

KÊNIA KIEFER PARREIRAS DE MENEZES

**FORTALECIMENTO MUSCULAR RESPIRATÓRIO EM INDIVÍDUOS PÓS-
ACIDENTE VASCULAR ENCEFÁLICO**

Belo Horizonte

Escola de Educação Física, Fisioterapia e Terapia Ocupacional / UFMG

2017

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**FORTALECIMENTO MUSCULAR RESPIRATÓRIO EM INDIVÍDUOS PÓS-
ACIDENTE VASCULAR ENCEFÁLICO.**

Tese apresentada ao Programa de Pós Graduação em Ciências da Reabilitação da Escola de Educação Física, Fisioterapia e Terapia Ocupacional da Universidade Federal de Minas Gerais, como requisito parcial à obtenção do título de Doutor em Ciências da Reabilitação

Área: Desempenho Funcional Humano.

Linha de Pesquisa: Estudos em Reabilitação Neurológica do Adulto.

Orientadora: Luci Fuscaldi Teixeira-Salmela, Ph.D, UFMG

Co-orientador: Lucas Rodrigues Nascimento, Ph.D., UFES

Belo Horizonte

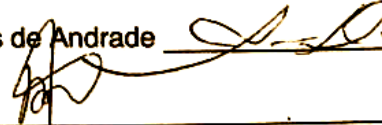
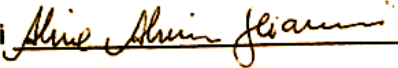
Escola de Educação Física, Fisioterapia e Terapia Ocupacional / UFMG

2017

COLEGIADO DE PÓS-GRADUAÇÃO EM CIÊNCIAS EM REABILITAÇÃO
DEPARTAMENTOS DE FISIOTERAPIA E DE TERAPIA OCUPACIONAL
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ATA DE NÚMERO 68 (SESSENTA E OITO) DA SESSÃO DE ARGUIÇÃO E DEFESA DE TESE APRESENTADA PELA CANDIDATA KÊNIA KIEFER PARREIRAS DE MENEZES DO PROGRAMA DE PÓS-GRADUAÇÃO EM CIÊNCIAS DA REABILITAÇÃO.

Aos 10 (dez) dias do mês de Novembro do ano de dois mil e dezessete, realizou-se na Escola de Educação Física, Fisioterapia e Terapia Ocupacional, a sessão pública para apresentação e defesa da Tese de Doutorado intitulada: **"FORTALECIMENTO MUSCULAR RESPIRATÓRIO EM INDIVÍDUOS PÓS-ACIDENTE VASCULAR ENCEFÁLICO"**. A comissão examinadora foi constituída pelos seguintes Professores Doutores: Luci Fuscaldi Teixeira-Salmela, Lucas Rodrigues Nascimento, Àrmele de Fátima Dornelas de Andrade, Henrique Silveira Costa, Raquel Rodrigues Britto, e Aline Alvim Scianni, sob a Presidência da primeira. Os trabalhos iniciaram-se às 09h30min com apresentação oral da candidata, seguida de arguição dos membros da Comissão Examinadora. Após avaliação, os examinadores consideraram a candidata **aprovada e apta a receber o título de Doutora após a entrega da versão definitiva da Tese**. Nada mais havendo a tratar, eu, Marilane Soares, secretária do Colegiado de Pós-Graduação em Ciências da Reabilitação dos Departamentos de Fisioterapia e de Terapia Ocupacional da Escola de Educação Física, Fisioterapia e Terapia Ocupacional, lavrei a presente Ata, que depois de lida e aprovada será assinada por mim e pelos membros da Comissão Examinadora. Belo Horizonte, 10 de Novembro de 2017.

Professora Dra. Luci Fuscaldi Teixeira-Salmela 
Professora Dra. Àrmele de Fátima Dornelas de Andrade 
Professor. Dr. Henrique Silveira Costa 
Professora Dra. Raquel Rodrigues Britto 
Professora. Dra. Aline Alvim Scianni 

Marilane Soares – SIAPE: 084190

Secretária do Colegiado de Pós-Graduação em Ciências da Reabilitação

UNIVERSIDADE FEDERAL DE MINAS GERAIS
COLEGIADO DE PÓS-GRADUAÇÃO EM CIÊNCIAS
DE REABILITAÇÃO / EEFFT
AV. ANTÔNIO CARLOS, Nº 6627 - CAMPUS UNIVERSITÁRIO
PAMPULHA - CEP 31270-901 - BH / MG

***Dedico este trabalho à Deus, à minha orientadora,
à minha família, marido e amigos.***

AGRADECIMENTOS

“Não há no mundo exagero mais belo que a gratidão”. Assim, resumir em palavras meus agradecimentos a todos que, direta ou indiretamente, me apoiaram nesta caminhada, é uma tarefa feliz, árdua, mas injusta. Primeiro, porque não me permitiriam escrever uma tese, em que apenas esta sessão ultrapassasse as 100 páginas. Além disso, certamente, também não obrigaria a todos ler tamanha declaração. Assim, tentarei, de forma breve e objetiva, agradecer nos próximos parágrafos, individual ou coletivamente, a todos que defendem comigo a presente tese.

Sempre, em primeiro lugar, meus agradecimentos Àquele que guia meus caminhos, ampara meus passos, e pega na minha mão quando peço, ou me carrega em Teu colo quando é necessário. Senhor, sem mim, Tu é Deus; sem Ti, nada sou. Obrigada meu Pai, pois se Tu sempre me dizes que meus problemas também são Teus, também digo que minhas alegrias e conquistas também são Tuas. Obrigada por não me abandonar, estando sempre comigo, por me fortalecer a cada obstáculo, por me dar problemas para que eu crescesse e amadurecesse, e por me capacitar para resolvê-los e superá-los.

Meus agradecimentos à minha orientadora, que acompanha meus passos há 10 anos. Luci, obrigada por acreditar naquela monitora que adorava cinesiologia e amava dar aula... que “sumiu” por alguns semestres e voltou, encontrando as portas abertas... que começou na iniciação científica já no último ano de faculdade e decidiu mudar o trabalho de conclusão de curso no último semestre, porque fazer este trabalho com você parecia ser o mais certo... que decidiu fazer mestrado e que você, gentilmente, deu o tempo necessário para estudar e se preparar... que decidiu ainda entrar para o doutorado, e que não encontrou nada além de apoio e estímulo. O que dizer para a senhora, que acreditou em mim quando, por vezes, sinceramente, nem eu acreditava? O que dizer para a senhora que representa tudo para mim, e que terá eternamente minha admiração, carinho, respeito, amizade e amor? O que dizer para a senhora, professora? Sinto que um singelo “Obrigada” não é

suficiente para traduzir em palavras a imensidão da gratidão que trago dentro de mim. No entanto, por desconhecer outra mais apropriada: Obrigada! Obrigada por me apoiar, me encorajar, me ensinar, me estimular, me orientar! Obrigada por me ajudar a crescer, me ajudar a alcançar o sonho da docência, e por me ajudar a trilhar caminhos que pareciam muito distantes para mim. Luci, obrigada por existir na minha vida, e por ter feito toda a diferença nela!

Meus agradecimentos sinceros ao meu co-orientador! Lucas, obrigada pela disponibilidade de sempre, nas infinitas reuniões e discussões, nos e-mails cercados de dúvidas, no whatsapp, com minhas frequentes perguntas e meus áudios com uma média geralmente superior a dois minutos (alguns ultrapassaram muito esta média), que não tinham hora para serem enviados, e que sempre foram prontamente respondidos. Obrigada pelos ensinamentos, pela ajuda, pela parceria e pelo otimismo e animação de sempre. Durante os últimos três anos (exceto períodos de férias), acredito que não tenhamos passado sequer 10 dias sem trocar um email ou mensagem (não só de trabalhos relacionados ao doutorado, como também do LEMOCOT, do ABILOCO... ☺). Isso representa o quanto você “abraçou” meus trabalhos, e consequentemente, me “abraçou”. Muito obrigada.

Agradeço também à minha co-co-orientadora (acabei de inventar)! Jana, você que foi idealizadora deste projeto, me ajudou em toda a sua estruturação e no desenvolvimento de parte das produções, muito obrigada! Obrigada pela generosidade, por me dar de presente e me ajudar nesta ideia, que se tornou minha vida nos últimos anos. Obrigada não só pela ajuda acadêmica, mas por se preocupar com minha formação, por me dar conselhos que nunca esquecerei, e que, se estou aqui, hoje, foi porque tentei seguir boa parte deles.

Minha gratidão à toda a família Teixeira-Salmela, agora NeuroGroup. Trabalhar nesta equipe é uma realização. A todos vocês, professores, colegas de pós-graduação e alunos de iniciação científica, “muito obrigada”! Em especial à elas, que tomaram para elas a responsabilidade das coletas e, que, de forma comprometida, me ajudaram durante mais de um ano de coleta: Maria

Tereza, Isabella, Ruani e Gabriela. Maria, minha bolsista, você foi além do que uma aluna de iniciação precisava ser, e isso reflete a mulher responsável, capaz e brilhante que você é! Gabi, Ruani e Isabella, alunas que conheci em uma aula de cinesiologia e que, voluntariamente, se ofereceram para me ajudar nas coletas. Deus coloca anjos em nossas vidas, em encontros ocasionais, que nos ajudam a travar grandes batalhas! Obrigada meus anjos pela generosidade e disponibilidade de todas, este trabalho também é de vocês. Agradeço também às alunas Bruna e Lorena, pela ajuda em parte das coletas.

Meus agradecimentos à professora Louise Ada, por toda a ajuda, ensinamentos, reuniões presenciais e virtuais. Obrigada pelo carinho, atenção e disponibilidade que renderam frutos grandiosos. À professora Verônica, à Mariana Horffman, ao Hugo e a todas as bolsistas do Labcare que sempre me ajudaram em minhas infinitas dúvidas, ao “entrar no mundo respiratório”.

Agradeço agora à minha família. Pai, o senhor que sempre incentivou meus estudos, se emocionou com minhas vitórias, nunca mediu esforços para que eu alcançasse meus objetivos, e que é exemplo de garra, honestidade, trabalho e dedicação: OBRIGADA! Obrigada por ser meu alicerce, e por acreditar, antes mesmo da vitória, que eu chegaria lá! Sister, nossa cumplicidade e parceria refletem perfeitamente nosso relacionamento. Obrigada por ser minha metade mais calma, compreensiva, sensível e amorosa. Obrigada por me aguentar, aturar, até mesmo me suportar. Obrigada por estar ao meu lado sempre, por acreditar no meu potencial, por chorar comigo minhas lágrimas e sorrir comigo nos momentos de alegria. Patrick, amor, que divide comigo a casa, a vida, e a profissão: muito obrigada! A você, que nos últimos três anos descobriu a árdua tarefa de morar comigo, e mesmo assim repete todos os dias que quer isso para o resto da vida, mesmo nesta reta final, quando os surtos de estresse eram recorrentes: OBRIGADA. Você é o homem que eu escolhi e Deus abençoou esta escolha. Casados e ambos no doutorado, caminhando lado a lado, podemos dizer que, ao final, conquistaremos dois títulos (risadas). Obrigada por me ajudar a conquistar o primeiro, pois daqui dois anos estaremos, juntos, comemorando o segundo.

Aos demais familiares, obrigada a todos pela presença e apoio, em especial à minha sogra, minhas madrinhas e meu irmão Henrique.

Agradeço também aos meus amigos, presentes que a vida me deu gratuitamente. Em especial aos amigos da Pastoral da Crisma/Igreja. A fé nos ajuda a caminhar, mas amigos pela fé caminham conosco. Obrigada família, por tornarem mais leves todos os fardos que me ajudaram a carregar. Aos meus amigos da FUNCESI (Thaianne, Susan e Henrique), que dividiram comigo o processo do doutorado (vivido por todos) e o sonho da docência. Vocês fazem parte de um dos maiores sonhos da minha vida, e dividir essa realização com vocês, foi o maior e melhor presente de Deus. Amizades verdadeiras não são somente as mais antigas, mas as que realmente fazem a diferença, como vocês fizeram em minha vida. Agradeço também ao amigo de sempre Fred, que compartilha comigo cada momento, mas principalmente me ampara e me conforta nos momentos de turbulência. Obrigada por ser este parceiro incrível, que tem o dom de sempre me fazer sorrir.

Um agradecimento especial ainda àquela que foi um anjo na terra, uma das flores mais belas do meu jardim, que Deus colheu para enfeitar o céu. Mãe, falo de você e as lágrimas são inevitáveis. Conversamos frequentemente, e a senhora sabe o quanto lhe sou grata por ter sido a melhor mãe e amiga que eu poderia ter tido. Você, com esse olhar sereno e sorriso doce, sempre acalmou meu coração, e mesmo de longe, sei que olha e cuida de mim. Obrigada pelo maior exemplo de solidariedade e fé que tive na vida, por ter me dado a honra de ser sua filha, e por ter me proporcionado 24 anos ao seu lado. Sei que se estivesse aqui, estaria com aquele largo e lindo sorriso estampado no rosto, os olhos azuis brilhando, e me daria aquele abraço e beijo que, espero ansiosamente, um dia receber de novo. “Quando, no céu, eu te encontrar, com lágrimas de amor, eu vou te regar, minha mãe, minha flor”.

Por fim, obrigada a todos os pacientes e seus acompanhantes pela gentileza e disponibilidades; aos funcionários, e a todos, que direta ou indiretamente, me ajudaram nessa caminhada. Obrigada a todos vocês!

**“A sabedoria é o melhor guia,
e a fé, a melhor companhia.”**

(Sakyamuni)

PREFÁCIO

A presente tese foi elaborada, conforme as normas do Colegiado do Programa de Pós-Graduação em Ciências da Reabilitação da Universidade Federal de Minas Gerais (UFMG). Este trabalho foi desenvolvido como requisito parcial à obtenção do título de Doutor em Ciências da Reabilitação. O programa de doutorado do Programa de Pós Graduação requer como obrigações o cumprimento de, no mínimo, 36 créditos acadêmicos, além da elaboração e desenvolvimento de uma tese, a produção de artigos científicos e a defesa oral da tese.

Dessa forma, a fim de atender os critérios exigidos pelo programa, o desenvolvimento da presente tese compreendeu duas fases distintas. A primeira, realizada durante os anos de 2014 e 2015, compreendeu o cumprimento dos créditos exigidos pelo programa (as disciplinas realizadas estão descritas no Anexo I), além da elaboração do projeto de pesquisa, submissão do trabalho ao Comitê de Ética e Pesquisa, aquisição de materiais e atualização bibliográfica. Já a segunda fase, realizada nos dois anos restantes, compreendeu a produção e publicação de artigos científicos relacionados ao tema, coleta de dados, processamento e elaboração da tese.

Para facilitar a compreensão dos achados da presente tese, esta foi estruturada a partir das normas do Programa de Pós Graduação em Ciências da Reabilitação da UFMG, sendo dividida em **oito** capítulos, conforme a descrição abaixo:

- **Capítulo 1:** Introdução, abrangendo a problematização das deficiências respiratórias após um Acidente Vascular Encefálico (AVE), os sintomas associados, o impacto na execução de atividades e participação social destes indivíduos, além de possíveis intervenções eficazes para esta condição. Este capítulo também compreende a justificativa, bem como os objetivos de cada um dos estudos. Além do ensaio clínico aleatorizado, que é o produto principal desta tese, outros cinco artigos científicos

foram elaborados, como complementação intelecto-científico em relação ao tema da tese. Por compreenderem objetivos e metodologias distintos, os seis estudos apresentados na presente tese podem ser lidos separadamente.

- **Capítulo 2:** Refere-se a uma revisão sistemática da literatura com metanálise, que objetivou descrever e comparar os efeitos de diferentes tipos de intervenções para melhora da função respiratória em indivíduos pós AVE.
 - Estudo 1 – MENEZES KKP, NASCIMENTO LR, AVELINO PR, ALVARENGA MTM, TEIXEIRA-SALMELA LF. Efficacy of interventions at improving respiratory function after stroke: A systematic review. Submetido à revista *Respiratory Care*. (ANEXO II).
- **Capítulo 3:** Refere-se a uma revisão sistemática da literatura com metanálise, que investigou os efeitos do treino muscular respiratório em indivíduos pós AVE.
 - Estudo 2 - MENEZES KKP, NASCIMENTO LR, ADA L, POLESE JC, AVELINO PR, TEIXEIRA-SALMELA LF. Respiratory muscle training increases respiratory muscle strength and reduces respiratory complications after stroke: a systematic review. *Journal of Physiotherapy*, 62:138-144, 2016.
- **Capítulo 4:** Refere-se a uma revisão da literatura, que objetivou descrever todos os tipos de dispositivos disponíveis no mercado utilizados para treinamento da musculatura respiratória.
 - Estudo 3 - MENEZES KKP, NASCIMENTO LR, AVELINO PR, POLESE JC, TEIXEIRA-SALMELA LF. A review on respiratory muscle training devices. Submetido à revista *The Clinical Respiratory Journal* (ANEXO III).

- **Capítulo 5:** Refere-se a um estudo observacional transversal, que objetivou investigar a prevalência e severidade da dispneia em indivíduos pós AVE.
 - Estudo 4 – MENEZES KKP, NASCIMENTO LR, ALVARENGA MTM, AVELINO PR, TEIXEIRA-SALMELA LF. Prevalence of dyspnea after a stroke: A telephone-based survey. Submetido à Revista *Topics in Stroke Rehabilitation* (ANEXO IV).

- **Capítulo 6:** Refere-se aos métodos do estudo principal desta tese, um ensaio clínico aleatorizado, que investigou os efeitos de um programa domiciliar de fortalecimento da musculatura respiratória de alta intensidade em indivíduos pós AVE. Dessa forma, este capítulo é dividido em duas partes, sendo a primeira, o método detalhado e resultados iniciais; e a segunda, o protocolo do estudo, publicado no *Brazilian Journal of Physical Therapy*.
 - Estudo 5 - MENEZES KKP, NASCIMENTO LR, POLESE JC, ADA L, TEIXEIRA-SALMELA LF. Effect of high-intensity home-based respiratory muscle training on strength of respiratory muscles following a stroke: a protocol for a randomized controlled trial. *Brazilian Journal of Physical Therapy*, 21(5):372-377, 2017.

- **Capítulo 7:** Refere-se ao artigo completo do ensaio clínico aleatorizado, a ser submetido à revista *Journal of Physiotherapy*.
 - Estudo 6 - MENEZES KKP, NASCIMENTO LR, AVELINO PR, ALVARENGA MTM, ADA L, POLESE JC, BARBOSA MH, TEIXEIRA-SALMELA LF. High-intensity home-based respiratory muscle training increases strength and endurance of respiratory muscles and reduces dyspnea after stroke: a randomized controlled trial. A ser submetido ao *Journal of Physiotherapy*.

- **Capítulo 8:** Refere-se às considerações finais.

As referências bibliográficas utilizadas, as quais estão de acordo com as normas da Associação Brasileira de Normas Técnicas (ABNT NBR 14724:2005), estão incluídas ao final da tese, juntamente com os anexos e apêndices utilizados/desenvolvidos.

Ressalta-se ainda que, durante os dois primeiros anos do doutorado (2014-2015), foram produzidos outros oito artigos científicos, relacionados abaixo, referentes aos dados da dissertação de mestrado (2012-2013).

- *Original article:* MENEZES KKP, SCIANNI AA, FARIA-FORTINI I, AVELINO PR, FARIA CDCM, TEIXEIRA-SALMELA LF. Measurement properties of the lower extremity motor coordination test in individuals with stroke. *Journal of Rehabilitation Medicine*, 47: 502-7, 2015.
- *Original article:* MENEZES KKP, SCIANNI AA, FARIA-FORTINI I, AVELINO PR, CARVALHO AC, FARIA CDCM, TEIXEIRA-SALMELA LF. Potential predictors of lower extremity impairments in motor coordination of stroke survivors. *European Journal of Physical and Rehabilitation Medicine*, 51:1-24, 2015.
- *Short communication:* MENEZES KKP, SCIANNI AA, FARIA-FORTINI I, AVELINO PR, FARIA CDCM, TEIXEIRA-SALMELA LF. Lower limb motor coordination of stroke survivors, based upon their levels of motor recovery and ages. *Journal of Neurology & Neurophysiology*, 6(6):1-2, 2015.
- *Short communication:* MENEZES KKP, SCIANNI AA, FARIA-FORTINI I, AVELINO PR, FARIA CDCM, TEIXEIRA-SALMELA LF. Motor recovery, tonus of the plantar flexor muscles, and age are predictors of the lower limb motor coordination in stroke survivors. *Journal of Yoga & Physical Therapy*, 5(3):1-2, 2015.

- *Original article:* MENEZES KKP, Avelino PR, SCIANNI AA, FARIA-FORTINI I, FARIA CDCM, NASCIMENTO LR, TEIXEIRA-SALMELA LF. Learning effects of the Lower Extremity Motor Coordination Test in individuals with stroke. *Physical Medicine and Rehabilitation - International*, 4(1)>1111, 2017.
- *Original article:* MENEZES KKP, NASCIMENTO LR, PINHEIRO MB, SCIANNI AA, FARIA CDCM, AVELINO PR, FARIA-FORTINI I, TEIXEIRA-SALMELA LF. Lower-limb motor coordination is significantly impaired in ambulatory people with chronic stroke: A cross-sectional study. *Journal of Rehabilitation Medicine*, 49:322-6, 2017.
- *Original article:* MENEZES KKP, FARIA CDCM, SCIANNI AA, AVELINO PR, FARIA-FORTINI I, TEIXEIRA-SALMELA LF. Previous lower limb dominance does not affect measures of impairment and activity after stroke. *European Journal of Physical and Rehabilitation Medicine*, 53:24-31, 2017.
- *Original article:* MENEZES KKP, NASCIMENTO LR, FARIA CDCM, AVELINO PR, SCIANNI AA, POLESE JC, FARIA-FORTINI I, TEIXEIRA-SALMELA LF. Deficits in motor coordination of the paretic lower limb best explained activity limitations after stroke. Submetido à revista *American Journal of Physical Medicine and Rehabilitation*.

Além destes trabalhos supracitados (6 do doutorado e 8 do mestrado), foram desenvolvidas outras seis produções (três publicadas, uma aceita e duas submetidas) e participação em outras 10 (seis publicadas, uma aceita e três submetidas) durante os quatro anos de doutorado, totalizando a produção/desenvolvimento de 30 artigos (20 produções e 10 co-autorias). Por fim, destaca-se ainda como atividades neste período:

- Formação complementar: 2

- Aulas ministradas como professora convidada na graduação – UFMG: 4
- Atuação como representante discente no colegiado de Pós-graduação: 2014-2015
- Aula ministrada como professora convidada na Pós-graduação – UFMG: 1
- Aprovação e exercício no cargo de professora adjunta na Fundação Comunitária de Ensino Superior de Itabira, desde março de 2016 (12–18 horas) – Disciplinas: Cinesiologia, Próteses e Órteses, Cinesioterapia, Recursos Terapêuticos Manuais, Trabalho de Conclusão de Curso I, Estágio supervisionado II – Neurologia adulto, Estágio supervisionado III – Neuropediatria.
- Participação como membro do Núcleo de Ensino (NDE) do curso de Fisioterapia da Fundação Comunitária de Ensino Superior de Itabira: Agosto/2016 – Fevereiro/2017
- Premiação nos seguintes trabalhos:
 - Relevância acadêmica - Trabalho apresentado na XXV Semana de Iniciação Científica (2016): CORRELAÇÃO ENTRE MEDIDAS DE FORÇA DA MUSCULATURA MUSCULAR RESPIRATÓRIA, ENDURANCE, DISPNEIA E CAPACIDADE FUNCIONAL EM INDIVÍDUOS HEMIPARÉTICOS. Universidade Federal de Minas Gerais.
(Trabalho referente à tese de doutorado)
 - Relevância acadêmica - Trabalho apresentado na XXV Semana de Iniciação Científica (2016): INCIDÊNCIA DE DISPNEIA EM INDIVÍDUOS PÓS ACIDENTE VASCULAR

ENCEFÁLICO. Universidade Federal de Minas Gerais.
(Trabalho referente à tese de doutorado)

- Relevância acadêmica - Trabalho apresentado na XXIII Semana de Iniciação Científica (2014): PROPRIEDADES PSICOMÉTRICAS DO LOWER EXTREMITY MOTOR COORDINATION TEST EM INDIVÍDUOS PÓS-AVE. Universidade Federal de Minas Gerais.
 - Menção Honrosa - Trabalho apresentado na XXIII Semana de Iniciação Científica (2014): PROPRIEDADES PSICOMÉTRICAS DO LOWER EXTREMITY MOTOR COORDINATION TEST EM INDIVÍDUOS PÓS-AVE. UFMG.
- Publicações de resumos em anais de congressos: 50
 - Apresentação de trabalhos: 15
 - Apresentação de palestra na MOSTRA DE PROFISSÕES DA UFMG – 2016
 - Participação de mesas redondas/mini-cursos ministrados: 4
 - Participação em bancas de trabalhos de conclusão de curso – Graduação: 3
 - Participação em bancas de trabalhos de conclusão de curso – Especialização: 23
 - Participação em bancas de avaliação de trabalhos em outros eventos: 3
 - Participação em eventos: 12
 - Organização de eventos: 1
 - Orientação – Graduação: 4 (2 em andamento e 2 concluídas)

- Orientação – Especialização: 8 (5 em andamento e 3 concluídas)

Por fim, outros dois estudos, secundários à presente tese, estão sendo desenvolvidos como trabalho de conclusão de curso de uma das alunas de iniciação científica que auxiliou nas coletas de dados da presente tese:

- Functional capacity and quality of life of neurological conditions associated with respiratory muscle strength: a systematic review.
- Correlação entre fraqueza muscular respiratória e medidas de dispneia, capacidade funcional e qualidade de vida em indivíduos pós Acidente Vascular Encefálico (**Trabalho premiado como “Relevância Acadêmica” na XXV Semana de Iniciação Científica da Universidade Federal de Minas Gerais**).

Ao final da tese, encontra-se o minicurrículo da doutoranda, com todas as atividades e produções desenvolvidas somente durante o período do doutorado (2014-2017).

