimental and qualitative studies: up to 3500 words
• Observational studies: up to 2500 words

Authors may be invited, or in some cases required, to place important supplementary material as electronic addenda (eAddenda) on the JoP web site.

MANUSCRIPT PRESENTATION

Research manuscripts should consist of a title page, abstract, text, references, tables, and figures. Manuscripts should be prepared with 2.5 cm margins and a footer containing an abbreviated title, the first author's family name, page number and date. The abstract, introduction, method, results, and discussion should be 1.5 line-spaced, but all other text should be single-spaced. Put a double return between paragraphs. Download the journal's manuscript template.

Title Page

The title of the manuscript should not be more than 25 words and should be in two parts. Give the main results of the study followed by a colon and the method used, e.g., 'A resource-efficient exercise program after discharge from rehabilitation improves standing ability in people after stroke: a randomised trial'. Download example titles for different research designs.

Then, list all authors and their degrees, positions, institutions, country, and email address. Nominate a corresponding author for the review who is authorised to negotiate and approve editorial revisions, provide his/her title (Professor, Dr, etc.), and give contact details (email address). You may nominate a different corresponding author for publication; provide his/her title (Professor, Dr, etc.) and short contact details (department/institution, postal address and email address).

Provide a running head of up to six words. Next, for indexing purposes, select up to five key words from the Index Medicus Medical Subject Headings (MeSH). MeSH Headings can be found on the PubMed MeSH browser at http://www.nlm.nih.gov/mesh/meshhome.html.

List the word count for the abstract and the body of the text, as well as the number of references, tables, and figures.

Finally, list the Ethics Committee(s) that approved the study and the procedures for gaining consent, source(s) of support, acknowledgements, and any competing interests. The statements regarding ethics and consent do not need to be re-stated in the body of the manuscript. Acknowledgments should include statements of important contributions that do not justify authorship. The nature of the contribution should be specified. It is customary to seek permission of people named in the acknowledgments. Download the journal's Title Page template.

Abstract

An abstract of no more than 250 words is required for all submissions using the headings: Question, Design, Participants, Intervention, Outcome measures, Results, Conclusion, and Trial registration (if appropriate). The results should include estimates of effect sizes and their confidence intervals rather

than *p* values. Abstracts should not contain references. Download examples of abstracts for different research designs

Introduction

The introduction should justify the aims of the research. Only references essential to understanding these aims should be included. Introductions rarely need to be longer than five paragraphs. At the end of the introduction, list the research questions as given in the Abstract again. Download Research question examples for different research designs

Method

Use the subheadings: Design; Participants, therapists, centres; Intervention; Outcome measures; and Data analysis, as appropriate to the design of the study. Restrict headings to no more than two levels of importance (i.e., avoid sub-subheadings). Where aspects of the method have been described in other widely-available publications a reference to those publications may suffice, whereas newly-developed procedures should be described in more detail.

In the **Design** section, describe the overall design, especially the timing of intervention and measurement, and any randomisation or blinding procedures.

In the **Participants, therapists, centres** section, outline the recruitment procedures and the inclusion and exclusion criteria for eligibility of participants, therapists, and centres.

In the **Intervention** section, give as much detail as necessary so that the intervention could be faithfully replicated by a reader. If this requires extensive material, consider placing some in an Appendix, which can be an electronic-only addendum to the paper.

In the **Outcome measures** section, state the impairment/activity limitation/participation restriction being collected (e.g., walking) and its measurement with units (e.g., velocity during 10 m Walk Test in m/s). Other examples are: strength measured as peak isometric elbow extensor torque using hand-held dynamometry in Nm, or pain measured as intensity at rest on a 10 cm VAS in cm. It can be useful to divide outcome measures into those examining impairments vs activity limitations vs participation restrictions. It is only necessary to refer to manufacturers' information for equipment when the precise specifications could be important to interpretation of the study. Information should be placed in a footnote at the end of the text, coded using consecutive, superscripted lower case letters.