RESUMO

Dentre as várias deficiências apresentadas por indivíduos hemiparéticos, a perda de força é o contribuinte mais importante. Esta fraqueza afeta, inclusive, a musculatura respiratória destes indivíduos, podendo gerar sintomas como dispneia até mesmo durante atividades leves. Assim, seis estudos foram desenvolvidos em relação à fraqueza e treinamento da musculatura respiratória em hemiparéticos. O primeiro estudo, uma revisão sistemática, objetivou descrever e comparar diferentes tipos de intervenções reportados na literatura para melhora da função respiratória em indivíduos pós AVE. Foram encontrados 17 estudos, com escore médio na escala PEDro de 5,7 (4 a 8), envolvendo 616 participantes. Os resultados da metanálise evidenciaram que o treinamento muscular respiratório melhorou significativamente todas as medidas de desfecho investigadas: P_{Imáx} (MD: 11 cmH₂O; IC 95%: 7 a 15; I²=0%), P_{Emáx} (8 cmH₂O; IC 95%: 2 a 15; I²=65%), CVF (0,25 L; IC 95%: 0,12 a 0,37; I²=29%), VEF₁ (0,24 L; IC 95%: 0,17 a 0,30; I²=0%), PFE (0,51 L/s ; IC 95% 0,10 a 0,92; I²=0%), dispneia (SMD -1,6 pontos; IC 95% -2,2 a -0,9; I²=0%) e atividade (SMD 0,78; IC 95%: 0,22 a 1,35; I²=0%). Os resultados da metanálise não demonstraram efeitos significativos dos exercícios respiratórios sobre a função pulmonar. Para as intervenções remanescentes, ou seja, exercícios aeróbicos e posturais, e a adição de estimulação elétrica, não foram realizadas metanálises por falta de dados e/ou estudos. O segundo estudo, novamente uma revisão sistemática, objetivou investigar somente os efeitos específicos do treino muscular respiratório em indivíduos pós AVE. Foram incluídos cinco ensaios clínicos envolvendo 224 participantes. O escore médio na escala PEDro foi de 6,4 (3 a 8), representando qualidade metodológica moderada. O treinamento muscular respiratório aumentou a força dos músculos inspiratórios em 7 cmH₂O (95% IC 1 a 14) e dos músculos expiratórios em 13 cmH₂O (IC 95% 1 a 25), além de diminuir o risco de complicações respiratórias (RR 0,38; IC 95%: 0,15 a 0,96), quando comparado com nenhuma intervenção ou intervenção placebo. Os efeitos para atividade e participação permanecem incertos. O terceiro estudo objetivou descrever os mecanismos e características de todos os dispositivos de treinamento dos músculos respiratórios, atualmente disponíveis no mercado, e discutir seus méritos e limitações, através de uma revisão narrativa. Dentre os 11 dispositivos descritos, todos apresentaram aspectos positivos e limitações, que devem ser considerados pelos profissionais, baseando-se também nos aspectos clínicos do paciente. O quarto estudo objetivou investigar a prevalência e a gravidade da dispneia em indivíduos pós AVE, e sua associação com possíveis limitações nas atividades e restrições na participação social desta população. A pesquisa, composta por 23 questões desenvolvidas pelos autores, incluiu perguntas específicas sobre a presença e severidade da dispneia, usando a escala *Medical Reserch Council*, e se este sintoma limitava a execução de atividades e/ou a participação social. Dentre os 285 indivíduos entrevistados, a prevalência da dispneia foi de 44%. Destes, 62 participantes (51%) relataram dispneia severa. Além disso, 105 participantes (85%) informaram que a dispneia limitava suas atividades e 51 (49%) que

restringia a participação social. A dispneia foi significativamente correlacionada com as limitações de atividade ($r=0,87$; IC 95%: 0,82 a 0,92; $p<0,01$) e com restrições de participação ($r=0,53$; IC 95%: 0,46 a 0,62; $p<0,01$). Além disso, as análises indicaram que indivíduos com dispneia são mais propensos a relatar limitações em atividades (RR: 6,5; IC 95%: 4,3 a 9,9) e restrições em participação social (RR: 1,7; IC 95%: 1,5 a 2,0). Por fim, o ensaio clínico objetivou investigar os efeitos de um programa domiciliar de fortalecimento da musculatura respiratória de alta intensidade em indivíduos pós AVE. A amostra foi composta de 38 indivíduos pós AVE, dividida em grupo experimental (intervenção) e grupo controle (placebo). O grupo experimental realizou um programa domiciliar de treinamento dos músculos respiratórios durante 40 minutos, sete vezes por semana, durante oito semanas. Em comparação com o controle, o grupo experimental apresentou aumento da força inspiratória (27 cmH₂O; 95% IC 15 a 39) e expiratória (42 cmH₂O; IC 95%: 25 a 59), resistência inspiratória (34 respirações, IC 95%: 21 a 47) e redução da dispneia (-1,3 fora de 5,0; IC 95% -2,1 a -0,5). Além disso, tais benefícios foram mantidos um mês após o término do treinamento. Não houve diferença significativa entre os grupos para a capacidade de marcha e complicações respiratórias.

Palavras chave: Acidente vascular encefálico. Fraqueza muscular respiratória. Dispneia. Intervenções. Treino muscular respiratório. Revisão sistemática. Ensaio clínico aleatorizado.

ABSTRACT

Amongst the several impairments presented by individuals with stroke, loss of strength is the main important contributor. This weakness also affects the respiratory muscles, which can lead to symptoms, such as dyspnea even during mild activities. Thus, six studies were carried-out regarding weakness and training of the respiratory muscles. The aim of the first study was to systematically review all current interventions, which have been employed to improve respiratory function and activity performance after stroke. The 17 included trials had a mean PEDro score of 5.7 (range: 4 to 8) and involved 616 participants. Meta-analyses showed that respiratory muscle training significantly improved all outcomes of interest, as follows: MIP (MD:11cmH₂O; 95%CI 7 to 15; I²=0%), MEP (8cmH₂O; 95%CI 2 to 15; I²=65%), FVC (0.25 L; 95%CI 0.12 to 0.37; I²=29%), FEV¹ (0.24 L; 95%CI 0.17 to 0.30, I²=0%), PEF (0.51 L/s; 95%CI 0.10 to 0.92; I²=0%), dyspnea (SMD -1.6 points; 95%CI -2.2 to -0.9; I²=0%), and activity (SMD 0.78; 95%CI 0.22 to 1.35; I²=0%). Meta-analyses found no significant results for the effects of breathing exercises on lung function. For the remaining interventions, i.e., aerobic and postural exercises, and addition of electrical stimulation, meta-analyses could not be performed. The second study aimed to investigate, by a systematic review, the effects of respiratory muscle training after stroke. Five trials involving 224 participants were included. The mean PEDro score was 6.4 (range 3 to 8), showing moderate methodological quality. Random-effects meta-analyses showed that respiratory muscle training increased strength of the inspiratory muscles by 7 cmH₂O (95% CI 1 to 14) and of the expiratory muscles by 13 cmH₂O (95% CI 1 to 25) and decreased the risk of respiratory complications (RR 0.38, 95% CI 0.15 to 0.96), compared with no/sham respiratory intervention. Carry-over effects to activity and participation remain uncertain. The purpose of the third study was to describe the mechanisms and characteristics of all available respiratory muscle training devices, and discuss their merits and limitations. Amongst the 11 evaluated devices, all of them showed positive aspects and limitations, that should be considered, also based on the specific health condition, the nature of the impairments, the purpose of the training for each patient. The aim of the forth study was to investigate the prevalence and severity of dyspnea after stroke, as well the associations between dyspnea, activity limitations, and participation restrictions. A 23-question telephone-based survey was developed by the research team. The survey included information about the onset of dyspnea, severity of dyspnea, activity limitations and participation restrictions. The prevalence of dyspnea was 44% and severe symptoms were reported by 51% of the participants. In addition, dyspnea limited activity and restricted social participation in 85% and 49%, respectively. Dyspnea was significantly correlated with activity limitations ($r=0.87$; 95% CI 0.82 to 0.92; $p<0.01$) and participation restrictions ($r=0.53$; 95% CI 0.46 to 0.62; $p<0.01$). The analyses indicated that individuals, who had dyspnea, were more likely to report that it limited their activities (RR: 6.5; 95% CI 4.3 to 9.9) and restricted social participation (RR: 1.7; 95% CI 1.5 to 2.0). Finally, the randomized controlled clinical trial, aimed at investigating the effects of a high-

intensity home-based strengthening of the respiratory muscles after stroke, was carried-out. This was a two-arm, prospectively registered, randomized trial, with blinded measurers, which included 38 individuals with respiratory muscle weakness, following stroke. The intervention was high-intensity home-based respiratory muscle training. The experimental group received 40-min home-based respiratory muscle training, seven days/week, over eight weeks, while the control group received sham respiratory muscle training. Compared to the controls, the experimental group showed increased inspiratory (27 cmH₂O; 95% CI 15 to 39) and expiratory (42 cmH₂O; 95% CI 25 to 59) strength, inspiratory endurance (34 breathes; 95% CI 21 to 47) and reduced dyspnea (-1.3 out of 5.0; 95% CI -2.1 to -0.5) and the benefits were maintained at one month beyond training. There was no significant between-group difference for walking capacity and occurrence of respiratory complication.

Keywords: Stroke. Respiratory muscle weakness. Dyspnea. Intervention. Respiratory muscle training. Systematic review. Randomized clinical trial.

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Capítulo 1

INTRODUÇÃO

O Acidente Vascular Encefálico (AVE) é definido pela Organização Mundial de Saúde como uma síndrome clínica, de desenvolvimento rápido de sinais de distúrbios focais ou globais da função cerebral, de origem vascular, com sintomas que perduram por um período superior a 24 horas (SUDLOW; WARLOW, 1996). O AVE é uma das maiores causas de morte e incapacidade no mundo (KELLY-HAYES *et al.*, 1998). Embora sua incidência esteja diminuindo em muitos países desenvolvidos, o número absoluto está aumentando, devido ao envelhecimento da população (KELLY-HAYES *et al.*, 1998). Além disso, com o declínio da mortalidade por doenças cardiovasculares, como o AVE, um maior número de indivíduos enfrenta as sequelas decorrentes da lesão (UEMURA; PISA, 1998). Estudos indicaram que mais de 30 milhões de pessoas no mundo sobreviveram a um episódio de AVE (NORRVING; KISSELA, 2011). No Brasil, desde 1996, o AVE vem se constituindo a principal causa de internações, mortalidade e deficiências, acometendo principalmente a faixa etária acima de 50 anos (SOCIEDADE BRASILEIRA DE DOENÇAS CEREBROVASCULARES, 2001; PERLINI; FARO, 2005; BOCCHI; ANGELO, 2005). Apesar de a partir dos 60 anos de idade haver um aumento significativo na incidência do AVE, a ocorrência em adultos jovens, a partir dos 20 anos, também está aumentando devido, principalmente, a mudanças no estilo de vida (FALCÃO *et al.*, 2004; RABELO; NÉRI, 2006).

Após um AVE, geralmente o indivíduo apresenta fraqueza ou paralisia em um lado do corpo, denominada hemiparesia ou hemiplegia, contralateral à lesão encefálica (CARR; SHEPHERD, 2008) em aproximadamente 80% dos sobreviventes (LEBRAUSSER *et al.*, 2006). Esta condição pode gerar alterações na funcionalidade do indivíduo e interferir na realização de suas atividades de vida diária (CUNHA *et al.*, 2002). Além disso, é a causa mais importante de incapacidade grave em pessoas vivendo em suas próprias casas (CARR; SHEPHERD, 2008). Cerca de 30 a 40% dos sobreviventes são incapazes de retornar ao trabalho, requerendo algum tipo de auxílio no desempenho de atividades cotidianas básicas (PEREIRA *et al.*, 1993).

Neste contexto, a Classificação Internacional de Funcionalidade, Incapacidade e Saúde (CIF) tem sido recomendada como uma forma de estabelecer um consenso para o cuidado e manejo de indivíduos com doenças crônicas, como o AVE (OMS, 2003; SAMPAIO *et al.*, 2005). A CIF é um modelo que enfoca não apenas a condição de saúde, mas os diferentes domínios de funcionalidade e suas relações que norteiam contemporaneamente os modos de pensar e agir no processo de reabilitação (OMS, 2003). Todo indivíduo pode ser exposto a uma perda ou diminuição na sua saúde e/ou funcionalidade e, desta forma, experimentar alguma incapacidade (OMS, 2003). Assim, a estrutura conceitual desta classificação apresenta um modelo de funcionalidade e incapacidade, dividida em duas partes, cada uma com dois componentes (OMS, 2003; SAMPAIO; LUZ, 2009). Os componentes da primeira parte, denominada Funcionalidade e Incapacidade, incluem Funções e Estruturas do Corpo e Atividades e Participação; os dois componentes da segunda parte, que correspondem aos Fatores Contextuais, são Fatores Ambientais e Fatores Pessoais (OMS, 2003). Assim, funcionalidade é o termo genérico para referir a funções e estruturas do corpo, atividades e participação e indica os aspectos positivos e neutros da interação entre um indivíduo (com uma condição de saúde) e seus fatores contextuais. Por outro lado, incapacidade é o aspecto negativo dessa interação, sendo o termo genérico para deficiências nas funções e estruturas do corpo, limitações de atividade e restrições de participação social (OMS, 2003).

Assim, de acordo com o modelo da CIF, deficiências nas estruturas e funções do corpo, tais como hemiparesia, alterações do tônus muscular e afasia são as desordens neurológicas primárias que são causadas pelo AVE (OMS, 2003). Limitações em atividades são manifestadas pela redução da habilidade de realizar funções diárias, tais como tomar banho, vestir-se ou caminhar, por exemplo (OMS, 2003). Por fim, restrições na participação social são problemas estes indivíduos podem ter ao se envolver em situações de vida diária em comunidade (OMS, 2003).

Dentre as várias deficiências apresentadas por indivíduos pós-AVE, uma das mais prevalentes é a motora, sendo apontada como uma das mais incapacitantes (KELLY-HAYES *et al.*, 1998). No entanto, embora existam várias possibilidades de sequelas motoras, a perda de força é o fator mais importante, contribuindo significativamente para a presença de limitações em atividades durante os primeiros seis meses após AVE (CANNING *et al.*, 2004). Esta fraqueza pode afetar todos os músculos do corpo humano, inclusive a musculatura respiratória (TEIXEIRA-SALMELA *et al.*, 2005). No entanto, uma vez que os sintomas associados à esta fraqueza específica geralmente não estão associados às queixas mais comumente relatadas pelos pacientes, pouca atenção é dispensada a esta musculatura (SIMIŁOWSKI *et al.*, 1996), gerando uma carência de informações científicas na literatura.

A força adequada da musculatura respiratória é fundamental para o corpo humano (MCCONNELL, 2013). Disfunções na função respiratória, como redução da capacidade pulmonar e diminuição da pressão respiratória máxima podem ser consequências da fraqueza destes músculos (TEIXEIRA-SALMELA *et al.*, 2005; ANNONI; ACKERMANN; KESSELRING, 1990; LANINI *et al.*, 2003). Além disso, geralmente estes pacientes também podem apresentar redução da resistência muscular respiratória, bem como alterações na cinemática da caixa torácica (TEIXEIRA-SALMELA *et al.*, 2005; MCCONNELL, 2013). Teixeira-Salmela *et al.* encontraram valores de pressão inspiratória e expiratória máximas menores para indivíduos pós-AVE (73.6 e 89.4 cmH₂O, respectivamente), quando comparados aos do grupo controle (99.2 e 134.2 cmH₂O, respectivamente) (TEIXEIRA-SALMELA *et al.*, 2005). Já Pollock *et al.*, em uma revisão sistemática, também investigaram a fraqueza dos músculos respiratórios em indivíduos pós-AVE e encontraram quatro estudos que relataram que a média das pressões inspiratória e expiratória máximas foram, respectivamente, 45,7% e 43,6% menores do que nos grupos controles (POLLOCK *et al.*, 2012). Outros estudos relataram ainda valores médios para pressão inspiratória máxima variando de 17 a 57 cmH₂O em indivíduos pós-AVE, em comparação com aproximadamente 100 cmH₂O em adultos

saudáveis (MESSAGGI-SARTOR *et al.*, 2015; BRITTO *et al.*, 2011; QUEIROZ *et al.*, 2014). Já para a pressão expiratória, os valores médios variaram de 25 a 68 cmH₂O, em comparação com aproximadamente 120 cmH₂O em adultos saudáveis (MESSAGGI-SARTOR *et al.*, 2015; BRITTO *et al.*, 2011; QUEIROZ *et al.*, 2014). Dessa forma, já está bem descrito na literatura que a força muscular respiratória é significativamente reduzida em indivíduos pós-AVE, com valores de, aproximadamente, metade daqueles esperados em indivíduos saudáveis.

Esta fraqueza muscular respiratória pode gerar sintomas respiratórios tais como dispneia, até mesmo durante atividades leves, que podem comprometer a capacidade funcional e a qualidade de vida destes indivíduos (POLLOCK *et al.*, 2012, BRITTO *et al.*, 2011; OCKO; COSTA, 2014). Dispnea é definida pela *American Thoracic Society* como "uma experiência subjetiva de incompatibilidade respiratória, que consiste em sensações qualitativamente distintas, que variam em intensidade" (PARSHALL *et al.*, 2012). Embora inexistam dados relacionados à prevalência da dispneia em indivíduos pós AVE, sabe-se que este sintoma é uma queixa significativa em pacientes com fraqueza muscular generalizada (PARSHALL *et al.*, 2012). A dispneia, associada a um estilo de vida sedentário e ao descondicionamento, pode aumentar a presença deste sintoma, criando um ciclo vicioso (BILLINGER *et al.*, 2014). Esta combinação de fatores também pode aumentar o risco de internações hospitalares, devido a complicações respiratórias, que são uma das principais causas de morte não vascular após o AVE (KATZAN *et al.*, 2003). Um estudo retrospectivo observacional indicou que a pneumonia e as demais doenças respiratórias são os fatores mais comumente associados às readmissões hospitalares após um AVE, sendo responsável por 15% das readmissões (BRAVATA *et al.*, 2007). Além disso, dentre as possíveis complicações respiratórias, a pneumonia é descrita como a principal causa de morte não-vascular tanto na fase aguda (KATZAN *et al.*, 2003) como na fase crônica (YAMAYA *et al.*, 2001) pós lesão. Embora alguns estudos já estejam investigando os efeitos do fortalecimento da musculatura respiratória sobre a

dispneia e o número de complicações respiratórias nesta população (MESSAGGI-SARTOR *et al.*, 2015; SUTBEYAZ *et al.*, 2010; KULNIK *et al.*, 2015), o número reduzido de estudos e a presença de resultados conflitantes faz com que esta relação ainda não esteja clara na literatura.

A função respiratória diminuída também pode estar associada a uma capacidade de marcha reduzida (PAZ *et al.*, 2015; PINHEIRO *et al.*, 2014), um padrão de vida sedentário (LEE; FOLSOM; BLAIR, 2003) e uma piora da percepção da qualidade de vida (COSTA, 2002; SUTBEYAZ *et al.*, 2010) em indivíduos pós-AVE. Pinheiro *et al.* investigaram o padrão respiratório, movimento toracoabdominal e força muscular respiratória em indivíduos pós-AVE crônicos e encontraram que a fraqueza muscular inspiratória é mais evidente em indivíduos com menor velocidade de marcha (PINHEIRO *et al.*, 2014). Velocidade de marcha reduzida está associada a limitações nas atividades diárias e restrições na comunidade (ALZAHRANI; DEAN; ADA; 2011; ADA *et al.*, 2003). Ensaios anteriores já demonstraram que melhorias nos parâmetros de marcha são acompanhadas por redução nos níveis de incapacidade e transferência de efeitos para a participação social (KIM; CHO; LEE; 2014, TILSON *et al.*, 2010). Dessa forma, a presença da fraqueza muscular respiratória associada a presença de sintomas, pode gerar uma capacidade de marcha reduzida e vida em comunidade limitada.

Várias modalidades terapêuticas apareceram nos últimos anos destinadas a melhorar a função respiratória em distúrbios neurológicos, demonstrando efeitos positivos, como o treino muscular respiratório (POLLOCK *et al.*, 2012, BRITTO *et al.*, 2011; MESSAGGI-SARTOR *et al.*, 2015; SUTBEYAZ *et al.*, 2010; KULNIK *et al.*, 2015; XIAO *et al.*, 2012), estimulação elétrica neuromuscular (GUILLÉN-SOLÀ *et al.*, 2016), e os exercícios respiratórios (SUTBEYAZ *et al.*, 2010; KIM; SHIN; CHOI; 2015; SEO; LEE; KIM, 2013). No entanto, embora o conhecimento específico de cada uma dessas modalidades possa ajudar os profissionais a selecionar cuidadosamente a melhor a ser utilizada, escolher uma entre as numerosas terapias descritas na literatura representa um desafio. O aumento no número

de publicações científicas associado à falta de tempo e treinamento adequado para leitura e síntese da evidência desafiam pesquisadores a produzir informações sumarizadas, como revisões sistemáticas da literatura, de modo a facilitar o acesso clínico à informação de alta qualidade metodológica. As revisões sistemáticas são consideradas a melhor forma de sintetizar a informação existente sobre um determinado tópico, pois são realizadas seguindo um método de características sistemáticas e explícitas (HERBERT *et al.*, 2011; PADULA *et al.*, 2012). Curiosamente, nenhuma revisão foi encontrada para descrever o efeito desta gama de intervenções na função respiratória de indivíduos pós-AVE.

Dentre estas diversas modalidades terapêuticas, o treinamento da musculatura respiratória é o mais comumente utilizado em diversas populações, objetivando o ganho de força e resistência (*endurance*) destes músculos (RAMÍREZ-SARMIENTO *et al.*, 2002; XIAO *et al.*, 2012). Ramírez-Sarmiento *et al.* investigaram os efeitos de um protocolo de treinamento muscular inspiratório na estrutura da musculatura inspiratória em pacientes com doença pulmonar obstrutiva crônica. Os resultados encontrados mostraram que os músculos intercostais externos destes pacientes apresentaram uma remodelação estrutural após o treinamento inspiratório aplicado (RAMÍREZ-SARMIENTO *et al.*, 2002). Tanto a proporção de fibras do tipo I como o tamanho das fibras do tipo II aumentaram depois do treino. Essas adaptações estruturais podem explicar, em parte, as melhoras funcionais observadas nos músculos treinados (força e *endurance*), após o treinamento em diversas populações (RAMÍREZ-SARMIENTO *et al.*, 2002).

Revisões sistemáticas com metanálises também comprovaram, com resultados significativos, os efeitos do treino muscular respiratório em diferentes condições de saúde (ELKINS; DENTICE, 2015; TAMPLIN; BERLOWITZ, 2014; SMART; GIALLAURIA; DIEBER, 2013). Elkins e Dentice investigaram os efeitos do treino muscular inspiratório em pacientes em ventilação mecânica. Os resultados mostraram que o treino muscular inspiratório, para pacientes selecionados na unidade de terapia intensiva,

aumentou a pressão inspiratória máxima (MD 7 cmH₂O, 95% IC 5 a 9), facilitou o desmame, além de potenciais reduções na duração da estadia e na duração do suporte ventilatório não invasivo após a extubação (ELKINS; DENTICE, 2015). Já Tamplin e Berlowitz investigaram os efeitos do treino respiratório em pacientes tetraplégicos e encontraram aumento significativo nas pressões inspiratória e expiratória máximas (MD 10,7 cmH₂O, 95% IC 3,6 a 17,7; MD 10,3 cmH₂O, 95% IC 2,8 a 17,8; respectivamente), na função e na endurance respiratória (TAMPLIN; BERLOWITZ, 2014). Finalmente, Smart *et al.* investigaram os efeitos do treino muscular respiratório em pacientes com insuficiência cardíaca e também encontraram melhora significativa no condicionamento, na pressão inspiratória máxima (20,0 cmH₂O, 95% IC 13.9 a 26.1), na distância percorrida no teste de caminhada de seis minutos (34.35 m, 95% IC 22.5 a 46.2) e na qualidade de vida (-12.25 score, 95% IC -17.1 1 - 7.4) (SMART; GIALLAURIA; DIEBER, 2013).

Para indivíduos pós AVE, foi encontrada na literatura uma revisão crítica sobre os efeitos de treino muscular respiratório. Embora os autores tenham concluído que o treino muscular respiratório pode trazer benefícios na melhora da função respiratória e da força dos músculos respiratórios nesta população (OCKO; COSTA, 2014), as conclusões foram baseadas em apenas dois ensaios clínicos (BRITTO *et al.*, 2011; SUTBEYAZ *et al.*, 2010). Além disso, uma vez que a revisão crítica da literatura não segue, necessariamente, uma metodologia pré-definida, a consideração destes resultados merecem cautela. Assim, para se obter conclusões confiáveis e específicas, as revisões devem detalhar explicitamente como a busca foi feita, as fontes, as escolhas feitas em relação aos critérios de inclusão e/ou exclusão, as características e qualidade dos estudos e os procedimentos analíticos adotados (THOMAS; NELSON; SILVERMAN, 2012). Este é o método exigido para o desenvolvimento de revisões sistemáticas, que são estruturadas, analíticas e críticas (THOMAS; NELSON; SILVERMAN, 2012), e, como dito anteriormente, são consideradas a melhor forma de sintetizar a informação existente sobre um determinado tópico. Além disso, sempre que possível, a revisão sistemática deve incluir a

metanálise (HERBERT *et al.*, 2011), uma análise estatística que permite quantificar os resultados de vários estudos para uma métrica padrão (THOMAS; NELSON; SILVERMAN, 2012). A revisão sistemática com metanálise fornece uma maior precisão da informação em relação ao tamanho de efeito de uma determinada intervenção (HERBERT *et al.*, 2011). Dessa forma, sempre que possível, pesquisadores devem sumarizar a evidência proveniente de ensaios clínicos de alta qualidade por meio de revisões sistemáticas com meta-análise, afim de fornecer respostas imediatas a pesquisadores, clínicos e pacientes.

Três revisões sistemáticas foram encontradas investigando os efeitos do treino muscular respiratório em indivíduos pós-AVE (XIAO *et al.*, 2012; POLLOCK *et al.*, 2012, MARTÍN-VALERO *et al.*, 2015). Pollock *et al.* investigaram os efeitos do treino muscular respiratório em indivíduos pós-AVE. Com apenas dois estudos incluídos (BRITTO *et al.*, 2011; SUTBEYAZ *et al.*, 2010), o efeito do treinamento na pressão inspiratória máxima foi de 7 cmH₂O (IC 95% 2 a 12), mas com heterogeneidade estatística substancial ($I^2=95\%$). Além disso, não foi encontrado efeito na pressão expiratória máxima. Assim, os autores concluíram que não há evidência suficiente para recomendar o treinamento muscular respiratório como um tratamento eficaz em indivíduos pós-AVE (POLLOCK *et al.*, 2012). Xiao *et al.* também investigaram os efeitos do treino muscular respiratório na função muscular respiratória, nas atividades da vida diária, no condicionamento cardiorrespiratório e na qualidade de vida de indivíduos pós-AVE. No entanto, foram encontrados os mesmos dois estudos da revisão anterior (BRITTO *et al.*, 2011; SUTBEYAZ *et al.*, 2010), impossibilitando maiores conclusões (XIAO *et al.*, 2012). Já Martín-Valero *et al.*, em uma revisão sistemática mais recente, que também objetivou investigar os níveis de evidência do treinamento muscular inspiratório em indivíduos pós-AVE, incluíram seis artigos. No entanto, destes, dois eram os mesmos estudos reportados pelas revisões anteriores (BRITTO *et al.*, 2011; SUTBEYAZ *et al.*, 2010), três eram estudos transversais, que avaliaram somente a relação da força muscular respiratória com outras variáveis (PINHEIRO *et al.*, 2014,

POLESE *et al.*, 2013; SILVA *et al.*, 2013) e, por fim, o último era um protocolo, (KULNIK *et al.*, 2014). Dessa forma, uma vez que nenhum estudo acrescentou informação relevante, em relação aos efeitos do treino muscular respiratório em indivíduos pós-AVE, esta revisão também não esclareceu sobre a eficácia desta intervenção nesta população.

Revisões sistemáticas de efeitos de intervenção são, entretanto, dependentes da existência de ensaios clínicos de alta qualidade, para fornecer as respostas clínicas necessárias (HERBERT *et al.*, 2011). Ensaios clínicos aleatorizados são considerados como os estudos que servem de base para o avanço da ciência, pois é o tipo de estudo com menor possibilidade de ocorrência de vieses durante a investigação do fenômeno de interesse (SCHULZ, 1995). Foram encontrados na literatura seis ensaios clínicos de moderada a alta qualidade (5 a 8 na escala PEDro) sobre os efeitos do treino muscular respiratório em indivíduos pós-AVE (BRITTO *et al.*, 2011; SUTBEYAZ *et al.*, 2010, MESSAGGI-SARTOR *et al.*, 2015; KULNIK *et al.*, 2015; CHEN *et al.*, 2016; GUILLÉN-SOLÀ *et al.*, 2017). Três estudos (BRITTO *et al.*, 2011; CHEN *et al.*, 2016; SUTBEYAZ *et al.*, 2010) investigaram os efeitos do treino muscular inspiratório. Sutbeyaz *et al.* encontraram efeitos significativos a curto prazo na função muscular respiratória, capacidade de exercício e qualidade de vida (SUTBEYAZ *et al.*, 2010), enquanto Britto *et al.* encontraram efeitos significativos, também a curto prazo, para a força e resistência inspiratórias (BRITTO *et al.*, 2011). Já Chen *et al.*, reportaram melhora na força inspiratória e nas atividades da vida diária (CHEN *et al.*, 2016). No entanto, todos os estudos incluíram apenas o treino da musculatura inspiratória e avaliaram os efeitos a curto prazo. Outros três estudos (MESSAGGI-SARTOR *et al.*, 2015; KULNIK *et al.*, 2015; GUILLÉN-SOLÀ *et al.*, 2017) investigaram os efeitos do treino muscular inspiratório e expiratório em indivíduos pós AVE. Messaggi-Sartor *et al.* encontraram melhora significativa na força muscular inspiratória e expiratória e redução nas complicações respiratórias (MESSAGGI-SARTOR *et al.*, 2015), enquanto Kulnik *et al.* reportaram melhora na função muscular respiratória e no fluxo da tosse (KULNIK *et al.*, 2015) e Chen *et al.* encontraram

efeitos somente na força muscular (CHEN *et al.*, 2016). No entanto, nenhum dos estudos avaliaram os efeitos sobre a capacidade funcional ou dispneia destes indivíduos. Além disso, os seis estudos apresentaram grande variabilidade, em relação aos parâmetros de treinamento (tempo, frequência, carga, etc), às medidas de desfecho avaliadas e os resultados encontrados.

Como observado, ainda não existe consenso na literatura sobre qual seria o melhor protocolo de treinamento dos músculos respiratórios em pacientes pós-AVE e os reais efeitos desta intervenção. Dentre todos os ensaios clínicos já realizados, foram encontrados estudos que treinaram somente os músculos inspiratórios (BRITTO *et al.*, 2011; CHEN *et al.*, 2016; SUTBEYAZ *et al.*, 2010), tiveram um período de treinamento igual ou inferior a quatro semanas (MESSAGGI-SARTOR *et al.*, 2015; KULNIK *et al.*, 2015; GUILLÉN-SOLÀ *et al.*, 2017) e não realizaram ajuste de carga progressivo sistematicamente (CHEN *et al.*, 2016, MESSAGGI-SARTOR *et al.*, 2015; GUILLÉN-SOLÀ *et al.*, 2017). Embora estes resultados pareçam animadores, a magnitude média dos efeitos encontrados é relativamente pequena. No entanto, uma vez que os músculos respiratórios respondem ao estímulo do treinamento de forma semelhante a outros músculos esqueléticos, eles podem ser sobrecarregados, exigindo que trabalhem por um maior período de tempo, em intensidades mais altas e/ou com maior frequência, do que normalmente estão acostumados. Assim, um treino de fortalecimento muscular respiratório de alta intensidade em indivíduos pós-AVE, por exemplo, poderia, potencialmente, aumentar a magnitude dos efeitos encontrados tanto para a função respiratória como, inclusive, transferir para atividade e participação social desta população.

Por fim, realizar um treinamento da musculatura respiratória não exige somente conhecimento do tipo de protocolo a ser aplicado, mas também do dispositivo a ser utilizado. No entanto, uma vez que atualmente existem no mercado diversos aparelhos utilizados para treinar os músculos respiratórios, essa seleção representa um desafio para os profissionais. Nesta linha, estudos anteriores objetivaram descrever todos os dispositivos de treinamento muscular

respiratório (MCCONNELL, 2013; MCCONNELL; ROMER, 2004; CROITORU; BOGDAN, 2013; SAPIENZA, 2008). No entanto, alguns dispositivos com eficácia comprovada não foram incluídos em nenhuma destas referências. Além disso, dentre as mais recentes, a publicação de McConnell de 2013 é um capítulo de livro, nem sempre acessível para os profissionais (MCCONNELL, 2013;), enquanto a revisão de Croitoru & Bogdan foi escrita em outro idioma (romeno) (CROITORU; BOGDAN, 2013). Uma publicação recente, incluindo todos os dispositivos, poderia ajudar os profissionais a selecionarem cuidadosamente o melhor a ser usado em cada paciente, a fim de alinhar os objetivos da intervenção com os mecanismos e características destes dispositivos, tais como o alcance da sobrecarga, portabilidade, usabilidade e custo.

Dessa forma, pode-se notar que, devido à pouca atenção dispensada à função respiratória após o AVE, ainda existem algumas lacunas a serem preenchidas e que merecem atenção. A ausência de estudos indicando a prevalência e severidade da dispneia nesta população, ou de revisões sistemáticas indicando as intervenções mais eficazes na melhora da função respiratória destes indivíduos, são exemplos de lacunas da literatura que precisam ser preenchidas. Além disso, sendo o treino muscular respiratório a intervenção mais comumente utilizada em pacientes pós-AVE para o fortalecimento da musculatura respiratória, ainda há a necessidade de revisões sistemáticas atuais indicando os reais efeitos desta intervenção nesta população. Destaca-se também a importância de se reunir e sumarizar as informações técnicas/características dos diversos dispositivos utilizados para este fim, disponíveis atualmente no mercado. Por fim, embora já existam ensaios clínicos aleatorizados apresentando resultados encorajadores do treino muscular respiratório pós AVE, ainda não está claro se a magnitude dos efeitos poderia ser maximizadas, em relação aos atuais achados da literatura, caso a intensidade do treinamento também fosse elevada, comparada aos protocolos já descritos previamente. O esclarecimento destes questionamentos pode ajudar os profissionais a selecionarem as melhores estratégias de intervenção,

com protocolos de aplicação e dispositivos apropriados, considerando a presença e severidade dos sintomas associados. Tais tomadas de decisão, fundamentadas em produções científicas de alta qualidade, auxiliam na integração entre pesquisa, conhecimento prático e preferências do cliente, assegurando a implementação de uma prática baseada em evidências (HERBERT *et al.*, 2011; SARAGIOTTO *et al.*, 2014; SILVA *et al.*, 2014).

Objetivos

Objetivo geral

Avaliar os efeitos do treinamento muscular respiratório em indivíduos pós-AVE.

Objetivos específicos

- Descrever e comparar os efeitos de diferentes tipos de intervenções para melhora da função respiratória em indivíduos pós-AVE, através de uma revisão sistemática da literatura com metanálise (**Estudo 1**).
- Investigar os efeitos do treinamento muscular respiratório em indivíduos pós-AVE, através de uma revisão sistemática da literatura com meta-análise (**Estudo 2**).
- Descrever os tipos de dispositivos disponíveis no mercado utilizados para treinamento muscular respiratório em indivíduos pós-AVE, através de uma revisão crítica da literatura (**Estudo 3**).
- Investigar a prevalência e a severidade da dispneia, e o impacto deste sintoma na atividade e participação de indivíduos pós-AVE (**Estudo 4**).

- Avaliar se um programa domiciliar de fortalecimento muscular respiratório de alta intensidade é eficaz no aumento da força e resistência dos músculos respiratórios, na redução da dispnéia e de complicações respiratórias e melhora da capacidade de marcha após o AVE (**Estudos 5 e 6**).

Abaixo, um fluxograma demonstrando a linha de raciocínio para o desenvolvimento de cada um dos estudos, com suas respectivas perguntas e títulos, para facilitar a compreensão da ordem dos artigos adotada na presente tese.

Uma vez que o AVE é uma condição incapacitante, que afeta inclusive a musculatura respiratória, surgiram os seguintes questionamentos: Quais são os tipos de intervenções atualmente utilizados para melhorar a função respiratória destes indivíduos? Quais intervenções são eficazes para melhorar a função respiratória desta população?

Estudo 1. A eficácia de intervenções para melhorar a função respiratória após acidente vascular encefálico: uma revisão sistemática.



Uma vez que o treino muscular respiratório demonstrou ser a intervenção com maior nível de evidência na literatura para melhorar a função respiratória de indivíduos pós- AVE, surgiram os seguintes questionamentos: O treinamento muscular respiratório (inspiratório e expiratório) aumenta a força e/ou a resistência dos músculos respiratórios após o AVE? Os benefícios são transferidos para atividade e/ou participação? O treinamento muscular respiratório reduz a ocorrência de complicações respiratórias?

Estudo 2. O treinamento muscular respiratório aumenta a força muscular respiratória e reduz complicações respiratórias após acidente vascular encefálico: uma revisão sistemática



Uma vez que diversos dispositivos foram descritos e utilizados nos estudos como opção para a realização do treino muscular respiratório, surgiram os seguintes questionamentos: Quais os tipos e modelos de dispositivos de treinamento dos músculos respiratórios atualmente disponíveis no mercado? Quais são seus mecanismos de ação, bem como demais características, como vantagens e limitações.?

Estudo 3. Uma revisão sobre dispositivos de treinamento muscular respiratório.

Uma vez que após o AVE, a musculatura respiratória é afetada, gerando sintomas incapacitantes, como a dispneia, em muitos destes indivíduos, surgiram os seguintes questionamentos: Qual é a prevalência e o nível de gravidade da dispneia em indivíduos pós-AVE? A dispneia está associada a limitações de atividade e/ou restrições de participação nesta população?

Estudo 4. Prevalência de dispneia após um acidente vascular encefálico: uma pesquisa por telefone.



A dispneia afeta quase metade da população pós-AVE, gerando limitações em atividades e restrições sociais nesta população, além do treino muscular respiratório ser a intervenção com maior nível de evidência para melhorar a função respiratória destes indivíduos. No entanto, uma vez que os estudos com essa intervenção nesta população encontraram um tamanho de efeito relativamente pequeno, surgem os seguintes questionamentos: Um treinamento de alta intensidade dos músculos respiratórios é mais eficaz para aumentar a força e resistência dos músculos respiratórios e diminuir a dispneia e as complicações respiratórias após o AVE? Os efeitos são mantidos após o término da intervenção ou são transferidos para atividade?

Estudo 5. Efeitos do treinamento muscular respiratório domiciliar de alta intensidade na força dos músculos respiratórios após acidente vascular encefálico: um protocolo para um ensaio controlado randomizado.

Estudo 6. Treinamento muscular respiratório domiciliar de alta intensidade aumenta a força e a resistência dos músculos respiratórios e reduz a dispneia após acidente vascular encefálico: um ensaio clínico randomizado e controlado.

Capítulo 2

ARTIGO 1

Efficacy of interventions aiming at improving respiratory function after stroke: A systematic review.

2.1 ABSTRACT

Introduction: The aim of this study was to systematically review all current interventions, which have been employed to improve respiratory function and activity performance after stroke. **Methods:** Specific searches were conducted in four databases. Experimental intervention had to be a planned, structured, repetitive, purposive, and delivered with the aim to improve respiratory function. Outcomes included respiratory strength (maximum inspiratory and expiratory pressures – MIP and MEP) and endurance, lung function (forced vital capacity - FVC, forced expiratory volume in 1 second - FEV₁, and peak expiratory flow - PEF), dyspnea, and activity. The quality of the randomized trials was assessed by the PEDro scale. **Results:** The 17 included trials had a mean PEDro score was 5.7 (range: 4 to 8) and involved 616 participants. Meta-analyses showed that respiratory muscle training significantly improved all outcomes of interest, as follows: MIP (MD:11cmH₂O; 95%CI 7 to 15; I²=0%), MEP (8cmH₂O; 95%CI 2 to 15; I²=65%), FVC (0.25 L; 95%CI 0.12 to 0.37; I²=29%), FEV₁ (0.24 L; 95%CI 0.17 to 0.30, I²=0%), PEF (0.51 L/s; 95%CI 0.10 to 0.92; I²=0%), dyspnea (SMD -1.6 points; 95%CI -2.2 to -0.9; I²=0%), and activity (SMD 0.78; 95%CI 0.22 to 1.35; I²=0%). Meta-analyses found no significant results for the effects of breathing exercises on lung function. For the remaining interventions, i.e., aerobic and postural exercises, and addition of electrical stimulation, meta-analyses could not be performed. **Conclusions:** This systematic review reported five possibilities of interventions, aiming at improving respiratory function after stroke. Respiratory muscle training proved to be effective for improving inspiratory and expiratory strength, lung function, dyspnea, and benefits were carried-over to activity. However, there is still no evidence to accept or refute the efficacy of aerobic, breathing, and postural exercises, or the addition of electrical stimulation in respiratory function.

Key-words: stroke, respiratory function, respiratory strength, intervention, dyspnea, activity.

[Menezes KKP, Nascimento LR, Avelino PR, Alvarenga MTM, Teixeira-Salmela LF (*submitted*) Efficacy of interventions aiming at improving respiratory function after stroke: A systematic review. *Respiratory Care*].

2.2. INTRODUCTION

Stroke is the second-leading global cause of death and the leading cause of disability worldwide [1]. Previous studies have demonstrated that stroke affects not only the muscles of the upper and lower limbs, but also those of the respiratory system [2,3]. Individuals with stroke typically demonstrate breathing pattern changes [4], decreased ventilatory function [5], decreased strength of the respiratory muscles [2,6], and reduction in diaphragmatic activity of the paretic side [7,8]. In addition, decreased respiratory function is associated with deconditioning, activity limitations, and elevated risk for respiratory complications [9]. Disabilities of the respiratory system after stroke, associated with dysphagia and ineffective cough, may increase the risks of aspiration pneumoniae, which has been described as the leading cause of non-vascular death after stroke [10]. Thus, implementing interventions with the potential to improve respiratory function and, consequently, prevent morbidity and mortality in people with stroke, is vindicated [11].

Since 1992, research in respiratory physiotherapy has been increasing, associated with the emergence and growth of centers of excellence in this area [12]. These centers, and many individual physiotherapists, have strived rigorously to evaluate and upgrade interventions for improving respiratory function [12]. Respiratory function is related to the breathing process, in which the lungs perform their function of ventilation and perfusion, and, thus, properly oxygenate all body tissues [13]. However, this process depends on proper functioning of all the involved structures, such as suitable strength and endurance of the respiratory muscles, as well as lung volumes and flows [13]. These variables have been commonly used to reflect respiratory function and to evaluate the effectiveness of various types of interventions in people with stroke [14-16]. Neuromuscular electrical stimulation [14], transcranial magnetic stimulation [15], breathing exercises [16], and respiratory muscle training [6] are examples of the applied interventions, which have the potential to improve respiratory function. These interventions may increase the strength and endurance of the respiratory muscles, speed of contractions and power outputs,

diaphragm thickness, and lung volumes and flows [6,14-16]. Thus, the knowledge of the most effective interventions is fundamental for professionals, since this information may help them to integrate the best research evidence, and when associated with clinical expertise and client preferences, will produce appropriate and effective services [17,18].

There have been four systematic reviews, which examined improvements in outcomes related to respiratory function in people with stroke, but the delivered intervention was always respiratory muscle training [3,6,19,20]. The results indicated that respiratory muscle training resulted in increased strength of the inspiratory (7cmH₂O) [6,19] and expiratory (13cmH₂O) muscles [6] and improved lung function, such as forced vital capacity (2,0 L) [19]. Although numerous randomized clinical trials [14-16] have investigated the effects of other interventions aiming at improving respiratory function in people with stroke, there were not found any systematic reviews, which were capable of summarizing the current evidence. In addition, improvements in impairments related to respiratory function have the potential to reduce activity-related symptoms, such as dyspnea, and the benefits could be carried over to everyday activities, due to more efficient use of the respiratory muscles in activities of daily living. Therefore, the effects of respiratory interventions on dyspnea and the carry-over effects to activity should also be investigated.

Thus, a review investigating all current interventions, which have been employed to improve respiratory function and activity performance after stroke, is warranted. The findings may help professionals to carefully select the best one. The specific research questions were:

1. What are the interventions, which have been delivered to improve respiratory function after stroke?
2. Which interventions are effective in improving respiratory function after stroke? Are any benefits carried over to activity?

In order to make recommendations based upon the highest level of evidence, this review included only randomized controlled trials [21,22].

2.3 METHODS

2.3.1 Identification and selection of trials

Searches for relevant studies, without date or language restrictions, were conducted in the following databases: CINAHL (1986 to January 2017), LILACS (1986 to January 2017), MEDLINE (1946 to January 2017), and PEDro (to January 2017). Optimized and specific search strategies were used for all databases, by combining keywords, such as *stroke* and *randomized controlled trials* and words related to *respiratory interventions*, such as *inspiratory muscle training*, *expiratory muscle training*, *breathing exercises*, and *respiratory therapy*. See Appendix 1 on the eAddenda for the full-search strategies. Title and abstracts were displayed and screened by two reviewers (KKPM and PRA), to identify relevant studies. Full-text copies of peer-reviewed relevant papers were retrieved and their reference lists were screened, to identify further relevant studies. The method section of the retrieved papers was extracted and independently reviewed by KKPM and PRA, using pre-determined criteria (Box 1). Both reviewers were blinded to authors, journals, and results of the studies. Disagreement or ambiguities were resolved, after discussion, by consensus.

2.3.2 Assessment of characteristics of trials

2.3.2.1 *Quality*

The quality of the included trials was assessed, by extracting the PEDro scores from the Physiotherapy Evidence Database (www.pedro.org.au). Where a trial was not included in the database, it was independently scored by two reviewers, who had completed the PEDro scale training tutorial. The PEDro is an 11-item scale, designed for rating the methodological quality (internal validity and statistical information) of randomized trials. Each item, except for Item 1, contributes to one point to the total PEDro score (range: 0 to 10 points) [23].

2.3.2.2 Participants

Trials involving adult participants of both sexes at any time following stroke onset were included. The number of participants, age, and time since stroke were registered for description purposes. At admission to the trial, participants who were less than six months after stroke were categorized as acute/sub-acute, and those, who were more than six months after stroke, were categorized as chronic.

2.3.2.3 Interventions

The experimental intervention had to be a planned, structured, repetitive, purposive and delivered with the aim to improve respiratory function after stroke. All forms of active exercises (e.g., aerobic, strength, breathing, and electrical stimulation) were included. Trials were excluded if the experimental interventions were: multidisciplinary, primarily occupational therapy, invasive procedures, drug therapy, single-session therapy, education, sensory or brain stimulation, without active exercises. Feasibility studies and study protocols were not examined.

2.3.2.4 Outcome measures

Trials were examined when at least one outcome related to respiratory function was measured. Accepted outcomes were strength measures of the respiratory muscles (e.g., maximum inspiratory and expiratory pressures – MIP and MEP - and endurance) or lung function, measured via spirometry (e.g., forced vital capacity - FVC, forced expiratory volume in 1 second – FEV₁, and peak expiratory flow - PEF).

Secondary outcomes were dyspnea and activity. Dyspnea was defined as an uncomfortable abnormal awareness of breathing and had to be measured using validated self-reported scales (eg., Borg scale). The activity measurement

had to be representative of the ability to execute tasks or actions. Direct measures or self-reported questionnaires were used, regardless of whether they produced continuous or categorical data. Measures of general activity (e.g., Barthel Index) were used, if they were the only available measure of activity.

2.3.3 Data analyses

Information regarding the method (i.e., design, participants, intervention, outcome measures) and results (i.e., number of participants, and mean (SD) of respiratory outcomes) were extracted by two independent reviewers and verified by a third one. When information was not available in the published trials, details were requested from the corresponding author.

To obtain the pooled estimate of the effect of the interventions, the change scores and/or post-intervention scores were extracted and analyzed, using a random effects model. The pooled data for all outcomes were reported as weighted mean difference (MD) or standardized mean difference (SMD), along with their respective 95% confidence intervals (95% CI). Analyses were performed using the Comprehensive Meta-Analysis software (Version 3.0). The critical value for rejecting H_0 was set at a level of 0.05 (2-tailed). Where insufficient data were available for a study result to be included in the pooled analysis, the between-group difference was reported.

2.4 RESULTS

2.4.1 Flow of trials through the review

The electronic search strategy identified 2,914 papers, but 344 were duplicates. After screening titles, abstracts, and reference lists, 46 potentially relevant full papers were retrieved. However, 29 failed to meet the inclusion criteria (see Appendix 2 on the eAddenda for a summary of the excluded

papers) and, therefore, 17 papers were included in this systematic review. Figure 1 outlines the flow of the studies through the review

2.4.2 Characteristics of the included trials

The 17 included trials involved 616 participants and investigated the effects of five modalities of interventions delivered to improve respiratory function after stroke. Eleven trials compared experimental interventions versus nothing [14, 16, 24-32], three compared with sham interventions [33-35], and three compared two different modalities of respiratory interventions [36-38]. The characteristics of the included trials are summarized in Table 1.

2.4.2.1 Quality

The mean PEDro score of the 17 randomized included trials was 5.7 (range: 4 to 8) (Table 2). All trials randomly allocated participants into groups, had similar groups at baseline, and reported between-group differences, point estimates, and variability. The majority had less than 15% dropouts (65%). On the other hand, the majority of trials did not report blinding of assessors (53%), concealed allocation (65%), intention-to-treat analysis (82%), or blinded the participants (100%) or therapists (100%).

2.4.2.2 Participants

The mean age of the 616 participants ranged from 54 to 71 years across trials, and the mean time after stroke ranged from 9 days to 66 months. The majority of trials (59%) included participants at the chronic phases after stroke.

2.4.2.3 Intervention

The experimental interventions were: aerobic exercises (two trials) [36,38], breathing exercises (i.e., breathing/chest expansion/diaphragmatic exercises) (four trials) [16,25,29,32], postural exercises (one trial) [31], respiratory muscle training (11 trials) [14,24,26-30,32-35,], and addition of electrical stimulation (two trials) [14,37]. Three trials included two interventions (two experimental groups) and were included in two different comparisons [14,29,33]. Concerning respiratory muscle training, six trials delivered training to the inspiratory muscles [24,26,30,32,34,35], one to the expiratory muscles [34], and five trials to both inspiratory and expiratory muscles [14,27-29,33]. Participants undertook training for 20 to 30 minutes (or 25 to 100 repetitions), three to seven times per week, over three to 10 weeks.

2.4.2.4 Outcome measures

Six trials [14,24,32-35] measured strength of the respiratory muscles, as maximal pressures generated during inspiration or expiration, and data were reported in cmH₂O. Thirteen trials [16, 24-32,36-38] measured lung function, using spirometry: data on FVC and FEV₁ were reported in L, and data on PEF were reported in L/s. Two trials [29,37] reported lung function, as percentages of the predicted values. Regarding the secondary outcomes, two trials [28,32] measured dyspnea using the Borg scale and six [24,28,32,35,36,38] measured activity. Activity was measured using timed walk measures (three trials) [28,36,38], cycle ergometer (two trials) [23, 46], and self-reported questionnaires (three trials) [24,32,35].