In the **Data analysis** section, outline any *a priori* power analysis carried out to determine the number of participants needed for the study. Outline any conversions or calculations made with the data. Explain how the research questions are answered by the interpretive tests but do not name the statistical package used if it is widely available.

Results

The first subheading should be **Flow of participants, therapists, and centres through the study** where the numbers at each point in the study are presented as well as baseline characteristics. The remainder of the results should report only the data that answer the research questions and should be organised under subheadings that reflect those questions. Pertinent results should be reported using text and/or tables and/or figures; tables are more useful than figures because exact values are given. Avoid repeating in the text data presented in tables or figures. Do not duplicate data in tables and figures.

When reporting data, be conscious of the precision of the data and only report a meaningful number of decimal places. Usually, report numbers between 0 and 1 to 2 decimal places, between 1 and 10 to 1 decimal place, and above 10 with no decimal place.

All data reported as numbers should also be given as a percentage of the sample (in brackets) rounded off, e.g., 17 (34%) participants were men. All data reported as means should also be accompanied by the standard deviation (in brackets), e.g., the mean height of participants was 1.53 m (SD 0.23).

When reporting the results of interpretive tests, report the size of the effect rather than its statistical significance, e.g., 'People with arthritis were twice as likely to sprain their ankle (OR 0.50, 95% CI 0.25 to 0.75)' or 'People after stroke walked 0.65 m/s (95% CI 0.60 to 0.70) slower than their age-matched healthy counterparts', but not 'People with asthma were significantly more breathless after exercise ($p = 0.02$)'.

Discussion

New and important findings should be emphasised but, as a rule, data already presented in the Method

and Results sections should not be repeated. Implications and limitations of the findings and their clinical application should be discussed. The length of the Discussion should be commensurate with the number of important findings; usually it will be less than 750 words. Do not include a separate conclusion at the end of the Discussion.

References

Only essential references should be cited. Most research will require fewer than 30 references. If the research requires considerably more (e.g., systematic reviews of areas with many clinical trials), references may be provided as supplementary material or eAddenda.

The referencing style used by the journal is the JAMA style, which can be found as a standard referencing style in EndNote, RefWorks, Mendeley, and Zotero. If you use reference management software such as these, please convert your paper to the JAMA style before submission. Journal titles should be abbreviated according to the journals list in PubMed (). Please ensure that all references are complete and presented using numbered style.

Tables

Tables should appear after the references and each table should start on a separate page. They should be numbered consecutively in the order to which they are referred in the text. A short caption should be given above each table (e.g., 'Table 1. Characteristics of participants.'). Within the table, give the units of outcome measures in brackets and italics, e.g., *(m/s)*. When reporting counts (frequencies), give percentages in brackets. Use abbreviations for time (i.e., *s, min, hr*, etc.) and amount (i.e., *kg, deg, Nm*, etc.) without a legend explaining them. Where abbreviations for physiotherapy-specific terms are used (e.g., ROM, MCP, etc.), provide a legend below the table. Tables should be presented with a minimum of horizontal lines and no vertical lines. Download examples of tables.

Figures

Figures should start on a separate page after the tables. They should be displayed at the proposed publication size and numbered consecutively in the order to which they are referred in the text. A short caption should be given below each figure, e.g., 'Figure 1. Mean (SD) effect of posture on forced expiratory volume for the experimental group (closed circles) and the control group (open circles)'. Do not place boxes around figures. Do not put axes on the top and right sides of graphs. Use symbols and/or line types rather than colour to differentiate data. Where several graphs refer to closely-related material, present them as separate panels of a single figure labelled A, B, C, etc., and provide one caption explaining what is in each panel. Photographs should be in sharp focus, have simple backgrounds, and be in black and white unless colour is essential to illustrate the point (e.g., MRI).