2.4.3 Effect of respiratory interventions

Aerobic exercise

The effects of aerobic exercise on respiratory function were examined in two trials [36,38], that had a mean PEDro score of 6. The first trial compared intensive with self-selected aerobic exercises [36] and the second compared

self-selected aerobic exercises with inspiratory muscle training [38]. A meta-analysis was not performed, due to clinical heterogeneity. Results from the first trial [36] indicated that intensive aerobic exercises improved FVC (MD 0.4L; 95% CI 0.1 to 0.7), FEV₁ (MD 0.4 L; 95% CI 0.1 to 0.7), walking speed (MD 0.1m/s; 95% CI 0.01 to 0.19), and walking capacity (MD 59m; 95% CI 2 to 116). Results from the second trial [38] indicated that the effects of aerobic exercise were worse, than inspiratory muscle training for FVC (MD -0.3L; 95% CI -0.1 to -0.5) and FEV₁ (MD -0.4 L; 95% CI -0.1 to -0.7), but there was no difference between the groups for walking speed (MD 0.11m/s; 95% CI -0.03 to 0.25), and walking capacity (MD 50m; 95% CI -22 to 121).

Breathing exercises

The effects of breathing exercises on respiratory function were examined in four trials [16,25,29,32], with a mean PEDro score of 5.3. In all trials, the control group received no intervention. Detailed results were provided regarding the outcomes of interest, as follows:

MIP and MEP: Only one trial, with a PEDro score of 7, examined the effects of breathing exercises on muscle strength after stroke [32]. The mean differences between the groups were 4 cmH₂O (95% CI 1 to 7) and 2 cmH₂O (95% CI 1 to 4) for MIP and MEP, respectively, in favour of the experimental group.

FVC: The effects of breathing exercises on FVC were examined by pooling the data from three trials [16,25,32] (n=98 participants), with a mean PEDro score of 5.3, representing moderate quality. Breathing exercises did not significantly change FVC (MD: 0.28 L, 95% CI -0.04 to 0.60; I² = 54%), compared with nothing (Figure 2, see Figure 3 on the eAddenda for the detailed forest plot). One trial, with a PEDro score of 5, examined the effects of breathing exercises associated with respiratory muscle training, compared to respiratory muscle training alone on FVC [29]. Results were reported as

percentages of the predicted values, and the mean difference between the groups was 4 % (95% CI 3 to 6), in favour of the association of breathing exercises and respiratory muscle training.

FEV₁: The effects of breathing exercises on FEV₁ were examined by pooling the data from three trials [16,25,32] (n=98 participants), with a mean PEDro score of 5.3, representing moderate quality. Breathing exercises did not significantly change FEV₁ (MD: -0.01 L; 95% CI -0.30 to 0.28; I² = 50%), compared with nothing. (Figure 4, see Figure 5 on the eAddenda for the detailed forest plot). One trial, with a PEDro score of 5, examined the effects of breathing exercises associated with respiratory muscle training, compared to respiratory muscle training alone on FEV₁ [29]. Results were reported as percentages of the predicted values, and the mean difference between the groups was 10% (95% CI 8 to 11), in favour of the association of breathing exercises and respiratory muscle training.

PEF: The effects of breathing exercises on PEF were examined by pooling the data from two trials [16,32] (n= 60 participants), with a mean PEDro score of 5.5, representing moderate quality. Breathing exercises did not significantly change PEF (MD: 0.21 L/s; 95% CI -0.38 to 0.80; I² = 0%), compared with nothing. (Figure 6, see Figure 7 on the eAddenda for the detailed forest plot). Two trials [25,29] did not measure PEF.

Dyspnea: Only one trial, with a PEDro score of 7, examined the effects of breathing exercises on dyspnea after stroke [32]. The mean difference between the groups on the Borg scale (4-20), was 0.1 (95% CI -1 to 1).

Activity: Only one trial, with a PEDro score of 7, examined the effects of breathing exercise on activity [32]. The mean difference between the groups was not calculated, due to insufficient data, but the authors reported significantly improvement in the Barthel index, in favor of breathing exercises.

Postural exercises

The effects of postural exercises on respiratory function, compared to nothing, were examined in one trial [31], with a PEDro score of 5. The results indicated that postural exercises improved FVC (MD 1.2 L; 95% CI 0.6 to 1.8), FEV₁ (MD 1.3 L; 95% CI 0.8 to 1.8), and PEF (MD 1.4 L; 95% CI 0.6 to 2.2). The remaining outcomes of interest, i.e., MIP, MEP, dyspnea and activity, were not examined.

Respiratory muscle training

The effects of respiratory muscle training on respiratory function was examined in 11 trials [14,24,26-30,32-35], with a mean PEDro score of 6. The control group received nothing [14,24,26-30, 32] or sham intervention [33-35]. Detailed results were provided regarding the outcomes of interest, as follows:

MIP: The effects of inspiratory muscle training on inspiratory muscle strength were examined by pooling the data from six trials [14,24,32-35] (n=229 participants), with a mean PEDro score of 6.7, representing moderate quality. Overall, inspiratory muscle training increased MIP by 11 cmH₂O (95% CI 7 to 15; $I^2 = 0\%$), compared with nothing/sham intervention. Four trials delivered both inspiratory and expiratory muscle training (MD: 11 cmH₂O; 95% CI 7 to 15; $I^2 = 0\%$), and two delivered only inspiratory muscle training (MD: 12 cmH₂O; 95% CI 2 to 22; $I^2 = 27\%$) (Figure 8, see Figure 9 on the eAddenda for the detailed forest plot). Five trials [26-30] did not measure MIP.

MEP: The effects of expiratory muscle training on expiratory muscle strength were examined by pooling the data from three trials [14,33,34] (n=160 participants), with a mean PEDro score of 7.0, representing moderate quality. Overall, expiratory muscle training increased MEP by 8 cmH₂O (95% CI 2 to 15; $I^2 = 65\%$); compared with nothing/sham intervention. Two trials delivered both expiratory and inspiratory muscle training (MD: 15 cmH₂O; 95% CI 6 to 24; $I^2 = 0\%$), and one trial delivered only expiratory muscle training (MD: 0 cmH₂O; 95%

CI -10 to 10). (Figure 10, see Figure 11 on the eAddenda for the detailed forest plot). Six trials [26-30,35] did not measure MEP.

FVC: The effects of respiratory muscle training, i.e., inspiratory and/or expiratory muscle training, on FVC were examined by pooling the data from six trials [24,26-28,30,32] (n=150 participants), with a mean PEDro score of 5.5, representing moderate quality. Overall, respiratory muscle training increased FVC by 0.25 L (95% CI 0.12 to 0.37; $I^2 = 29\%$), compared with nothing/sham intervention. One trial delivered both inspiratory and expiratory muscle training (MD: 0.45 L; 95% CI 0.03 to 0.87), and five trials delivered only inspiratory muscle training (MD: 0.23 L; 95% CI 0.09 to 0.36; $I^2 = 33\%$). (Figure 12, see Figure 13 on the eAddenda for the detailed forest plot). One trial, with a PEDro score of 5, examined the effects of respiratory muscle training versus nothing on FVC [29]. Results were reported as percentages of the predicted values, and the mean difference between the groups was 10% (95% CI 8 to 11), in favour of the respiratory muscle training. Four trials [14,33-35] did not measure FVC.

FEV₁: The effects of respiratory muscle training on FEV₁ were examined by pooling the data from six trials [24, 26-28,30,32] (n=150 participants), with a mean PEDro score of 5.5, representing moderate quality. Overall, respiratory muscle training increased FEV₁ by 0.24 L (95% CI 0.17 to 0.30, $I^2 = 0\%$), compared with nothing/sham intervention. One trial delivered both inspiratory and expiratory muscle training (MD: 0.36 L; 95% CI -0.02 to 0.74) and five trials delivered only inspiratory muscle training (MD: 0.23 L; 95% CI 0.17 to 0.30; $I^2 = 1\%$). (Figure 14, see Figure 15 on the eAddenda for the detailed forest plot). One trial, with a PEDro score of 5, examined the effects of respiratory muscle training versus nothing on FEV₁ [29]. Results were reported as percentages of the predicted values, and the mean difference between the groups was 4% (95% CI -1 to 9). Four trials [14,33-35] did not measure FEV₁.

PEF: The effects of respiratory muscle training on PEF were examined by pooling the data from five trials [26-28,30,32] (n=129 participants), with a mean PEDro score of 5.6, representing moderate quality. Overall, respiratory

muscle training increased PEF by 0.51 L/s (95% CI 0.10 to 0.92; $I^2 = 0\%$), compared with nothing/sham intervention. One trial delivered both inspiratory and expiratory muscle training (MD: 0.55 L/s; 95% CI -0.17 to 1.27), and four delivered only inspiratory muscle training (0.49 L/s; 95% CI -0.01 to 0.99; $I^2 = 0\%$). (Figure 16, see Figure 17 on the eAddenda for the detailed forest plot). Six trials [14,24,29,33-35] did not measure PEF.

Dyspnea: The effects of respiratory muscle training on dyspnea were examined by pooling the data from two trials [28,32] (n=50 participants), with a mean PEDro score of 5.5, representing moderate quality. Overall, respiratory muscle training reduced dyspnea (SMD -1.6 points; 95% CI -2.2 to -0.9; $I^2 = 0\%$), compared with nothing/sham intervention. (Figure 18, see Figure 19 on the eAddenda for the detailed forest plot). Nine trials [14,24,26,27,29,30,32,34,35] did not measure dyspnea.

Activity: The effects of respiratory muscle training on activity were examined by pooling the data from three trials [24,28,35] (n=59 participants), with a mean PEDro score of 5.5, representing moderate quality. Overall, respiratory muscle training improved activity, (SMD 0.78; 95% CI 0.22 to 1.35; $I^2 = 0\%$), compared with nothing/sham intervention. (Figure 20, see Figure 21 on the eAddenda for the detailed forest plot). One trial, with a PEDro score of 7, examined the effects inspiratory muscle training on activity [32] and significant improvements in the Barthel index were found, in favor of the experimental group. However, the mean difference between the groups could not be calculated, due to insufficient data. Seven trials [14,26,27,29,30,33,34] did not measure activity.

Addition of electrical stimulation

The effects of the addition of electrical stimulation on respiratory function were examined in two trials [14,37]. The first [17] (PEDro score of 6) compared electrical stimulation plus sham respiratory muscle training versus nothing on

MIP and MEP. The mean differences between the groups were 12 cmH₂O (95% CI 3 to 20) and 13 cmH₂O (95% CI 0.4 to 25) for the MIP and MEP, respectively, in favour of the experimental group. The second trial [31] (PEDro score of 5) compared electrical stimulation plus inspiratory muscle training versus inspiratory muscle training alone on FVC, FEV₁, and PEF. The results were reported as percentages of the predicted values, and the mean differences between the groups were 6 % (95% CI -8 to 20) for FVC, 15% (95% CI -2 to 31) for FEV₁, and 24% (95% CI 4 to 43) for PEF, in favour of the experimental group. None of the trials examined the effects of electrical stimulation on dyspnea or activity.

2.5 DISCUSSION

This review aimed at investigating all current interventions, which have been applied to improve respiratory function and carry-over effects to activity after stroke. Amongst the 17 included trials, the effects of five interventions on the following outcomes were investigated: inspiratory and expiratory muscle strength, FVC, FEV₁, PEF, dyspnea, and activity. Meta-analyses were performed for the effects of breathing exercises only on FVC, FEV₁, and PEF, while for respiratory muscle training, meta-analysis were performed for all outcomes of interest. For the remaining interventions, i.e., aerobic exercises, postural exercises, and addition of electrical stimulation, meta-analysis was not possible.

Two trials investigated the effects of aerobic exercises on respiratory function and activity after stroke [36,38]. Intensive aerobic exercises, compared with self-selected ones, were effective in improving FVC, FEV₁, walking speed, and walking capacity [36]. However, self-selected aerobic exercises, when compared with inspiratory muscle training was worse for FVC and FEV₁, and there was no difference between the groups for walking speed and walking capacity [38]. These results indicated that the effects of self-selected aerobic exercises on respiratory function were inferior to those related to intensive

aerobic exercises or inspiratory muscle training. These findings were somehow expected, since although low-intensity continuous training improves cardiorespiratory fitness and reduces lung function declines, individuals interested in enhanced outcomes should regularly do both larger volumes of training at higher intensities [39,40]. Furthermore, inspiratory muscle training is a specific intervention, with proven efficacy on measures of lung volumes and flows [19]. However, although the results are promising regarding the effects of intensive aerobic exercises and inspiratory muscle training, they were based only on two studies, of moderate methodological quality. Thus, further studies are necessary to allow a meta-analysis, to confirm these findings.

The effects of breathing exercises on respiratory function and activity after stroke were investigated in four studies [16,25,29,32]. Although all outcomes of interest were included, meta-analyses were only performed for the FVC, FEV₁, and PEF results. Only one trial examined the effects of breathing exercises on inspiratory and expiratory muscle strength, dyspnea, and activity after stroke [32]. Although significant mean differences between the groups were reported for MIP and MEP, the improvements were relatively small (4 and 2 cmH₂O, respectively), which were not considered clinically relevant. Breathing exercises were also not effective in reducing dyspnea, as measured by changes in the Borg scale [32]. Furthermore, although significant improvements in activity (Barthel Index) were reported, the mean difference between the groups and the confidence interval could not be calculated, due to insufficient data. The meta-analysis results also demonstrated no significant improvements in any of the lung function measures. These results indicate that breathing exercises, compared with nothing, appear not to be effective in improving FVC, FEV₁, and PEF. Different from the present results, a previous systematic review investigated the quality of evidence in systematic reviews, which analyzed the effects of breathing exercises in individuals with chronic obstructive pulmonary disease [41]. Although one high-quality systematic review reported significant positive effects on breathlessness, the results were based on pooled data of only two randomized clinical trials [41]. Thus, the authors concluded that before

high quality systematic reviews can be written and conclusions be drawn, more studies are necessary [41]. Similarly, the present review does not provide conclusive evidence to support or refute the effects of breathing exercises on respiratory function after stroke. Thus, future trials based upon high quality designs and adequate data reporting are necessary.

Only one study investigated the effects of postural exercises (lumbar stabilization) on respiratory function after stroke, compared with no intervention, and the results demonstrated that postural exercises improved FVC, FEV₁, and PEF [31]. It is well known that postural changes may affect respiratory function, due to decreased chest wall movements and reduced lung compliance [42]. The lungs are positioned inside the rib cage and normal or optimal thoracic spine, rib, and scapular positioning are needed for normal breathing and full lung capacity [13]. A recent study, that investigated the effects of specific motor control exercises of the lumbar-pelvic musculature on respiratory function in 20 obese men [43], reported significant improvement in respiratory function, concluding that positive respiratory effects can be obtained, by prescribing specific motor control exercises for the lumbar-pelvic muscles [43]. However, although the results also seem favorable, similar to those related to the aerobic exercises, they were based on only a single study of moderate methodological quality, requiring further studies to investigate the effects of postural exercises on respiratory function. Furthermore, the remaining outcomes of interest, i.e., MIP, MEP, dyspnea, and activity, were not examined.

The effects of respiratory muscle training on respiratory function and activity after stroke were investigated in 11 trials [14,24,26-30,32-35] and meta-analyses were performed for all outcomes of interest. Overall, respiratory muscle training significantly improved strength of the inspiratory and expiratory muscles, lung function (FVC, FEV₁, and PEF), dyspnea, and activity, when compared with nothing/sham intervention. Thus, this systematic review provided evidence that respiratory muscle training is effective in improving respiratory function and activity after stroke. During this intervention, individuals are asked to perform repetitive breathing exercises against an external load, using a flow-

dependent resistance or a pressure threshold [20,44]. Since respiratory muscles respond to training stimuli, by undergoing adaptations to their structure in the same manner as any other skeletal muscles, their fibers must be overloaded [6]. Furthermore, weakness of the respiratory muscles is associated with restrictive ventilatory patterns and reduced lung volumes and flows [45]. Thus, strengthening of the respiratory muscles has the potential to also improve lung function, as demonstrated by the meta-analysis results. In addition, abnormal respiratory function may lead to dyspnea in conditions of high and even under low effort demands, which may also interfere with the performance of daily activities [2,3,6,35]. These results are important for the area of stroke rehabilitation, since reduced dyspnea and increased walking capacity have the potential to improve physical activity levels and community participation after stroke [46]. Corroborating with the present results, two previous systematic reviews [6,19] also investigated the effects of respiratory muscle training after stroke and reported significant improvement in inspiratory and expiratory strength [6,19], lung function [19], exercise tolerance [19], besides decreased occurrence of respiratory complications [6], reinforcing the present findings. On average, 30 minutes of respiratory strength training, five times per week, for five weeks can be expected to improve respiratory function in individuals after stroke [6]. However, it is important to note that, although the results for dyspnea and activity were significant, more studies are still needed to investigate the effects of the training on these variables, since the meta-analyses were based on only two and three trials, respectively, of moderate methodological quality.

Finally, the effects of the addition of electrical stimulation to respiratory muscle training, compared to nothing, on respiratory function were examined in two trials [14,37]. Although the first found significant and positive results for respiratory strength, in favour of the electrical stimulation plus sham respiratory muscle training group, the control group did not receive any intervention. In addition, the experimental group received electrical stimulation plus sham respiratory training. This limits conclusions regarding the efficacy of electrical stimulation associated with respiratory muscle training. One could argue that

since a sham training was applied, the gains would be attributed to the effects of electrical stimulation. However, the sham training was delivered at a fixed load of 10cmH₂O, which could have the potential to improve respiratory function. On the other hand, the second trial applied electrical stimulation plus inspiratory muscle training, compared with inspiratory muscle training alone [31], but the results were not significant for any of the lung function measures, except for PEF. Different from these results, a recent systematic review, based on data of 14 trials, investigated the evidence surrounding the use of abdominal electrical stimulation on respiratory function after spinal cord injury [47]. Although functional electrical stimulation showed to be effective in improving respiratory function, the authors emphasized that further randomized controlled trials, with larger samples and standardized protocols, are needed to fully establish the clinical efficacy of this interventions. Thus, the present results, based only on two trials of moderate methodological quality, cannot affirm the effects of electrical stimulation on respiratory function after stroke. Furthermore, none of the trials examined its effects on dyspnea or measures of activity.

This review has both strengths and limitations. This is the first to investigate all current interventions, which have been applied, to improve respiratory function and activity after stroke. In addition, the majority of the outcome measures were reported in similar units, i.e., maximal respiratory pressures (cmH₂O), FVC and FEV₁ (L), and PEF (L/s). This is unusual in rehabilitation studies. Furthermore, publication bias inherent to systematic reviews was avoided, by including only randomized clinical trials, which were published in languages other than English. However, the mean PEDro score of the 17 included trials was 5.7, which is considered to be moderate. However, it is important to note that, because it is not usually possible to blind therapists or participants on such complex interventions, the maximum score to be reached would be eight. Other sources of bias were lack of reporting whether an intention-to-treat analysis was undertaken and the absence of concealed allocation and blinding of the assessors by the majority of the trials. Additionally, the number of participants per group (range 6 to 39) was quite low, opening the

results to small-trial bias. Heterogeneity was also high in three of the performed meta-analyses (>50%). Finally, it is necessary to emphasize the importance of specificity and overload principles during muscle strengthening exercises. Amongst all examined interventions, respiratory muscle training is the most specific and applies the highest overloads, which justifies its greatest effects.

2.6 CONCLUSION

This systematic review reported five possibilities of interventions, aiming at improving respiratory function after stroke. However, there is no evidence on the efficacy of aerobic, breathing, and postural exercises, as well as the addition of electrical stimulation. On the other hand, respiratory muscle training was the intervention that showed the most evidence, supporting its use within current clinical practice, with proved effects on inspiratory and expiratory strength, lung function (FVC, FEV₁, PEF), dyspnea, and activity. Thus, although nowadays there were found several interventions, which are potentially able to improve respiratory function after stroke, further randomized controlled trials, with larger samples and standardized protocols, are needed, to fully establish their clinical efficacies.

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Web Site

www.pedro.org.au

2.8 Quick Look

Current knowledge

There are currently many types of interventions, which have been employed to improve respiratory function after stroke. Summarize all current evidence may help professionals to carefully select the best intervention.

What this paper contributes to our knowledge

Respiratory muscle training was the intervention that showed the most evidence, supporting its use within current clinical practice, with proved effects on measures of inspiratory and expiratory strength, lung function, dyspnea, and activity. There is still no evidence to accept or refute the efficacy of aerobic, breathing, and postural exercises, and the addition of electrical stimulation on respiratory function after stroke.

2.9 Box

Design

- Randomized controlled trials

Participants

- Adults (>18 years of age)
- Diagnosis of stroke

Intervention

- Experimental intervention is a planned, structured, repetitive and purposive intervention, delivered to improve respiratory function

Outcome measures

- Inspiratory and/or expiratory muscle strength
- Lung function
- Dyspnea
- Activity

Box 1 Inclusion criteria.

2.10 Figures

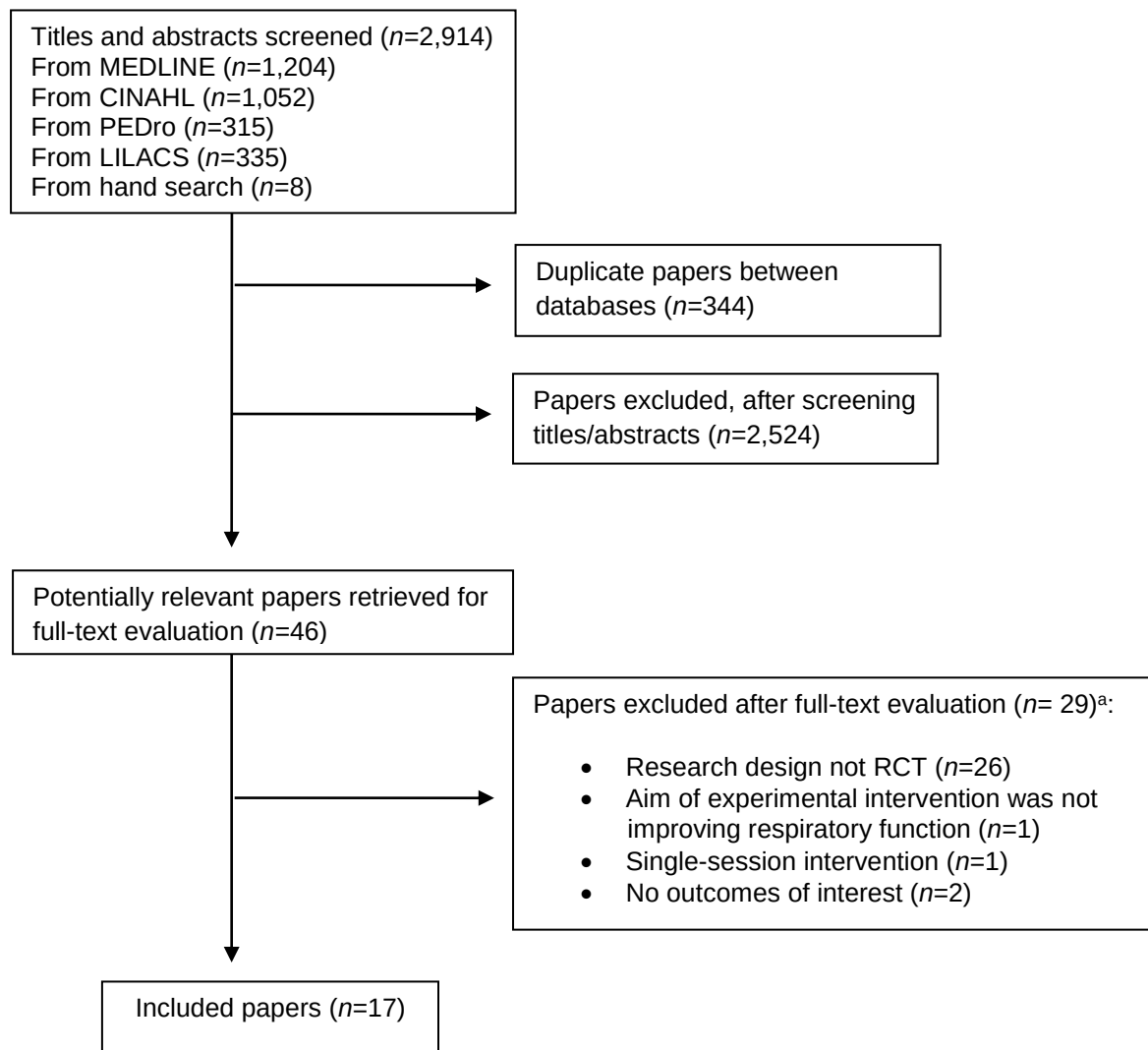


Figure 1. Flow of studies through the review. ^aPapers may have been excluded for failing to meet more than one inclusion criterion.

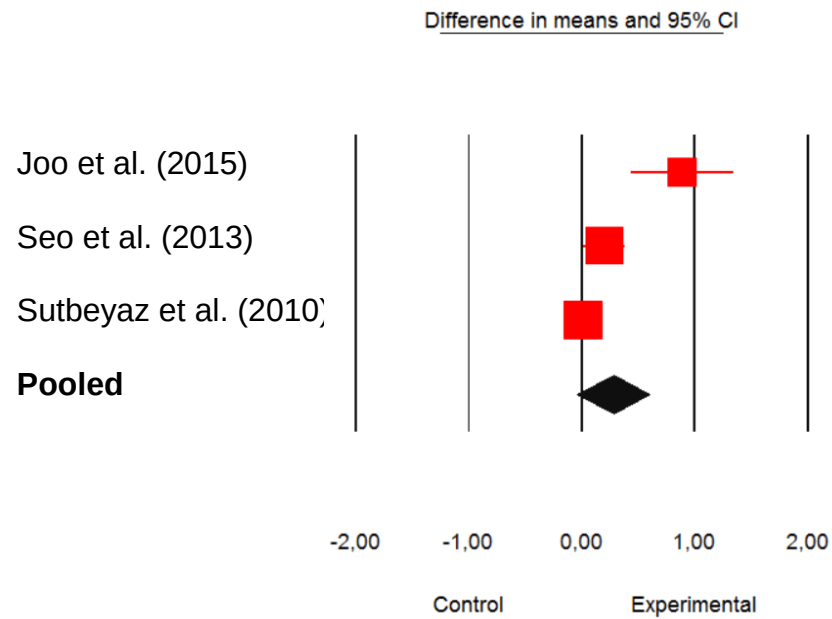


Figure 2. Mean difference (95% CI) of the effects of breathing exercises versus nothing/sham respiratory intervention on forced vital capacity, in L (n=98).

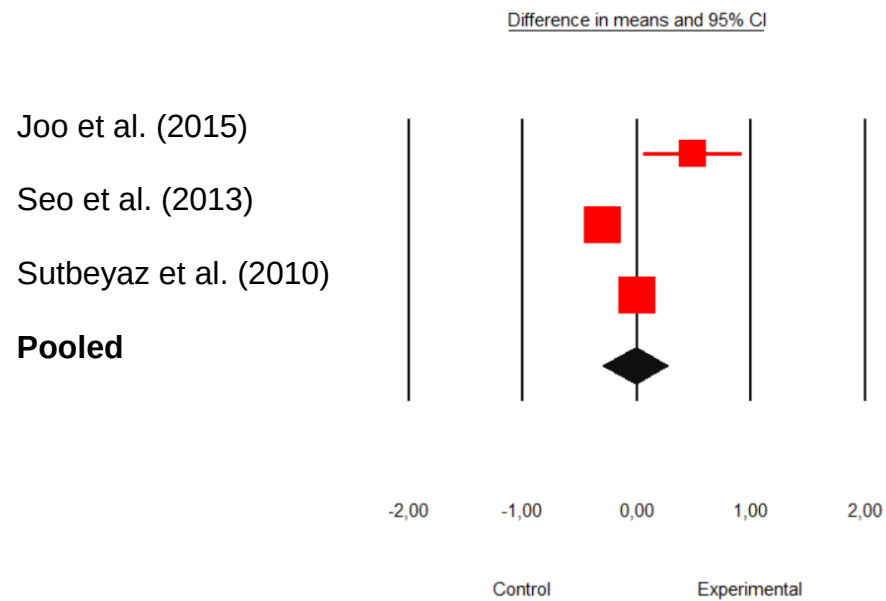


Figure 4. Mean difference (95% CI) of the effect of breathing exercises versus nothing/sham respiratory intervention on forced expiratory volume in 1 second, in L (n=98).

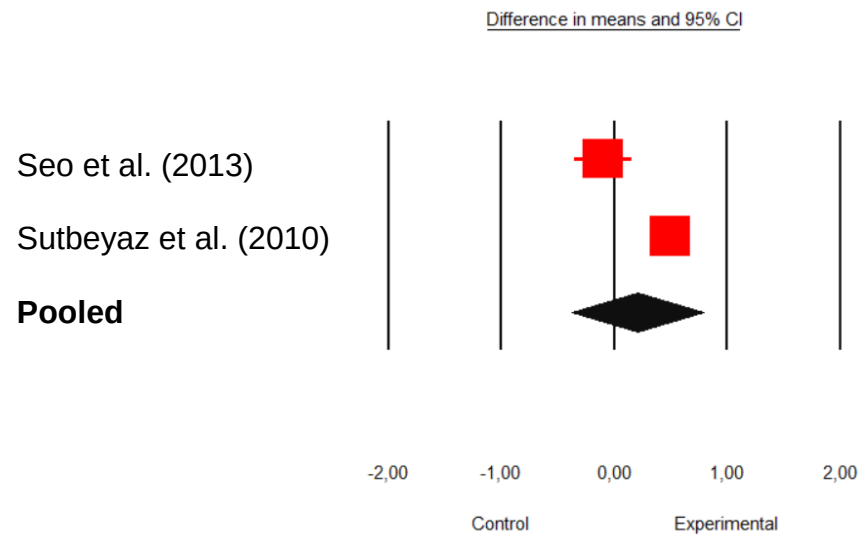


Figure 6. Mean difference (95% CI) of the effects of breathing exercises versus nothing/sham respiratory intervention on peak expiratory flow, in L/s (n=60).

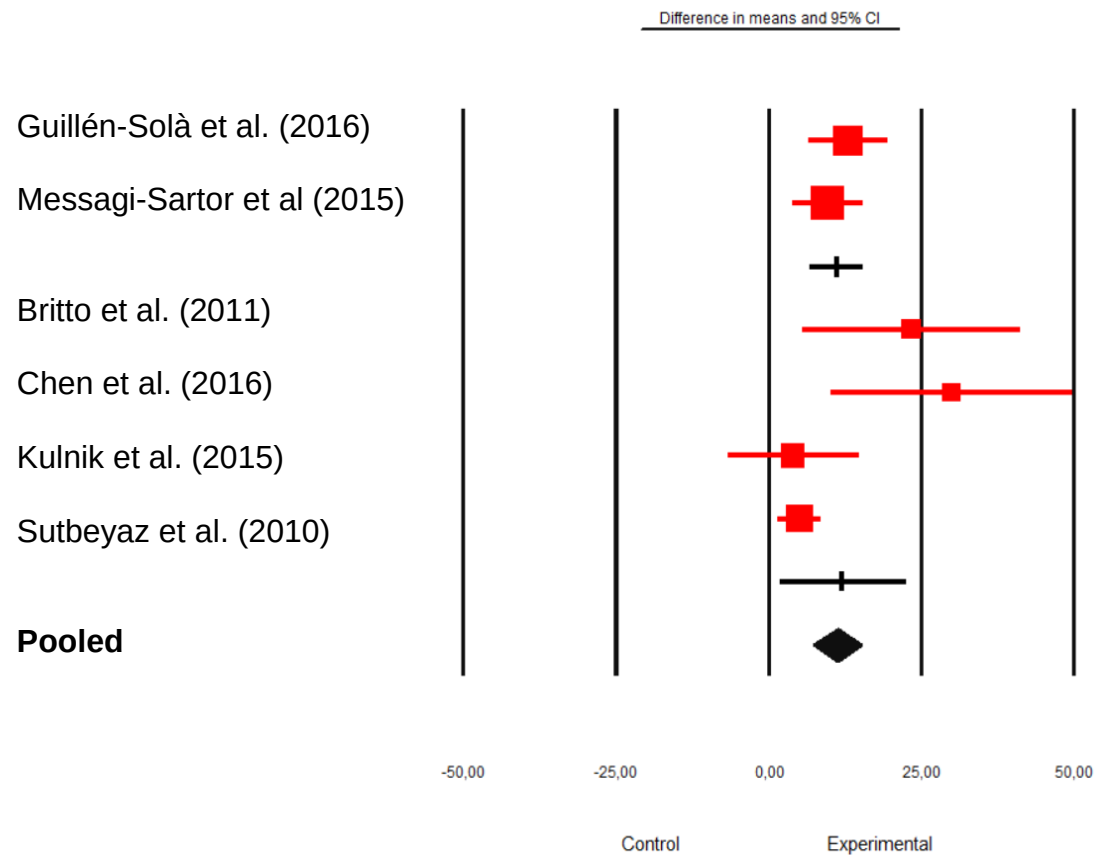


Figure 8. Mean difference (95% CI) of the effects of respiratory muscle training versus nothing/sham respiratory intervention on strength of the inspiratory muscles, in cmH₂O (n=229).

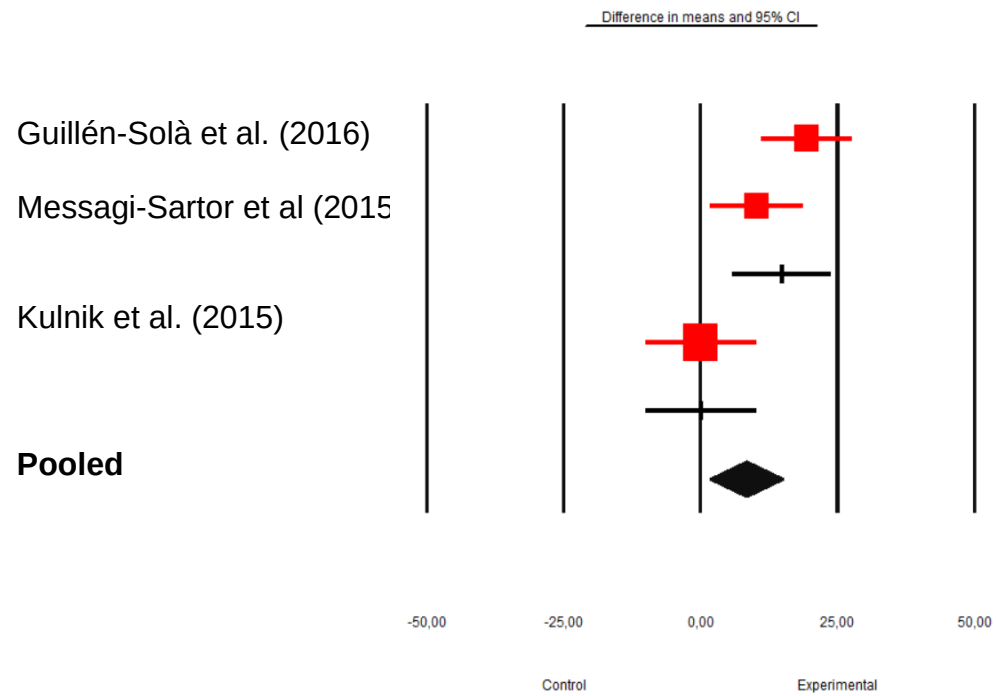


Figure 10. Mean difference (95% CI) of the effects of respiratory muscle training versus nothing/sham respiratory intervention on strength of the expiratory muscles, in cmH₂O (n=160).

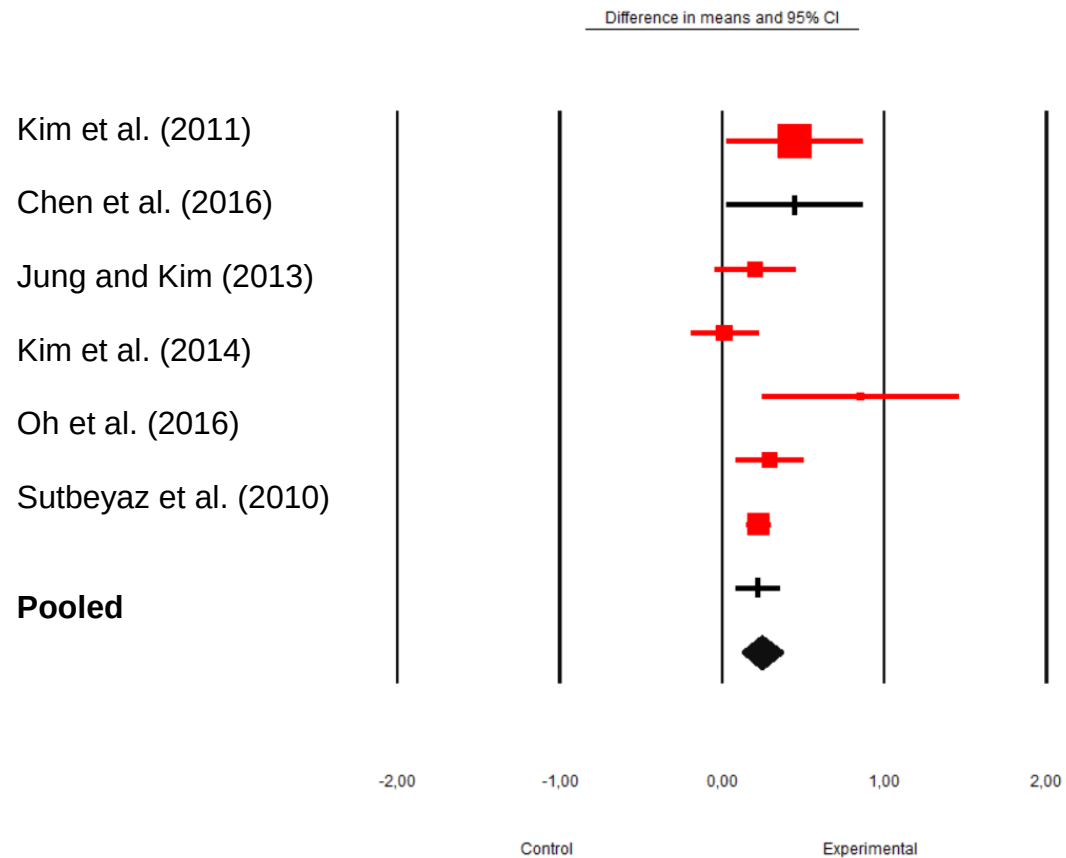


Figure 12. Mean difference (95% CI) of the effect of respiratory muscle training versus nothing/sham respiratory intervention on forced vital capacity, in L (n=150).

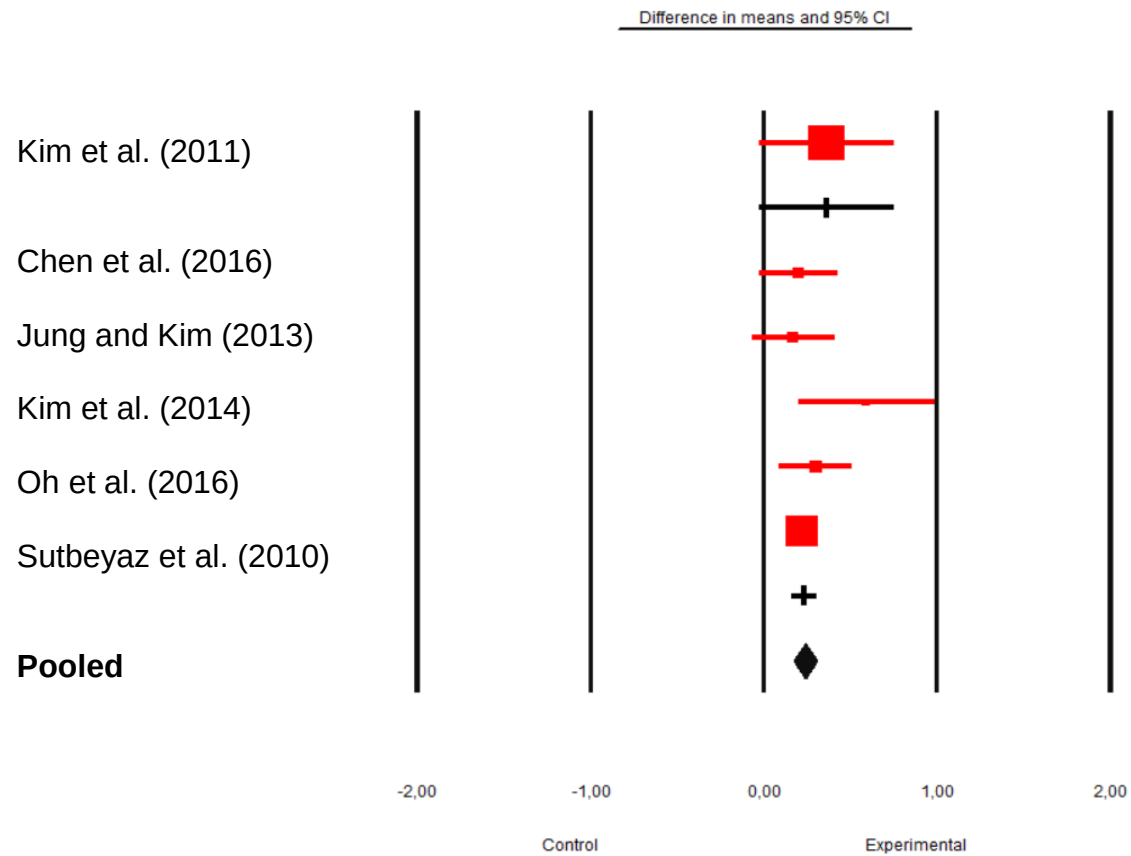


Figure 14. Mean difference (95% CI) of the effect of respiratory muscle training versus nothing/sham respiratory intervention on forced expiratory volume in 1 second, in L (n=150).

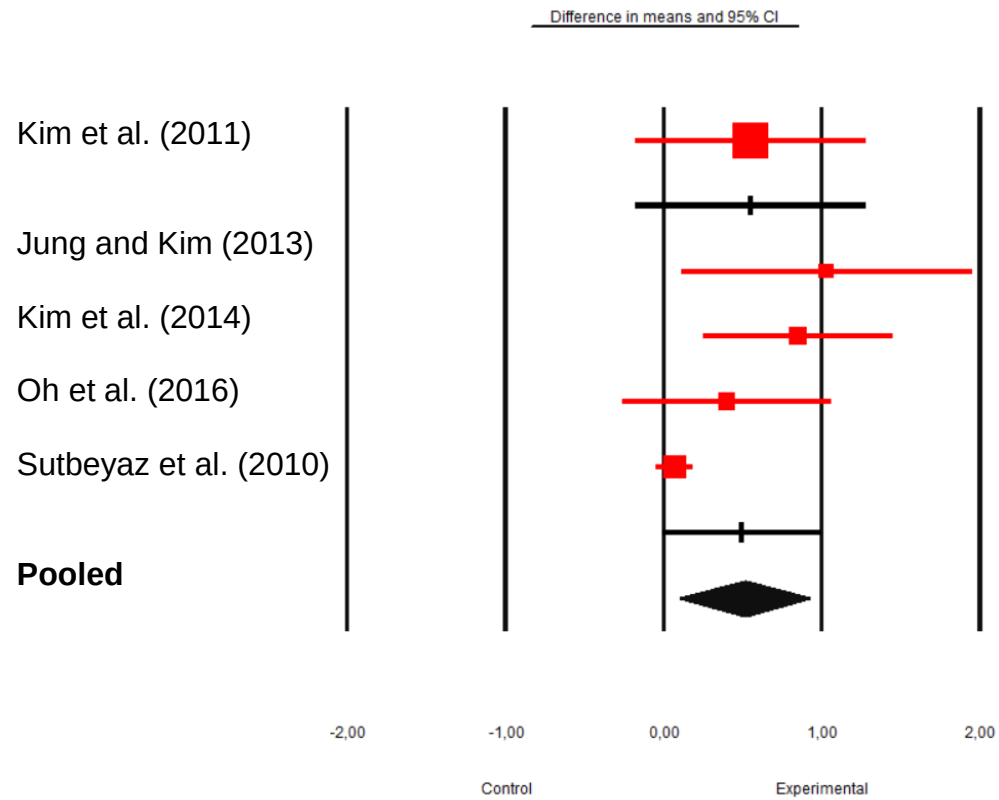


Figure 16. Mean difference (95% CI) of the effect of respiratory muscle training versus nothing/sham respiratory intervention on peak expiratory flow, in L/s (n=129).

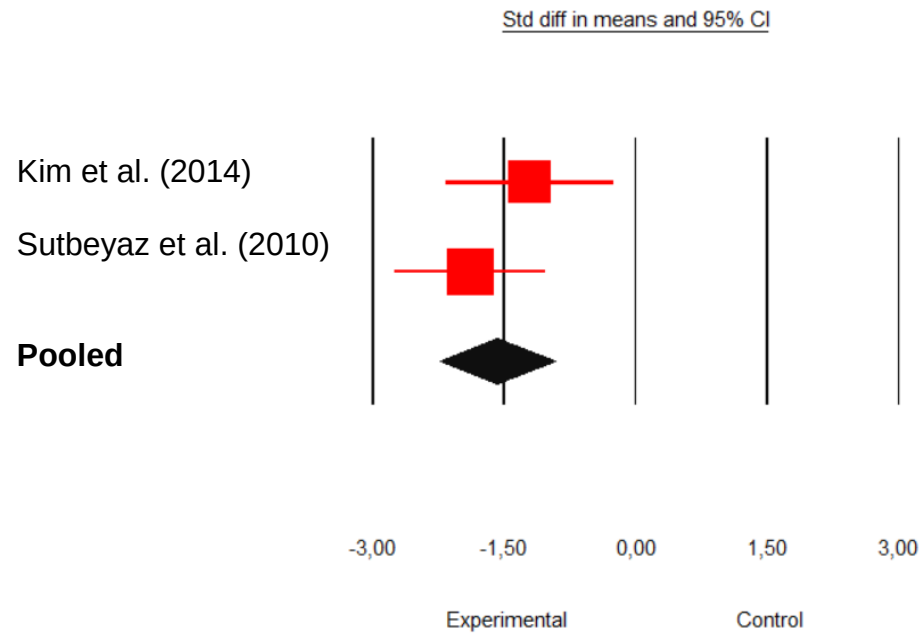


Figure 18. Mean difference (95% CI) of the effect of respiratory muscle training versus nothing/sham respiratory intervention on dyspnea (n=50).

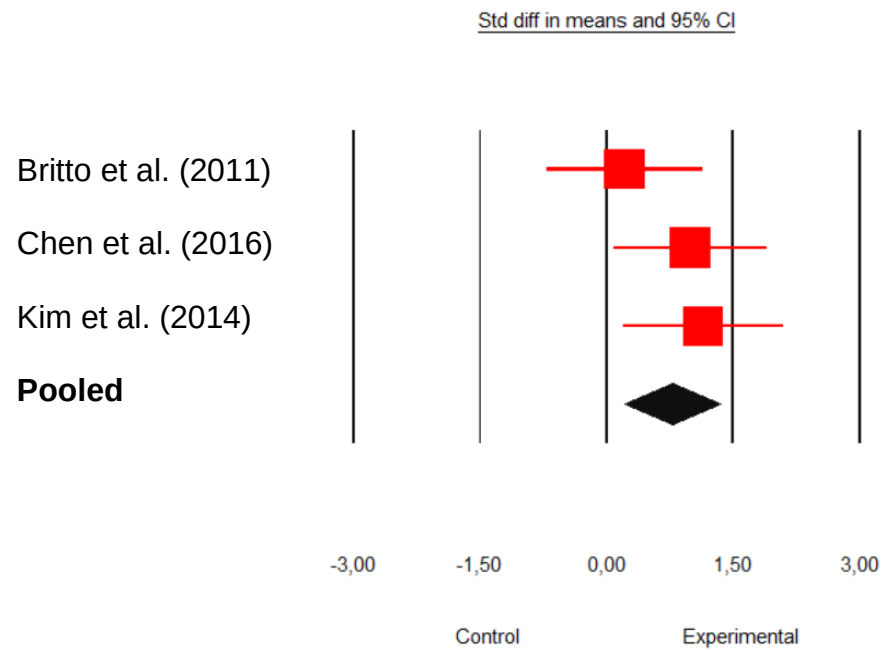


Figure 20. Mean difference (95% CI) of the effect of respiratory muscle training versus nothing/sham respiratory intervention on activity (n=59).