For publication, photographs should be supplied as digital images saved at a minimum of 300 dpi in .jpg format. Graphs and line drawings generated by commonly-used graphing programs (such as Microsoft Excel) are acceptable. Written permission should be obtained for use of previously published Figures and Tables, and for publication of photographs of recognisable subjects. These documents should be uploaded with the final manuscript once it has been accepted.

Boxes

When information needs to be listed but is not a table (contains numbers) or a figure (photograph, graph, or flow diagram), then it should be called a Box. Boxes should be numbered consecutively in the order to which they are referred in the text. A short caption should be given above each box (e.g., 'Box 1. Elements of a viable patient education program.') Download examples of boxesformatted to these specifications.

Style

Manuscripts should be written in simple, direct, and grammatically-correct English. Use Australian/English spelling. Use gender neutral and non-labelling language (e.g., 'People with back pain' rather than 'back pain patients'). When people are enrolled in a trial, use 'participant' rather than 'subjects'. Use capitals (upper case letters) sparingly but capitalise proper nouns. Divisions of the data set are also capitalised (e.g., 'Group 1' or 'Stage 2'). See previous issues for other specific aspects of JoP style.

Click below for the guidelines and examples available for the following types of studies:
- Systematic Review guidelines
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- Clinical Trial guidelines
- Clinical Trials examples
- Qualitative Study guidelines

• Papers reporting the results of questionnaires guidelines

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Compulsory Authorship Form

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Reviewers are asked to consult checklists where appropriate. Specifically, reviewers of randomised controlled trials are asked to consult the CONSORT e-checklist, reviewers of systematic reviews are asked to consult the PRISMA statement, and reviewers of studies of the accuracy of diagnostic tests are asked to consult the STARD checklist. These checklists can be found at http://www.consort-statement.org/resources/downloads

The Journal Editor considers the reviewers' comments and decides if the manuscript is to be accepted in its current form, accepted subject to minor revisions, potentially publishable but requiring significant revision, or not suited to publication in JoP. Authors are provided with the reviewers' comments, sometimes with additional comments made by the Scientific Editor, and are informed of the decision. Authors of manuscripts requiring revision are invited to consider and respond to the comments made by the reviewers and the Journal Editor, revise the manuscript accordingly, and re-submit. Usually the revised manuscript is returned to the original reviewers for further comment. Some manuscripts undergo several rounds of review before a final decision (accept or reject) is made.

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To be eligible for consideration the study must have received competitive research funding. Submissions will be reviewed by the Protocol Section Editor, and by members of the Journal's Editorial Board, with particular focus on the quality of the proposed methods, relevance of the study to physiotherapy, and innovation. The protocols we select for publication need to meet several high standards including that the trial will be likely to directly influence how physiotherapists practice, and/or the trial will significantly enhance understanding of conditions treated by physiotherapists.

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7.3 Parecer do CEP

UNIVERSIDADE FEDERAL DE CIÊNCIAS DA SAÚDE DE PORTO ALEGRE

PARECER CONSUBSTANCIADO DO CEP

DADOS DO PROJETO DE PESQUISA

Título da Pesquisa: Efeito de técnicas neurodinâmicas em indivíduos com dor irradiada para a perna: ensaio clínico randomizado
Pesquisador: Marcelo Faria Silva Área Temática:
Versão: 2
CAAE: 38042214.5.0000.5345
Instituição Proponente:Universidade Federal de Ciências da Saúde de Porto Alegre
Patrocinador Principal: Financiamento Próprio

DADOS DO PARECER

Número do Parecer:

940.742 Data da

Relatoria: 14/01/2015

Comentários e Considerações sobre a Pesquisa:
Nada a declarar.

Considerações sobre os Termos de apresentação obrigatória:
Todos os documentos obrigatórios foram apresentados.

Recomendações:
Nada a declara.

Conclusões ou Pendências e Lista de Inadequações:
Não há pendências

Situação do Parecer:
Aprovado

Necessita Apreciação da CONEP:

Não

Considerações Finais a critério do CEP:
Término do projeto maio/2016.