2.11 Tables

Table 1. Characteristics of the included randomized controlled trials

Study	Participants	Intervention	Outcome measures
Aerobic exercises			
Bang & Son (2016) [36]	Chronic stage n=12 Age (years) = 60 (6) Sex=7 men	<i>Experimental group:</i> Intensive aerobic exercise with an ergonomic cycle, at 50-80% of their maximal heart rate – 30 min x 5/wk x 4wk. <i>Control group:</i> Self-selected intensity exercise with an ergonomic cycle – 30 min x 5/wk x 4wk.	Pulmonary function (spirometric variables): FVC (L), and FEV ₁ (L) Oxygen saturation: pulse oximeter (%) Activity: 10MWT (seconds) and 6MWT (meters)
Jung & Bang (2017) [38]	Acute/sub-acute stages n=12 Age (years) = 62 (5) Sex =5 men	<i>Experimental group:</i> Inspiratory muscle training, with a fixed load of 30% of the MIP – 30 min x 5/wk x 4wk + conventional stroke rehabilitation program - 30 min x 5/wk x 4wk. <i>Control group:</i> Self-selected intensity aerobic exercise with an ergonomic cycle – 30 min x 5/wk x 4wk + conventional stroke rehabilitation program - 30 min x 5/wk x 4wk.	Pulmonary function (spirometric variables) = FVC (L), and FEV ₁ (L) Oxygen saturation = pulse oximeter (%) Activity = 10MWT (seconds) and 6MWT (meters)
Breathing /chest expansion /diaphragmatic exercise			
Joo et al. (2015) [25]	Chronic stage n=38 Age (years) = 56 (10) Sex = 22 men	<i>Experimental group:</i> Game-based breathing exercises, including 14 games, such as blowing a balloon, flying a kite, an airplane, and a windmill, etc – 25 min x 3/wk x 5wk + conventional stroke rehabilitation program- 30 min x 5/wk x 5wk. <i>Control group:</i> Conventional stroke rehabilitation program - 30 min x 5/wk x 5wk.	Pulmonary function (spirometric variables) = FVC (L), FEV ₁ (L), and MVV (L/min)

Kim et al. (2015) [29]	Acute/sub-acute stages n=37 Age (years) = 59 (6) Sex = 17 men	<i>Experimental group I:</i> Respiratory muscle training, with an incentive respiratory spirometer (load not reported) – 50 repetitions x 5/wk x 6wk + conventional stroke rehabilitation program- 60 min x 5/wk x 6wk. <i>Experimental group II:</i> Respiratory muscle training, with an incentive respiratory spirometer (load not reported) – 50 repetitions x 5/wk x 6wk + abdominal drawing-in maneuver – 50 repetitions x 5/wk x 6wk + conventional stroke rehabilitation program- 60 min x 5/wk x 6wk. <i>Control group:</i> Conventional stroke rehabilitation program- 60 min x 5/wk x 6wk.	Pulmonary function (spirometric variables) = FVC, and FEV₁ (All measures were reported as % predicted) Muscle activity = costal diaphragmatic and external intercostal muscles by surface electromyography (reported as % predicted).
Seo et al. (2013) [16]	Chronic stage n=30 Age (years) = 62 (3) Sex = 17 men	<i>Experimental group:</i> Inspiratory diaphragmatic and expiratory pursed-lip breathing exercises – 15 minutes x 5/wk x 4wk + feedback breathing device exercise - 15 minutes x 5/wk x 4wk + conventional stroke rehabilitation program - 30 minutes x 5/wk x 4wk. <i>Control group:</i> Feedback breathing device exercises - 15 minutes x 5/wk x 4wk + conventional stroke rehabilitation program - 30 minutes x 5/wk x 4wk.	Pulmonary function (spirometric variables) = FVC (L), FEV₁ (L), PEF (L/s), VC (L), TV (L), ERV (L), IRV (L), and IC (L)
Sutbeyaz et al. (2010) [32]	Acute/sub-acute stages n=45 Age (years) = 62 (7) Sex = 32 men	<i>Experimental group I:</i> Inspiratory muscle training, with a load of 40% of the MIP (adjusted 5-10% every week until 60% of maximal strength) – 30 minutes x 6/wk x 6wk + conventional stroke rehabilitation program- 5/wk x 6wk. <i>Experimental group II:</i> Breathing exercises – 30 minutes x 7/wk x 6wk + conventional stroke rehabilitation program- 5/wk x 6wk. <i>Control group:</i> Conventional stroke rehabilitation program- 5/wk x 6wk.	Pulmonary function (spirometric variables) = FVC (L), FEV₁ (L), VC (L), PEF (L/s), MVV (L/min), and and FEF 25–75% (%L) Strength = MIP (cmH₂O) Dyspnea = Borg Scale (4-20) Heart rate = bpm Oxygen consumption = peak oxygen consumption (ml/kg/min) Oxygen saturation = oximeter (%) Ventilação = minute ventilation (L/min) Activity = Barthel Index (score 0-100) / Cycle ergometer (W). Participation = Medical Outcomes Study Short Form 36 (score 0-100)

Postural exercises			
Oh & Park (2016) [31]	Chronic stage n=37 Age (years) = 56 (7) Sex = 22 men	<i>Experimental group:</i> Lumbar stabilization with eight-step exercises – 30 minutes x 3/wk x 8wk + conventional stroke rehabilitation program– 30 minutes x 3/wk x 8wk. <i>Control group:</i> Conventional stroke rehabilitation program– 60 minutes x 3/wk x 8wk.	Pulmonary function (spirometric variables) = FVC (L), FEV ₁ (L), and PEF (L/s)
Respiratory muscle training			
Britto et al. (2011) [35]	Chronic stage n=18 Age (years) = 54 (11) Sex = 9 men	<i>Experimental group:</i> Inspiratory muscle training, with a load of 30% of the MIP (adjusted every two weeks, according the new MIP value) - 30 min x 5/wk x 8wk. <i>Control group:</i> Sham inspiratory muscle training - 30 min x 5/wk x 8wk.	Strength : MIP (cmH₂O) Endurance: IME(cmH₂O) Activity: Human Activity Profile (0-94) / Cycle ergometer (W). Participation: Nottingham Health Profile (score 0-38)
Chen et al. (2016) [24]	Acute/sub-acute stages n=21 Age (years) = 66 (13) Sex = 8 men	<i>Experimental group:</i> Inspiratory muscle training, with a load of 30% of the MIP (adjusted by 2cmH₂O/wk) - 30 min x 5/wk x 10wk + conventional stroke rehabilitation program. <i>Control group:</i> Conventional stroke rehabilitation program	Strength: MIP and MEP (cmH₂O) Pulmonary function (spirometric variables): FVC (L), and FEV₁ (L) Oxygen saturation: pulse oximeter (%) Perceived exertion: Borg and Fatigue Assessment Scales (0-10) Activity: Barthel Index (0-100).
Guillén-Solà et al. (2016) [14]	Acute/sub-acute stages n=62 Age (years) = 69 (9) Sex = 38 men	<i>Experimental group I:</i> Respiratory muscle training, with a load of 30% of the MIP and MEP (adjusted by 10cmH₂O/wk) – 100 repetitions x 5/wk x 3wk + standard swallow therapy – 3hr x 5/wk x 3wk. <i>Experimental group II:</i> Sham respiratory muscle training, with a fixed load of 10cmH₂O/wk – 100 repetitions x 5/wk x 3wk + neuromuscular electrical stimulation in swallow muscles – 40min x 5/wk x 3wk + standard swallow therapy – 3hr x 5/wk x 3wk. <i>Control group:</i> Standard swallow therapy – 3hr x 5/wk x 3wk.	Strength: MIP and MEP (cmH₂O) Dysphagia: Penetration Aspiration Scale (1-8) Respiratory complications: Occurrence

Jung & Kim (2013) [26]	Chronic stage n=29 Age (years) = 59 (10) Sex = 17 men	<i>Experimental group:</i> Inspiratory muscle training, with a load of 30% of the MIP (adjusted gradually, according the Borg scale) - 20 min x 3/wk x 6wk. <i>Control group:</i> Nothing.	Pulmonary function (spirometric variables) = FVC (L), FEV ₁ (L), and PEF (L/s) Diaphragm thickness: Ultrasonography (cm) Chest expansion: Tapeline (cm)
Kim et al. (2011) [27]	Chronic stage n=27 Age (years) = 57 (7) Sex = 10 men	<i>Experimental group:</i> Feedback respiratory training, with the SpiroTiger device adjusted at 50 to 60% of the vital capacity and low frequency (12-13 breaths/minute) – 30 min x 3/wk x 4wk + conventional stroke rehabilitation program- 30 min x 3/wk x 4wk. <i>Control group:</i> Conventional stroke rehabilitation program- 30 min x 3/wk x 4wk.	Pulmonary function (spirometric variables): FVC (L), FEV ₁ (L), PEF (L/s), VC (L), TV (L), ERV (L), and IRV (L) Chest expansion: tapeline (cm)
Kim et al. (2014) [28]	Chronic stage n=20 Age (years) = 54 (9) Sex = Not reported	<i>Experimental group:</i> Respiratory muscle training and endurance, adjusted by the subjects' breathing capacities – 20 min x 3/wk x 4wk + conventional stroke rehabilitation program- 30 min x 3/wk x 4wk + exercises using an automated full-body workout machine - 20 min x 3/wk x 4wk. <i>Control group:</i> Conventional stroke rehabilitation program- 30 min x 3/wk x 4wk + exercises using an automated full-body workout machine - 20 min x 3/wk x 4wk.	Pulmonary function (spirometric variables): FVC (L), FEV ₁ (L), and PEF (L/s) Activity: 6MWT (meters) Dyspnea: Borg Scale (1-10).
Kim et al. (2015) [29]	Acute/sub-acute stages n=37 Age (years) = 59 (6) Sex = 17 men	<i>Experimental group I:</i> Respiratory muscle training, with an incentive spirometer (load not reported) – 50 repetitions x 5/wk x 6wk + conventional stroke rehabilitation program- 60 min x 5/wk x 6wk. <i>Experimental group II:</i> Respiratory muscle training, with an incentive spirometer (load not reported) – 50 repetitions x 5/wk x 6wk + abdominal drawing-in maneuver – 50 repetitions x 5/wk x 6wk + conventional stroke rehabilitation program- 60 min x 5/wk x 6wk. <i>Control group:</i> Conventional stroke rehabilitation program- 60 min x 5/wk x 6wk.	Pulmonary function (spirometric variables): FVC, and FEV ₁ (All measures were reported as % predicted) Muscle activity : Costal diaphragmatic and external intercostal muscles (surface electromyography, % predicted).

Kulnik et al. (2015) [34]	Acute/sub-acute stages n=78 Age (years) = 64 (15) Sex = 47 men	<i>Experimental group I:</i> Inspiratory muscle training, with a load of 50% of the MIP (adjusted every week, according the new MIP value) – 50 repetitions x 7/wk x 4wk. <i>Experimental group II:</i> Expiratory muscle training, with a load of 50% of the MEP (adjusted every week, according the new MEP value) – 50 repetitions x 7/wk x 4wk. <i>Control group:</i> Sham respiratory muscle training, with a fixed load of 10% of the maximal pressure - 50 repetitions x 7/wk x 4wk.	Strength: MIP, MEP (cmH₂O) Cough: Peak expiratory cough flow and capsaicin-induced involuntary cough (L/min) Respiratory complications: Occurrence of pneumonia
Oh et al. (2016) [30]	Chronic stage n=23 Age (years) = 71 (7) Sex = 13 men	<i>Experimental group:</i> Inspiratory muscle training, with a load of 30% of the MIP - 20 minutes x 3/wk x 6wk + conventional stroke rehabilitation program + abdominal strengthening and breathing exercises - 3/wk x 6wk. v <i>Control group:</i> Conventional stroke rehabilitation program plus abdominal strengthening and breathing exercises - 3/wk x 6wk.	Pulmonary function (spirometric variables): FVC (L), FEV₁ (L), and PEF (L/s) Thickness: Transverse abdominis and internal oblique muscles by ultrasonography (cm) Balance: Berg balance scale (0-56).
Messaggi-Sartor et al. (2015) [33]	Acute/sub-acute stages n=109 Age (years) = 67 (11) Sex = 63 men	<i>Experimental group:</i> Respiratory muscle training, with a load of 30% of the MIP and MEP (adjusted 10 cmH₂O every week) – 100 repetitions x 5/wk x 3wk. <i>Control group:</i> Respiratory muscle training – 100 repetitions x 5/wk x 3wk.	Strength: MIP, MEP (cmH₂O) Respiratory complications: Number of lung infections and pulmonary thromboembolisms. Peripheral muscle strength: Dynamometer (Kg)
Sutbeyaz et al. (2010) [32]	Acute/sub-acute stages n=45 Age (years) = 62 (7) Sex = 24 men	<i>Experimental group I:</i> Inspiratory muscle training, with a load of 40% of the MIP (adjusted 5-10% every week until 60% of maximal strength) – 30 minutes x 6/wk x 6wk + conventional stroke rehabilitation program- 5/wk x 6wk. <i>Experimental group II:</i> Breathing exercises – 30 minutes x 7/wk x 6wk + conventional stroke rehabilitation program- 5/wk x 6wk. <i>Control group:</i> Conventional stroke rehabilitation program- 5/wk x 6wk.	Pulmonary function (spirometric variables): FVC (L), FEV₁ (L), VC (L), PEF (L/s), MVV (L/min), and and FEF 25–75% (%L) Strength: MIP (cmH₂O) Dyspnea: Borg Scale (4-20) Heart rate: bpm Oxygen consumption: peak oxygen consumption (ml/kg/min) Oxygen saturation: oximeter (%)

			Ventilação: Minute ventilation (L/min) Functional capacity: electronically braked arm crank ergometer (W) Activity: Barthel Index (score 0-100) Participation: Medical Outcomes Study Short Form 36 (score 0-100)
Addition of electrical stimulation			
Guillén-Solà et al. (2016) [14]	Acute/sub-acute stages n=62 Age (years) = 69 (9) Sex = 38 men	<i>Experimental group I:</i> Respiratory muscle training, with a load of 30% of the MIP and MEP (adjusted by 10cmH₂O/wk) – 100 repetitions x 5/wk x 3wk + standard swallow therapy – 3hr x 5/wk x 3wk. <i>Experimental group II:</i> Sham respiratory muscle training, with a fixed load of 10cmH₂O/wk – 100 repetitions x 5/wk x 3wk + neuromuscular electrical stimulation in swallow muscles – 40min x 5/wk x 3wk + standard swallow therapy – 3hr x 5/wk x 3wk. <i>Control group:</i> Standard swallow therapy – 3hr x 5/wk x 3wk.	Strength: MIP and MEP (cmH ₂ O) Dysphagia: Penetration Aspiration Scale (1-8) Respiratory complications: Occurrence (number)
Jung et al. (2014) [37]	Chronic stage n=18 Age (years) = 55 Sex = 11 men	<i>Experimental group:</i> Inspiratory muscle training, with a fixed load of 30% of the MIP, while stimulation was applied to the abdominal region on the expiration moment – 20 min x 3/wk x 4wk. <i>Control group:</i> Inspiratory muscle training, with a fixed load of 30% of the MIP – 20 min x 3/wk x 4wk.	Pulmonary function (spirometric variables): FVC, FEV ₁ , PEF, and FEF 25–75% (All measures were reported as % predicted) Thickness = Diaphragm by ultrasonography (not reported)

10MWT= 10-meter walking test, 6MWT = six-minute walking test, MIP = maximal inspiratory pressure, MEP = maximal expiratory pressure, FVC = forced vital capacity, FEV₁ = forced expiratory volume in 1 second, PEF = peak expiratory flow, MVV = maximum voluntary ventilation, FEF 25–75% = forced expiratory flow between 25% and 75% of vital capacity, VC = vital capacity, TV = tidal volume, ERV = expiratory reserve volume, IRV = inspiratory reserve volume, and IC = inspiratory capacity.

Table 2: PEDro criteria and scores of the included randomized controlled trials (n=17).

Study	Random allocation	Concealed allocation	Groups similar at baseline	Participant blinding	Therapist blinding	Assessor blinding	< 15% dropouts	Intention-to-treat analysis	Between-group difference reported	Point estimate and variability reported	Total (0 to 10)
Bang & Son (2016)	Y	Y	Y	N	N	N	Y	N	Y	Y	6
Britto et al. (2011)	Y	Y	Y	N	N	Y	Y	N	Y	Y	7
Chen et al. (2016)	Y	N	Y	N	N	Y	N	N	Y	Y	5
Guillén-Solà et al. (2016)	Y	N	Y	N	N	Y	N	Y	Y	Y	6
Joo et al. (2015)	Y	N	Y	N	N	N	Y	N	Y	Y	5
Jung & Bang (2017)	Y	Y	Y	N	N	N	Y	N	Y	Y	6
Jung & Kim (2013)	Y	N	Y	N	N	Y	Y	N	Y	Y	6
Jung et al. (2014)	Y	N	Y	N	N	N	Y	N	Y	Y	5
Kim et al. (2011)	Y	N	Y	N	N	Y	N	N	Y	Y	5
Kim et al. (2014)	Y	N	Y	N	N	N	N	N	Y	Y	4
Kim et al. (2015)	Y	N	Y	N	N	N	Y	N	Y	Y	5
Kulnik et al. (2015)	Y	Y	Y	N	N	Y	N	Y	Y	Y	7
Messaggi-Sartor et al. (2015)	Y	Y	Y	N	N	Y	Y	Y	Y	Y	8
Oh et al. (2016)	Y	N	Y	N	N	N	Y	N	Y	Y	5
Oh & Park (2016)	Y	N	Y	N	N	N	Y	N	Y	Y	5

Seo et al. (2013)	Y	N	Y	N	N	N	N	N	Y	Y	4
Sutbeyaz et al. (2010)	Y	Y	Y	N	N	Y	Y	N	Y	Y	7

Y= yes; N=no

2.12 Search strategy

Appendix 1: Search strategies

Efficacy of interventions aiming at improving respiratory function after stroke: A systematic review.

Kênia KP Menezes, Lucas R Nascimento, Patrick R Avelino, Luci F Teixeira-Salmela.

Databases: MEDLINE, LILACS, PEDro, and CINAHL

MEDLINE

1. cerebrovascular disorders/ or exp basal ganglia cerebrovascular disease/ or exp brain ischemia/ or exp carotid artery diseases/ or exp intracranial arterial diseases/ or exp "intracranial embolism and thrombosis"/ or exp intracranial hemorrhages/ or stroke/ or exp brain infarction/ or vertebral artery dissection/
2. (stroke or poststroke or post-stroke or cerebrovasc\$ or brain vasc\$ or cerebral vasc\$ or cva\$ or apoplex\$ or SAH).tw.
3. ((brain\$ or cerebr\$ or cerebell\$ or intracran\$ or intracerebral) adj5 (isch?emi\$ or infarct\$ or thrombo\$ or emboli\$ or occlus\$)).tw.
4. ((brain\$ or cerebr\$ or cerebell\$ or intracerebral or intracranial or subarachnoid) adj5 (haemorrhage\$ or hemorrhage\$ or haematoma\$ or hematoma\$ or bleed\$)).tw.
5. hemiplegia/ or exp paresis/
6. (hemipleg\$ or hemipar\$ or paresis or paretic).tw.
7. or/1-6
8. breathing exercises/
9. respiratory therapy/
10. respiration/ or inhalation/ or exhalation/
11. exp inspiratory capacity/
12. exp respiratory muscles/
13. ((respirat\$ or inspirat\$ or expirat\$ or ventilat\$ or pulmonary) adj5 (therap\$ or train\$ or retrain\$ or exercise\$ or resist\$ or conditioning or strength\$ or weakness or endurance or muscle\$)).tw.
14. ((breathing or inhalation or exhalation) adj5 (exercise\$ or therap\$ or train\$ or retrain\$)).tw.
15. or/8-14
16. 7 and 15
17. exp animals/ not humans.sh.

18. 16 not 17
19. Randomized Controlled Trials as Topic/
20. random allocation/
21. Controlled Clinical Trials as Topic/
22. control groups/
23. clinical trials as topic/ or clinical trials, phase i as topic/ or clinical trials,
phase ii as topic/ or clinical trials, phase iii as topic/ or clinical trials, phase iv as
topic/
24. double-blind method/
25. single-blind method/
26. Placebos/
27. placebo effect/
28. cross-over studies/
29. Therapies, Investigational/
30. Research Design/
31. evaluation studies as topic/
32. randomized controlled trial.pt.
33. controlled clinical trial.pt.
34. (clinical trial or clinical trial phase i or clinical trial phase ii or clinical trial
phase iii or clinical trial phase iv).pt.
35. (evaluation studies or comparative study).pt.
36. random\$.tw.
37. (controlled adj5 (trial\$ or stud\$)).tw.
38. (clinical\$ adj5 trial\$).tw.
39. ((control or treatment or experiment\$ or intervention) adj5 (group\$ or
subject\$ or patient\$)).tw.
40. (quasi-random\$ or quasi random\$ or pseudo-random\$ or pseudo
random\$).tw.
41. ((multicenter or multicentre or therapeutic) adj5 (trial\$ or stud\$)).tw.
42. ((control or experiment\$ or conservative) adj5 (treatment or therapy or
procedure or manage\$)).tw.
43. ((singl\$ or doubl\$ or tripl\$ or trebl\$) adj5 (blind\$ or mask\$)).tw.

- 44. (coin adj5 (flip or flipped or toss\$)).tw.
- 45. versus.tw.
- 46. (cross-over or cross over or crossover).tw.
- 47. placebo\$.tw.
- 48. sham.tw.
- 49. (assign\$ or alternate or allocat\$ or counterbalance\$ or multiple baseline).tw.
- 50. controls.tw.
- 51. or/19-50
- 52. 18 and 51

LILACS

1. AVC OR “acidente vascular” OR AVE OR derrame OR hemiparesia OR hemiparéticos OR hemiparético OR paresia OR parético OR paréticos OR hemiplegia OR hemiplégico OR hemiplégicos OR isquêmico OR hemorrágico
2. Respiratório OR respiratórios OR respiração OR inspiração OR inspiratório OR inspiratórios OR expiração OR expiratório OR expiratórios OR ventilatório OR ventilatórios OR ventilação OR pulmonar OR diafragma OR abdominais
3. treino OR treinamento OR força OR fraqueza OR fortalecimento OR exercícios OR exercício OR condicionamento OR terapia OR retreino OR resistência OR endurance
4. 1 and 2 and 3

PEDro

1) Abstract & Title: Stroke OR Hemiparetic OR Hemiparesis
Therapy: respiratory therapy OR Strength Training

Problem: no selection

Body part: no selection

Subdiscipline: no selection

Method: Clinical Trial

CINAHL

1. (MH "Cerebrovascular Disorders+") or (MH "stroke patients") or (MH "stroke units")
2. TI (stroke or poststroke or post-stroke or cerebrovasc* or brain vasc* or cerebral vasc or cva or apoplex or SAH) or AB (stroke or poststroke or post-stroke or cerebrovasc* or brain vasc* or cerebral vasc or cva or apoplex or SAH)
3. TI (brain* or cerebr* or cerebell* or intracran* or intracerebral) or AB (brain* or cerebr* or cerebell* or intracran* or intracerebral)
4. TI (ischemi* or ischaemi* or infarct* or thrombo* or emboli* or occlus*) or AB (ischemi* or ischaemi* or infarct* or thrombo* or emboli* or occlus*)
5. S3 and S4
6. TI (brain* or cerebr* or cerebell* or intracerebral or intracranial or subarachnoid) or AB (brain* or cerebr* or cerebell* or intracerebral or intracranial or subarachnoid)
7. TI (haemorrhage* or hemorrhage* or haematoma* or hematoma* or bleed*) or AB (haemorrhage* or hemorrhage* or haematoma* or hematoma* or bleed*)
8. S6 and S7
9. (MH "Hemiplegia")
10. TI (hemipleg* or hemipar* or paresis or paretic) or AB (hemipleg* or hemipar* or paresis or paretic)
11. S1 or S2 or S5 or S8 or S9 or S10
12. (MH "Breathing Exercises (SabaCCC)") OR (MH "Breathing Exercises+")
13. (MH "Education, Respiratory Therapy") OR (MH "Home Respiratory Care") OR (MH "Inspiration, Respiratory") OR (MH "Respiratory Muscles+") OR (MH "Respiratory Nursing") OR (MH "Respiratory Nursing Society") OR (MH "Respiratory Therapists") OR (MH "Respiratory Therapy+") OR (MH "Respiratory Therapy Equipment and Supplies+") OR (MH "Respiratory Therapy Service")
14. (MH "Respiration (Omaha)") OR (MH "Respiration (Saba CCC)") OR (MH

"Respiration Alteration (Saba CCC)")

15. (MH "Respiration+") and (MH "Muscle Strengthening")

16. TI (respirat* or inspirat* or expirat* or ventilat* or pulmonary) OR AB (respirat* or inspirat* or expirat* or ventilat* or pulmonary)

17. TI (therap* or train* or retrain* or exercise* or resist* or conditioning or strength* or weakness or endurance or muscle*) OR AB (therap* or train* or retrain* or exercise* or resist* or conditioning or strength* or weakness or endurance or muscle*)

18. S16 and S17

19. TI (breathing or inhalation or exhalation) OR AB (breathing or inhalation or exhalation)

20. TI (exercise* or therap* or train* or retrain*) OR AB (exercise* or therap* or train* or retrain*)

21. S19 and S20

22. S12 or S13 or S14 or S15 or S18 or S21

23. S11 and S22

24. PT randomized controlled trial or clinical trial

25. (MH "Random Assignment") or (MH "Random Sample+")

26. (MH "Crossover Design") or (MH "Clinical Trials+") or (MH "Comparative Studies")

27. (MH "Control (Research)") or (MH "Control Group")

28. (MH "Factorial Design") or (MH "Quasi-Experimental Studies") or (MH "Nonrandomized Trials")

29. (MH "Placebo Effect") or (MH "Placebos") or (MH "Meta Analysis")

30. (MH "Clinical Research") or (MH "Clinical Nursing Research")

31. (MH "Community Trials") or (MH "Experimental Studies") or (MH "One-Shot Case Study") or (MH "Pretest-Posttest Design+") or (MH "Solomon Four-Group Design") or (MH "Static Group Comparison") or (MH "Study Design")

32. PT systematic review

33. TI random* or AB random*

34. TI (singl* or doubl* or tripl* or trebl*) or AB (singl* or doubl* or tripl* or trebl*)

- 35. TI (blind* or mask*) or AB (blind* or mask*)
- 36. S34 and S35
- 37. TI (crossover or cross-over or placebo* or control* or factorial or sham) or
AB (crossover or cross-over or placebo* or control* or factorial or sham)
- 38. TI (clin* or intervention* or compar* or experiment* or preventive or
therapeutic) or AB (clin* or intervention* or compar* or experiment* or
preventive or therapeutic)
- 39. TI trial* or AB trial*
- 40. S38 and S39
- 41. TI (counterbalance* or multiple baseline* or ABAB design) or AB (
counterbalance* or multiple baseline* or ABAB design)
- 42. TI (meta analysis* or metaanalysis or meta-analysis or systematic review*)
or AB (meta analysis* or metaanalysis or meta-analysis or systematic review*)
- 43. PT meta analysis
- 44. S24 or S25 or S26 or S27 or S28 or S29 or S30 or S31 or S32 or S33 or
S34 or S35 or S36 or S37 or S38 or S39 or S40 or S41 or S42 or S43
- 45. S23 and S44

2.13 Excluded papers

Appendix 2: Excluded papers

Efficacy of interventions aiming at improving respiratory function after stroke: A systematic review.

Kênia KP Menezes, Lucas R Nascimento, Patrick R Avelino, Luci F Teixeira-Salmela

Studies	Reasons for exclusion			
	1	2	3	4
Almeida et al (2011)	✓			
Aziz et al. (2008)	✓	✓		
Cuezy et al. (2010)	✓			✓
Gomes-Neto et al. (2016)	✓			
Harraf et al. (2008)	✓			
Hegland et al. (2016)	✓			
Jo et al. (2014)	✓			
Jo et al. (2016)	✓			
Jung and Kim (2015)	✓			
Kim et al. (2015)			✓	
Kulnik et al. (2014)	✓			
Martín-Valero et al. (2015)				
Meireles et al. (2012)	✓			
Menezes et al. (2016)	✓			
Menezes et al. (2017)	✓			
Narain and Puckree (2002)	✓			
Nuzzo et al. (1999)	✓			
Ocko and Costa (2014)	✓			
Ovando et al. (2010)	✓			
Park et al. (2016)				✓
Pollock et al. (2013)	✓			
Queiroz et al. (2014)	✓			
Raquel et al. (2015)	✓			
Rimmer et al. (2000)	✓			
Seo et al. (2012)	✓			
Song and Park (2015)	✓			
Veerbeek et al. (2014)	✓			
Xiao et al. (2012)	✓			
Yamashita et al. (2010)	✓			

1 = Research design not RCT

2 = Aim of experimental intervention was not to improve respiratory function

3 = Single-session intervention

4 = No outcomes of interest

Almeida ICL, Clementino ACR, Rocha EHT, Brandão DC, Andrade AD. Effects of hemiplegia on pulmonary function and diaphragmatic dome displacement. *Respir Physiol Neurobiol.* 2011; 178: 196- 201.

Aziz NA, Leonardi-Bee J, Phillips M, Gladman JR, Legg L, Walker MF (2008). Therapy-based rehabilitation services for patients living at home more than one year after stroke. *Cochrane Database Syst Rev*. 16;(2). Art No: CD005952. DOI: 10.1002/14651858.CD005952.pub2.

Cuesy PG, Sotomayor PL, Piña JO (2010). Reduction in the incidence of poststroke nosocomial pneumonia by using the "turn-mob" program. *J Stroke Cerebrovasc Dis*. 19(1): 23-28.

Gomes-Neto M, Saquetto MB, Silva CM, Carvalho VO, Ribeiro N, Conceição CS (2001). Effects of respiratory muscle training on respiratory function, respiratory muscle strength, and exercise tolerance in patients post stroke: A systematic review with meta-Analysis. *Arch Phys Med Rehabil*. 97:1994-2001.

Harraf F, Ward K, Man W, Rafferty G, Mills K, Polkey M, Moxham J, Kalra L (2008). Transcranial magnetic stimulation study of expiratory muscle weakness in acute ischemic stroke. *Neurology*. 9(24):2000-2007.

Hegland KW, Davenport PW, Brandimore AE, Singletary FF, Troche MS (2016). Rehabilitation of swallowing and cough functions following stroke: An expiratory muscle strength training trial. *Arch Phys Med Rehabil*. 97(8):1345-51.

Jo M, Kim N, Jung J (2014). The effects of respiratory muscle training on respiratory function, respiratory muscle strength, and cough capacity in stroke patients. *J Korean Soc Phys Med*. 9(4): 399-406.

Jo M-R, Kim N-S. The correlation of respiratory muscle strength and cough capacity in stroke patients (2016). *J Phys Ther Sci*. 28(10):2803-2805.

Jung J, Kim N. The effect of progressive high-intensity inspiratory muscle training and fixed high-intensity inspiratory muscle training on the asymmetry of diaphragm thickness in stroke patients. *J Phys Ther Sci*. 27(10):3267-3269.

Kim CB, Shin JH, Choi JD (2015). The effect of chest expansion resistance exercise in chronic stroke patients: a randomized controlled trial. *J Phys Ther Sci*. 27(2):451-453.

Kulnik ST, Rafferty GF, Birring SS, Moxham J, Kalra L (2014). A pilot study of respiratory muscle training to improve cough effectiveness and reduce the incidence of pneumonia in acute stroke: study protocol for a randomized controlled trial. *Trials*. 12;15:123.

Martín-Valero R, De La Casa Almeida M, Casuso-Holgado MJ, Heredia-Madrado A (2015). Systematic Review of Inspiratory Muscle Training After Cerebrovascular Accident. *Respir Care*. 60(11):1652-9.

Meireles ALF, Meireles LCF, Queiroz JCES, Tassitano RM, Soares FO, Oliveira AS (2012). Effectiveness of electrical stimulation in expiratory muscle on cough of patients after stroke. *Fisioter Pesqui*. 19(4):314-319.

Menezes KKP, Nascimento LR, Ada L, Polese JC, Avelino PR, Teixeira-Salmela LF (2016). Respiratory muscle training increases respiratory muscle strength and reduces respiratory complications after stroke: a systematic review. *J Physiother*. 62: 138-144.

Menezes KKP, Nascimento LR, Polese JC, Ada L, Teixeira-Salmela LF (2017). Effect of high-intensity home-based respiratory muscle training on strength of 1 respiratory muscles after stroke: A protocol for a randomised controlled trial. *Braz J Phys Ther. Ahead of print*

Narain S, Puckree T (2002). Pulmonary function in hemiplegia. *Int J Rehabil Res*. 25(1):57-59.

Nuzzo NA; Bronson LA, McCarthy T, Massery M (1999). Respiratory muscle strength and endurance following at CVA. *J Neuro Phys Ther*. 23(1):25-27.

Ocko R, Costa MC (2014). Respiratory Changes in Patients with Stroke. *Biomed Biopharm Res.* (11)2:141-150.

Ovando AC, Michaelsen SM, Dias JA, Herber V (2010). Gait training, cardiorespiratory training and strength training after stroke: strategies, dose and outcomes. *Fisioter mov.* 23(2):253-269.

Park JS, Oh DH, Chang MY, Kim KM (2016). Effects of expiratory muscle strength training on oropharyngeal dysphagia in subacute stroke patients: a randomised controlled trial. *J Oral Rehabil.* 43(5):364-72.

Pollock RD, Rafferty GF, Moxham J, Kalra L (2013). Respiratory muscle strength and training in stroke and neurology: a systematic review. *Int J Stroke.* 8(2):124-130.

Queiroz AGC, Silva DD, Lira RAC, Bassini SRF, Uematsu ESC. Respiratory muscle training associated with electrical stimulation diaphragmatic in hemiparesis. *Rev Neurocienc.* 22(2):294-299.

Raquel DFS, Quitério RJ, Campos MF, Vieira S, Ambrozini ARP (2015). Effects of the resisted exercise in the respiratory function of individuals with hemiparesis after stroke. *Pulm Res Respir Med Open J.* 2(2): 84-89.

Rimmer JH, Riley B, Creviston T, Nicola T (2000). Exercise training in a predominantly African-American group of stroke survivors. *Med Sci Sports Exerc.* 32(12):1990-1996.

Seo KC, Kim Ha, Lim SW (2012). Effects of feedback respiratory exercise and diaphragm respiratory exercise on the pulmonary function of chronic stroke patients. *J Int Acad Phys Ther Res.* 3(2): 413-478.

Song G bin, Park E cho (2015). Effects of chest resistance exercise and chest expansion exercise on stroke patients' respiratory function and trunk control ability. *J Phys Ther Scie.* 27(6):1655-1658.

Veerbeek JM, Wegen E, Peppen R, Wees PJ, Hendriks E, Rietberg M, Kwakkel G (2014). What is the evidence for physical therapy poststroke? A systematic review and meta-analysis. *PLoS One.* 9(2):1-33.

Xiao Y, Luo M, Wang J, Luo H (2012). Inspiratory muscle training for the recovery of function after stroke. *Cochrane Database Syst Rev.* 16:5. Art No:CD009360. DOI: 10.1002/14651858.CD009360.pub2.

Yamashita K, Kikuchi N, Ito K (2010). Effects of expiratory muscle training on respiratory muscle strength and cough intensity of stroke patients. *Rigakuryoho Kagaku.* 25(6):849-853.

2.14 Detailed forest plots

Figures 3, 5, 7, 9, 11, 13, 15, 17, 19, and 21: Detailed forest plots

Efficacy of interventions aiming at improving respiratory function after stroke: A systematic review.

Kênia KP Menezes, Lucas R Nascimento, Patrick R Avelino, Luci F Teixeira-Salmela

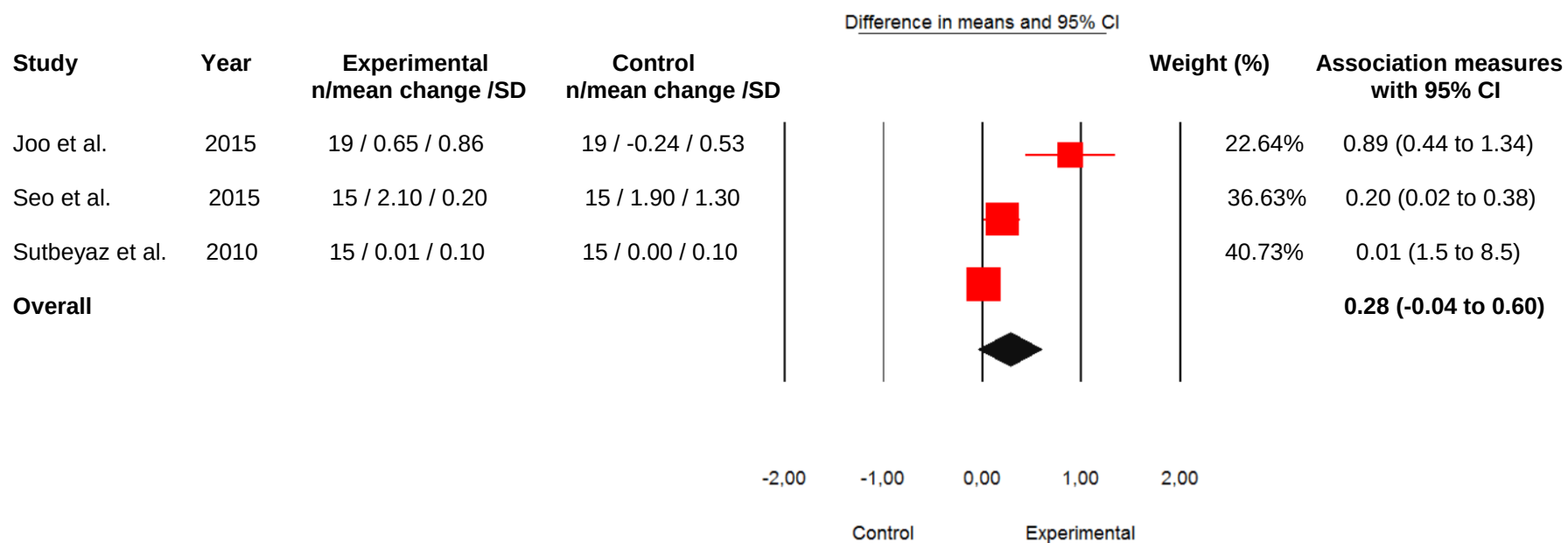


Figure 3. Mean difference (95% CI) of the effect of breathing exercises versus nothing/sham intervention on forced vital capacity, in L (n=98), with a random-effects model, $I^2=54\%$.

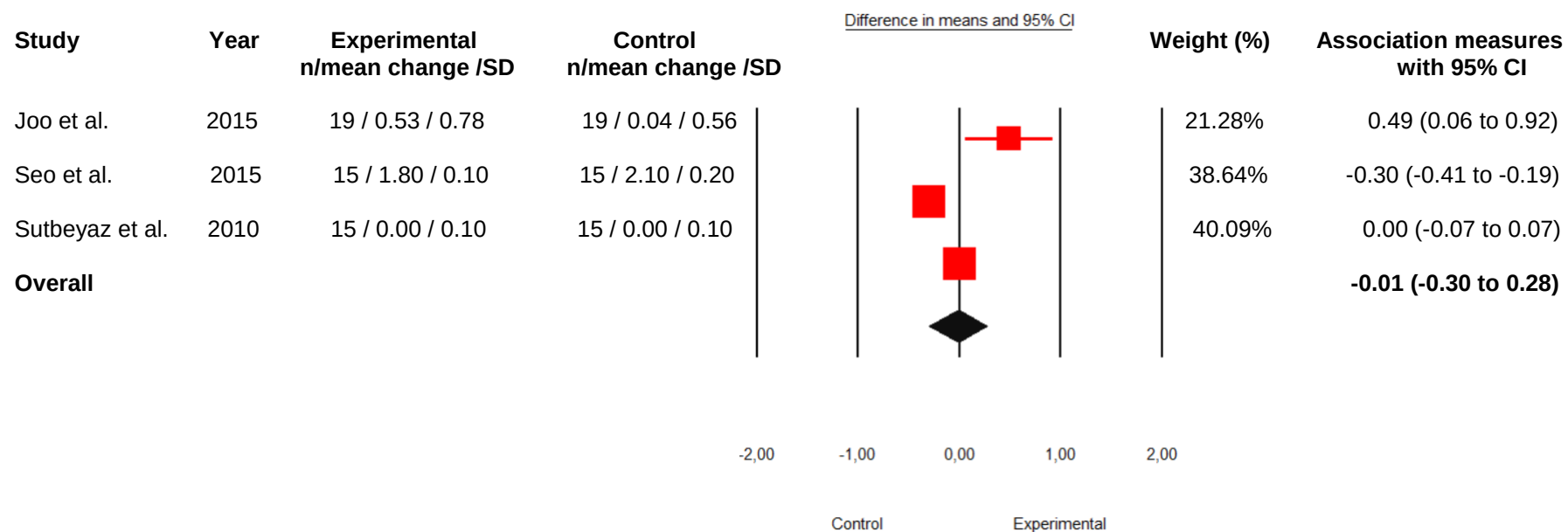


Figure 5. Mean difference (95% CI) of the effect of breathing exercises versus nothing/sham intervention on forced expiratory volume in 1 second, in L (n=98), with a random-effects model, $I^2 = 50\%$.

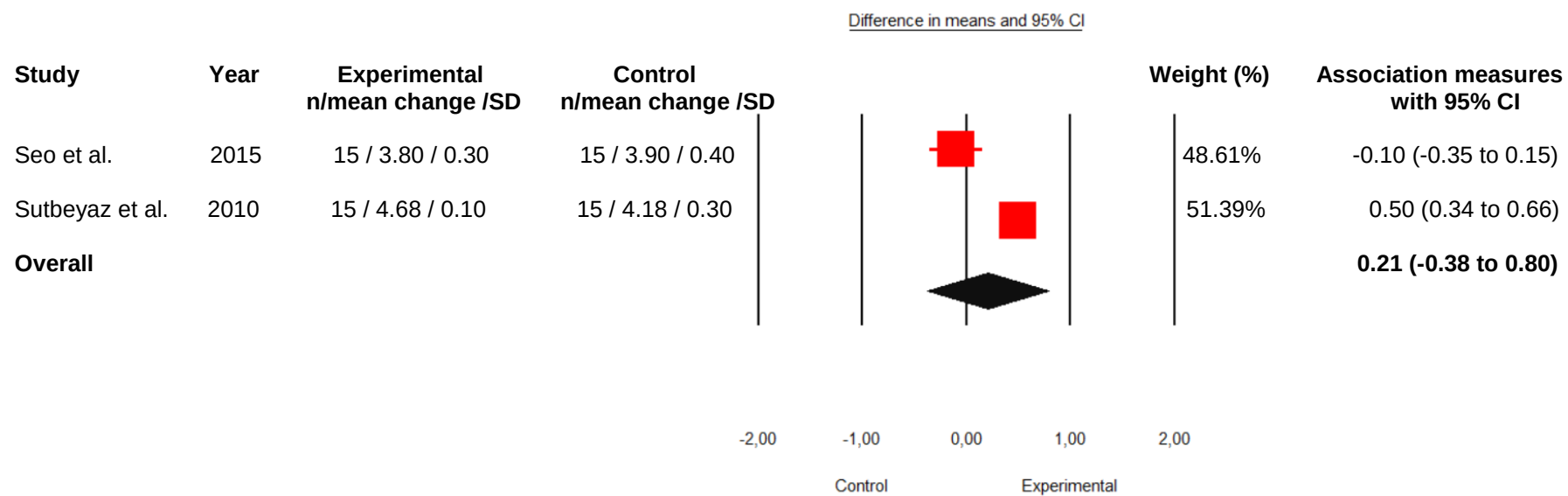


Figure 7. Mean difference (95% CI) of the effect of breathing exercises versus nothing/sham intervention on peak expiratory flow, in L/s (n=60), with a random-effects model, $I^2 = 0\%$.

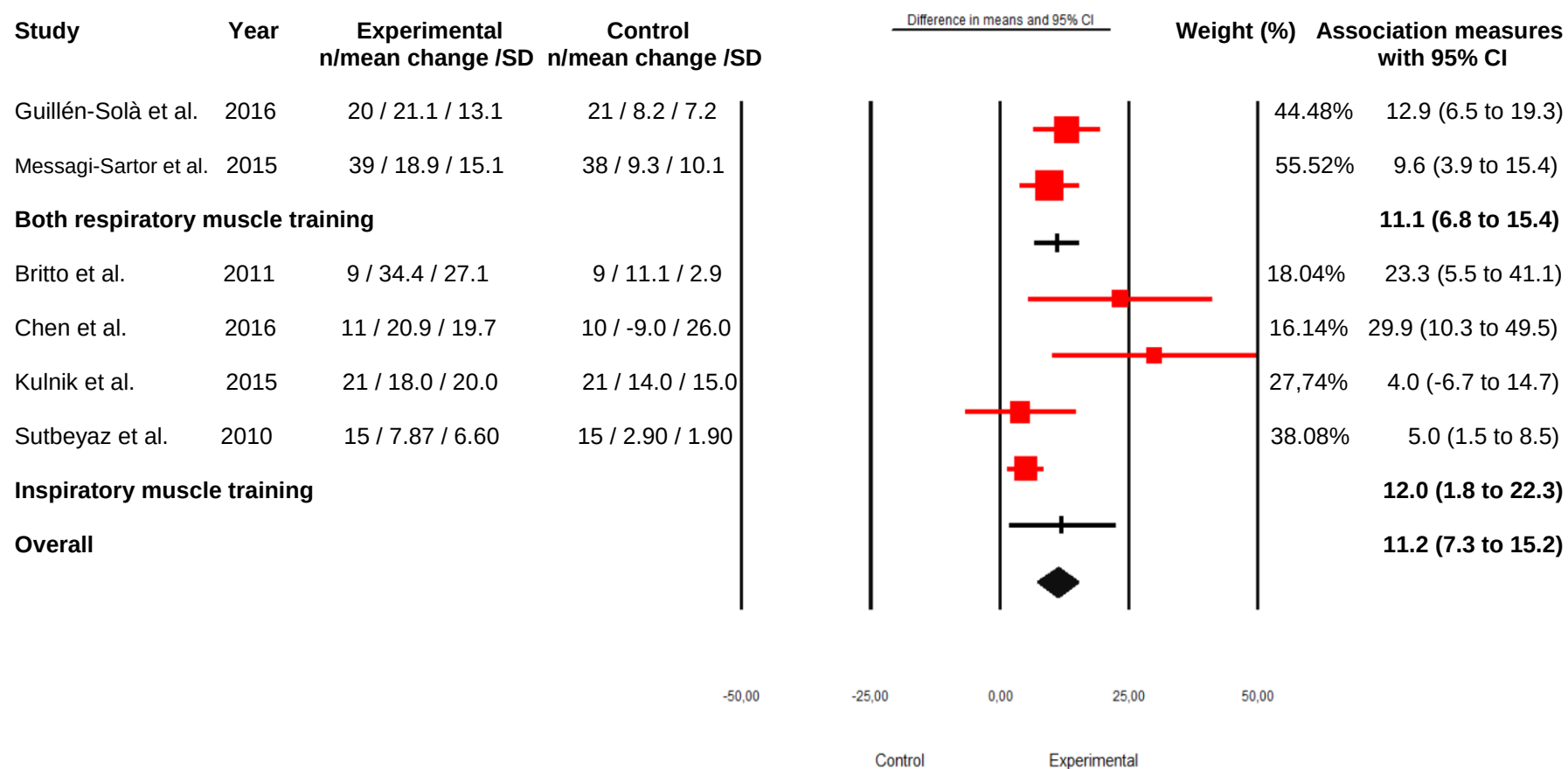


Figure 9. Mean difference (95% CI) of the effect of respiratory muscle training versus nothing/sham intervention on inspiratory muscle strength, in cmH₂O (n=229), with a random-effects model, I² =0%.

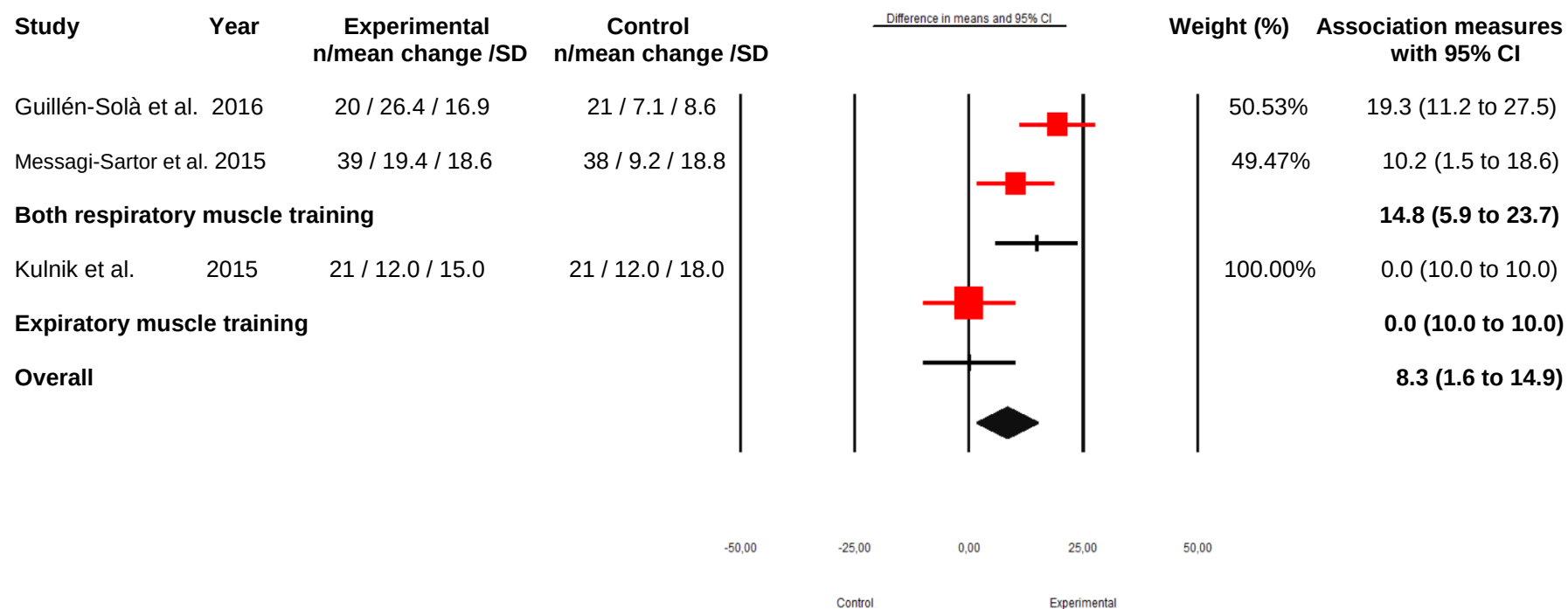


Figure 11. Mean difference (95% CI) of the effect of respiratory muscle training versus nothing/sham intervention on expiratory muscle strength, in cmH₂O (n=160), with a random-effects model, I² =65%.

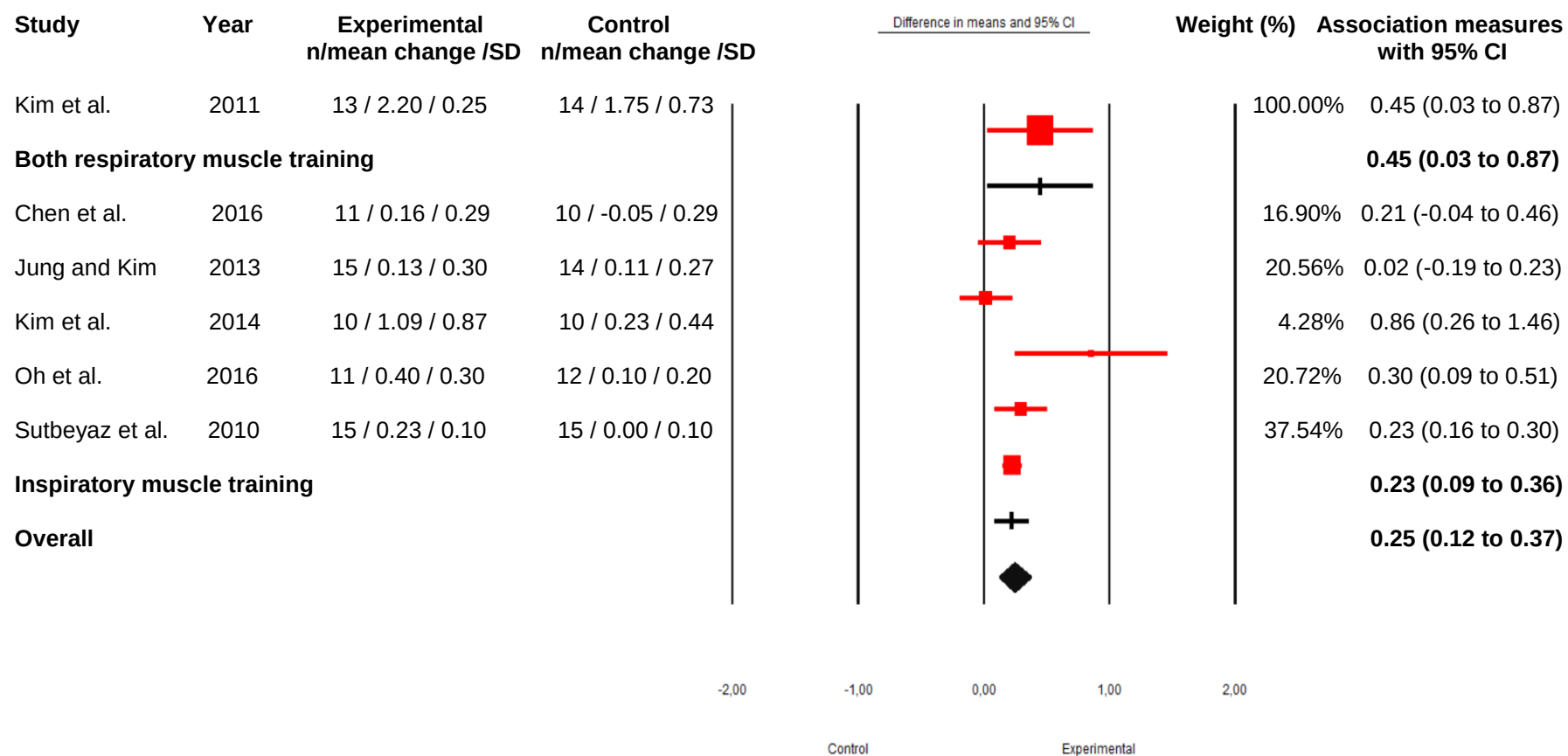


Figure 13. Mean difference (95% CI) of the effect of respiratory muscle training versus nothing/sham intervention on forced vital capacity, in L (n = 150), with a random-effects model, $I^2=29\%$.

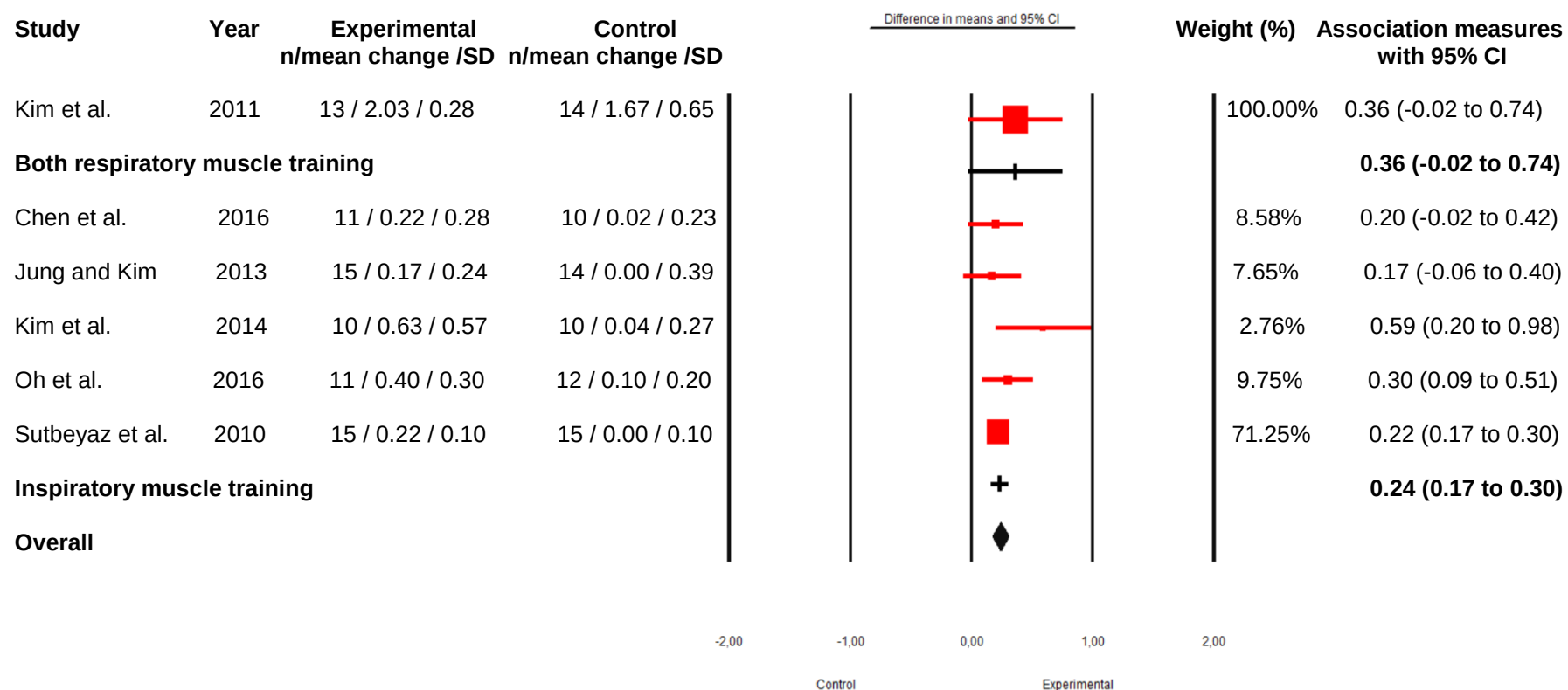


Figure 15. Mean difference (95% CI) of the effect of respiratory muscle training versus nothing/sham intervention on forced expiratory volume in 1st second, in L (n=150), with a random-effects model, $I^2 = 0\%$.

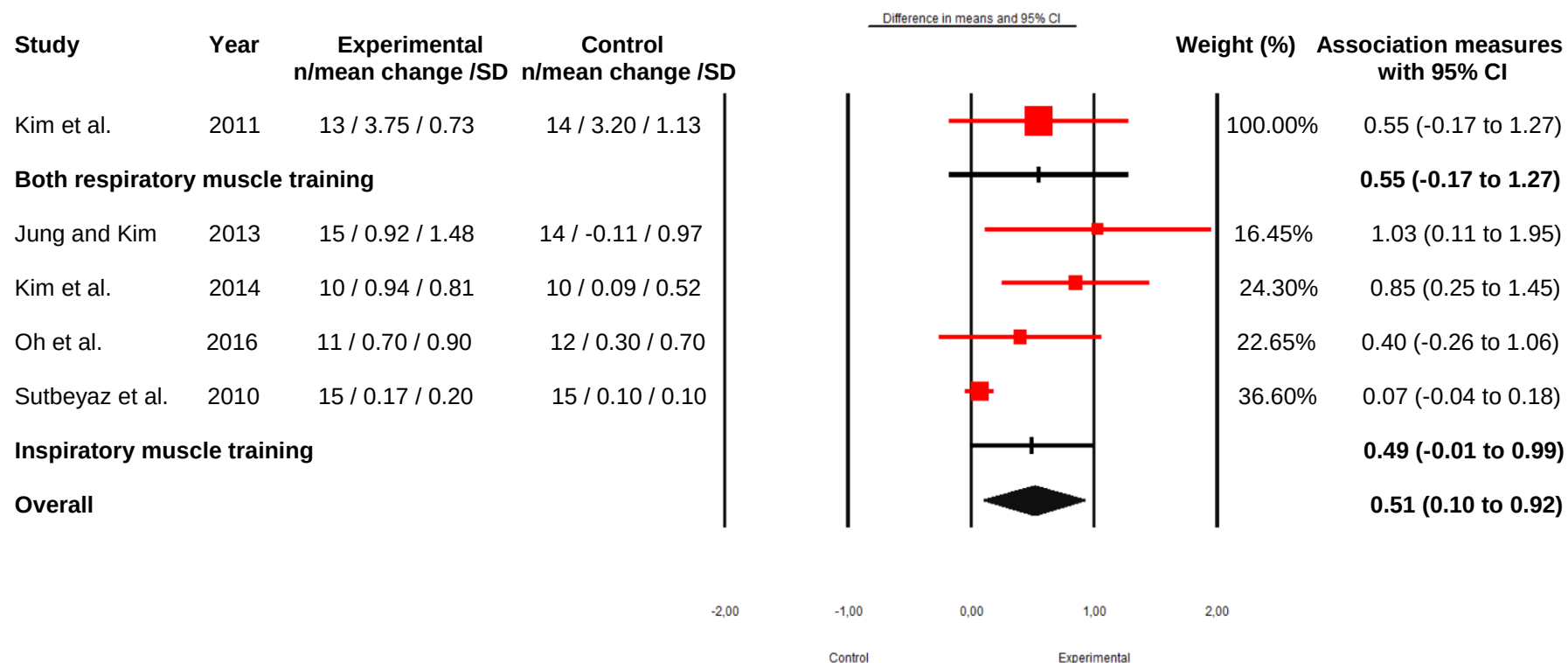


Figure 17. Mean difference (95% CI) of the effect of respiratory muscle training versus nothing/sham intervention on peak expiratory flow, in L/s (n=129), with a random-effects model, $I^2 = 0\%$.

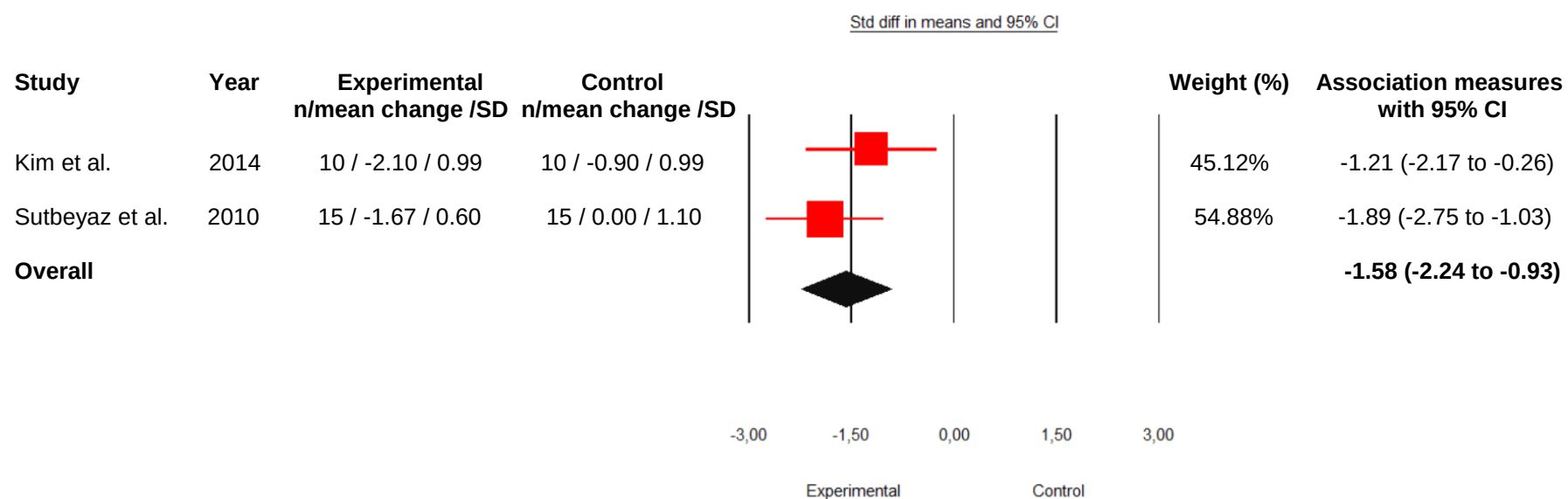


Figure 19. Mean difference (95% CI) of the effect of respiratory muscle training versus nothing/sham intervention on dyspnea, (n=50), with a random-effects model, $I^2 = 0\%$.

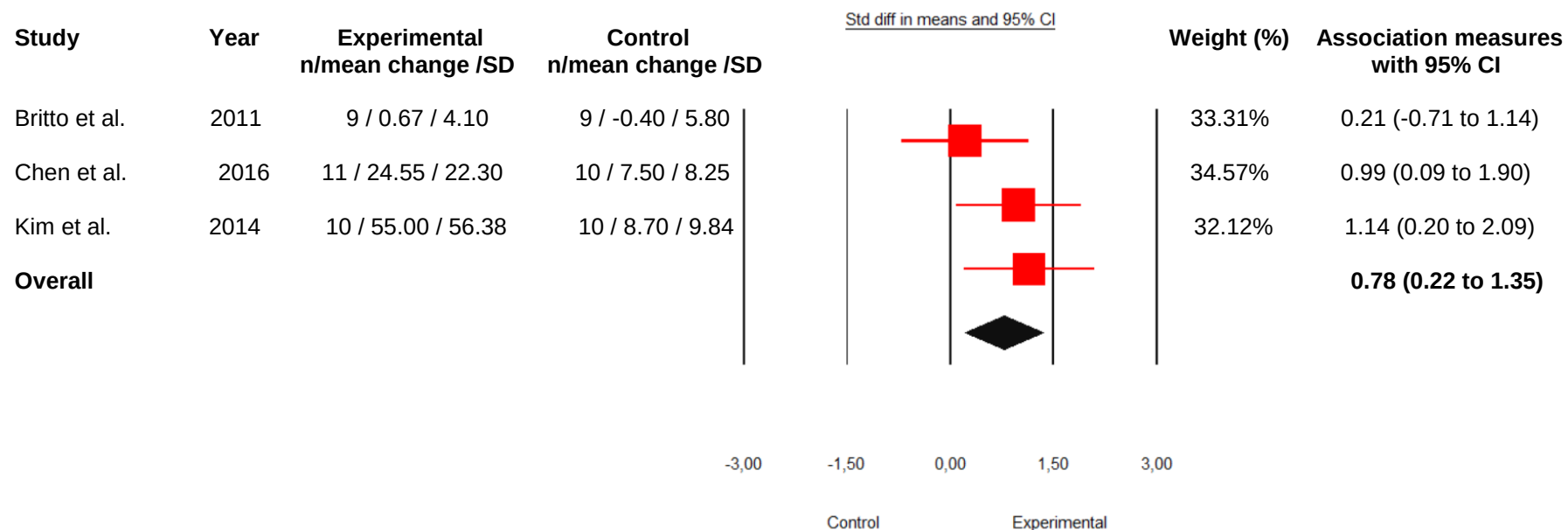


Figure 21. Mean difference (95% CI) of the effect of respiratory muscle training versus nothing/sham intervention on activity (n=59), with a random-effects model, $I^2 = 0\%$.

Capítulo 3

ARTIGO 2

Respiratory muscle training increases respiratory muscle strength and reduces respiratory complications after stroke: a systematic review

3.1 ABSTRACT

Question: After stroke, does respiratory muscle training increase respiratory muscle strength and/or endurance? Are any benefits carried over to activity and/or participation? Does it reduce respiratory complications? **Design:** Systematic review of randomised controlled trials. **Participants:** Adults with respiratory muscle weakness following stroke. **Intervention:** Respiratory muscle training aimed at increasing inspiratory and/or expiratory muscle strength. **Outcome measures:** Respiratory muscle strength, respiratory muscle endurance, activity, participation, and respiratory complications. **Results:** Five trials involving 263 participants were included. The mean PEDro score was 6.4 (range 3 to 8), showing moderate methodological quality. Random-effects meta-analyses showed that respiratory muscle training increased maximal inspiratory pressure by 7 cmH₂O (95% CI 1 to 14) and maximal expiratory pressure by 13 cmH₂O (95% CI 1 to 25); it also decreased the risk of respiratory complications (RR 0.38, 95% CI 0.15 to 0.96), compared with no/sham respiratory intervention. Whether these effects carry over to activity and participation remains uncertain. **Conclusion:** This systematic review provided evidence that respiratory muscle training is effective after stroke. Meta-analyses based on five trials indicated that 30 minutes of respiratory muscle training, five times per week, for 5 weeks can be expected to increase respiratory muscle strength in weak and very weak individuals after stroke. In addition, respiratory muscle training is expected to reduce the risk of respiratory complications after stroke. Further studies are warranted to investigate whether the benefits are carried over to activity and participation.

Registration: PROSPERO (CRD42015020683).

Key-words: stroke, systematic review, respiratory muscle training, strength.

[Menezes KKP, Nascimento LR, Ada L, Polese JC, Avelino PR, Teixeira-Salmela LF (2016). Respiratory muscle training increases respiratory muscle strength and reduces respiratory complications after stroke: a systematic review. *Journal of Physiotherapy* 62: 138–144].

3.2 Artigo publicado

Research

Respiratory muscle training increases respiratory muscle strength and reduces respiratory complications after stroke: a systematic review

Kênia KP Menezes^a, Lucas R Nascimento^a, Louise Ada^b, Janaine C Polese^a,
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KEY WORDS

Stroke
Systematic review
Respiratory muscle training
Strength
Physical therapy



ABSTRACT

Question: After stroke, does respiratory muscle training increase respiratory muscle strength and/or endurance? Are any benefits carried over to activity and/or participation? Does it reduce respiratory complications? **Design:** Systematic review of randomised or quasi-randomised trials. **Participants:** Adults with respiratory muscle weakness following stroke. **Intervention:** Respiratory muscle training aimed at increasing inspiratory and/or expiratory muscle strength. **Outcome measures:** Five outcomes were of interest: respiratory muscle strength, respiratory muscle endurance, activity, participation and respiratory complications. **Results:** Five trials involving 263 participants were included. The mean PEDro score was 6.4 (range 3 to 8), showing moderate methodological quality. Random-effects meta-analyses showed that respiratory muscle training increased maximal inspiratory pressure by 7 cmH₂O (95% CI 1 to 14) and maximal expiratory pressure by 13 cmH₂O (95% CI 1 to 25); it also decreased the risk of respiratory complications (RR 0.38, 95% CI 0.15 to 0.96) compared with no/sham respiratory intervention. Whether these effects carry over to activity and participation remains uncertain. **Conclusion:** This systematic review provided evidence that respiratory muscle training is effective after stroke. Meta-analyses based on five trials indicated that 30 minutes of respiratory muscle training, five times per week, for 5 weeks can be expected to increase respiratory muscle strength in very weak individuals after stroke. In addition, respiratory muscle training is expected to reduce the risk of respiratory complications after stroke. Further studies are warranted to investigate whether the benefits are carried over to activity and participation. **Registration:** PROSPERO (CRD42015020683). [Menezes KKP, Nascimento LR, Ada L, Polese JC, Avelino PR, Teixeira-Salmela LF (2016) Respiratory muscle training increases respiratory muscle strength and reduces respiratory complications after stroke: a systematic review. *Journal of Physiotherapy* 62: 138–144]

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Introduction

Stroke is the second leading global cause of death and the leading cause of disability.¹ After stroke, the loss of ability to generate normal amounts of force is a major contributor to activity limitations and participation restrictions.^{2–4} Previous studies have demonstrated that weakness after stroke affects not only the muscles of the upper and lower limbs, but also those of the respiratory system.^{5,6} Patients typically demonstrate reduced maximal voluntary strength and decreased endurance of the inspiratory and expiratory muscles, as well as altered chest wall kinematics.^{7–9} Studies have reported mean values of maximal inspiratory pressure ranging from 17 to 57 cmH₂O in people after stroke, compared with approximately 100 cmH₂O in healthy adults, and mean values of maximal expiratory pressure ranging from 25 to 68 cmH₂O, compared with approximately 120 cmH₂O in healthy adults.^{7,9,10} That is, respiratory muscle strength in people after stroke is less than half of that expected in healthy adults. In addition, decreased respiratory function is associated with deconditioning, activity limitations, and respiratory complications,¹¹ which are a

leading cause of non-vascular death after stroke.¹² Thus, implementing interventions with the potential to prevent morbidity and mortality in people with stroke is vindicated.¹³

One approach that has the potential to increase respiratory muscle strength and reduce respiratory complications after stroke is respiratory muscle training. In this type of training, patients are asked to perform repetitive breathing exercises against an external load, using a flow-dependent resistance or a pressure threshold.^{14,15} Respiratory muscle training is based on the premise that respiratory muscles respond to training stimuli by undergoing adaptations to their structure in the same manner as any other skeletal muscles, when their fibres are overloaded. Respiratory muscles can be overloaded by requiring them to work for longer, at higher intensities, and/or more frequently than their typical workload.^{16,17} Also, because respiratory muscle training not only imposes a resistance to the respiratory muscles, but also consists of hyperventilating for prolonged periods of time, it may have an additional effect on respiratory muscle endurance,^{16,17} which could translate into a more efficient use of the respiratory muscles in activities of daily living.

<http://dx.doi.org/10.1016/j.jphys.2016.05.014>

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Two systematic reviews have examined the effect of inspiratory muscle strength training regimens on respiratory muscle strength after stroke, based on randomised, controlled trials. A Cochrane review¹⁵ included two randomised trials (representing three comparisons), but did not perform a meta-analysis. When inspiratory muscle training was compared with no intervention, the effect on maximal inspiratory pressure was 3 cmH₂O (95% CI -2 to 9); when compared with sham intervention, the effect was 46 cmH₂O (95% CI 28 to 63); and when compared with other types of respiratory training, the effect was 0 cmH₂O (95% CI -6 to 6). When these results of strength training were entered into a meta-analysis in a recent review,⁵ the pooled effect on maximal inspiratory pressure was 7 cmH₂O (95% CI 2 to 12), but with substantial statistical heterogeneity ($I^2 = 95\%$).

An updated review of the current evidence is warranted because these reviews^{5,15} included only two trials and did not examine the effects on respiratory endurance, the carryover effects to activity or participation, nor the incidence of respiratory complications.

Therefore, the research questions for this systematic review were:

1. Does respiratory muscle training (inspiratory and/or expiratory) increase respiratory muscle strength and/or endurance after stroke?
2. Are the benefits carried over to activity and/or participation?
3. Does respiratory muscle training reduce the occurrence of respiratory complications?

In order to make recommendations based on the highest level of evidence, this review included only randomised or quasi-randomised trials.

Method

Identification and selection of trials

Searches were conducted in the CINAHL (1986 to April 2015), EMBASE (1980 to April 2015), LILACS (1986 to April 2015), MEDLINE (1946 to April 2015) and PEDro (to April 2015) databases for relevant studies, without date or language restrictions. The search strategy was registered at PubMed/Medline and the authors received notifications regarding potential papers related to this systematic review. Search terms included words related to *stroke*, to *randomised* or *quasi-randomised trials*, and to *respiratory muscle training* (such as *inspiratory muscle training*, *expiratory muscle training*, *breathing exercises* and *respiratory therapy*). See Appendix 1 on the eAddenda for the full search strategy. Title and abstracts were displayed and screened by two reviewers (KKPM and PRA) to identify relevant studies. Full-text copies of peer-reviewed relevant papers were retrieved and their reference lists were screened to identify further relevant studies. The method section of the retrieved papers was extracted and independently reviewed by two researchers (LRN and JCP) using pre-determined criteria (Box 1). Both reviewers were blinded to authors, journals and results of the studies. Disagreement or ambiguities were resolved by discussion with a third reviewer (KKPM).

Assessment of characteristics of trials

Quality

The quality of included trials was assessed by extracting PEDro Scale scores from the Physiotherapy Evidence Database (www.pedro.org.au). The PEDro Scale has 11 items, designed for rating the methodological quality (internal validity and statistical information) of randomised trials. Each item, except for Item 1, contributes one point to the total PEDro score (range 0 to 10 points). Where a trial was not included on the database, two reviewers, who had completed the PEDro scale training tutorial, scored it independently.

Box 1. Inclusion criteria.

Design

- randomised or quasi-randomised trials

Participants

- adults (> 18 years old)
- diagnosis of stroke
- respiratory muscle weakness (ie, < 90% normal maximal inspiratory or expiratory pressures)

Intervention

- respiratory muscle training aimed at increasing strength of the inspiratory and/or expiratory muscles

Outcome measure

- inspiratory and/or expiratory muscle strength

Comparisons

- respiratory muscle training versus nothing/sham respiratory intervention

Participants

To be eligible for inclusion, trials had to involve adult participants with respiratory muscle weakness following stroke. Participants were considered weak when the strength of their respiratory muscles, reported as maximal inspiratory or expiratory pressure, was < 90% of that predicted for age-matched and gender-matched healthy subjects.^{7,18,19} To describe each included trial, the number of participants and their gender, age, time since stroke, and magnitude of respiratory muscle weakness were recorded.

Interventions

The experimental intervention was respiratory muscle training that produced repetitive contractions of the respiratory muscles against resistance in order to increase strength. The control intervention could be nothing or a sham intervention (ie, the intervention was not delivered with enough specificity (non-respiratory training) or dose (low-dose training) to have an effect).

Outcome measures

Five outcomes were of interest: respiratory muscle strength (inspiratory and expiratory), respiratory muscle endurance, activity, participation, and occurrence of respiratory complications.

The strength measurement had to be representative of maximum voluntary contractions generated during maximum resistance of inspiration or expiration (eg, maximal voluntary inspiratory pressure or maximal voluntary expiratory pressure).²⁰ When multiple measures of strength were reported, the measure that reflected the trained muscle(s) was used. If both expiratory and inspiratory muscles had been trained and measured, the mean (SD) of the two measurements were summed so that only data from independent groups were entered into the meta-analyses.^{21,22} The endurance measurement had to be representative of the ability to breathe against increasing inspiratory or expiratory loads, or the ability to breathe at a fixed load during a predetermined amount of time (eg, 2-minute incremental load method).^{7,20,23} The activity measurement had to be representative of the ability to execute tasks or actions, and the participation measurement had to be representative of the involvement of the individual in real-life situations.²⁴ Direct measures or self-reported questionnaires were used, regardless of whether they produced continuous or ordinal data. Measures of general activity (eg, Barthel Index) were used if they were the only available measure of activity. Measures of quality of life were used if they were the only available measure of participation. Occurrence of respiratory complications was defined as number of participants with diagnosis of respiratory complications (eg, lung infections and pneumonia) after training commencement.

Data analysis

Two reviewers independently extracted information regarding the method (ie, design, participants, intervention, outcome

measures) and results (ie, number of participants and mean (SD) of respiratory outcomes), with checking by a third reviewer. When information was not available in the published trials, details were requested from the corresponding author.

Given that respiratory muscle strength was always reported as cmH₂O, the pooled estimate of the mean difference between the groups (95% CI) was determined for both inspiratory and expiratory muscles. In addition, where possible, change scores rather than post-intervention scores were used to obtain the pooled estimate of the effect of the intervention, using a fixed-effect model. In the case of significant statistical heterogeneity ($I^2 > 40\%$), a random effects model was applied.²⁵ Given that respiratory complications were originally reported as number of events (ie, a dichotomous outcome), the relative risk with 95% CI was calculated. Commercial software^a was used to perform the meta-analysis.²⁶ The critical value for rejecting the null hypothesis was set at a level of 0.05 (two-tailed). When data were unavailable to be included in the pooled analyses, between-group results were reported.

Results

Flow of trials through the review

The electronic search strategy identified 3522 papers, but 327 were duplicates. After screening titles, abstracts and reference lists, 27 potentially relevant full papers were retrieved. Twenty-two papers failed to meet the inclusion criteria (see Appendix 2 on the eAddenda for a summary of the excluded papers) and five papers were included in this systematic review. Four papers^{7,9,27,28} were included in the inspiratory training analysis and three papers^{9,26,29} were included in the expiratory training analysis. For the outcome 'respiratory complications', one paper²⁷ reported a trial with three arms of interest: inspiratory muscle training, expiratory muscle training and sham training. The experimental

groups were combined to create a single comparison, following Cochrane recommendations.²⁵ One paper⁹ delivered both inspiratory and expiratory training to the experimental group. Figure 1 outlines the flow of papers through the review.

Characteristics of the included trials

The five trials involved 263 participants and investigated the effect of respiratory muscle training on inspiratory ($n=4$) and expiratory muscle strength ($n=3$), inspiratory muscle endurance ($n=1$), activity ($n=2$), participation ($n=2$) and respiratory complications ($n=2$) after stroke (Table 1). Four trials were randomised clinical trials.^{7,9,27,28} In the other trial,²⁹ the randomisation criteria was the internment order, so it was classified as a quasi-randomised trial.

Quality

The mean PEDro score of the included trials was 6.4 (range 3 to 8) (Table 2). All trials reported between-group differences as well as point estimate and variability. The majority of trials had: similar groups at baseline (80%), < 15% dropouts (80%), randomly allocated participants (80%), concealed allocation (80%), and reported blinding of assessors (80%). However, only two trials reported an intention-to-treat analysis. No trials blinded participants or therapists, which is difficult or impossible during this type of intervention.

Participants

The mean age of participants ranged from 54 to 66 years across trials. The mean time after stroke ranged from 9 days to 66 months. The majority of trials (80%) comprised participants in the sub-acute phase of stroke (ie, < 6 months after stroke) on admission to the trial. The mean baseline strength of the inspiratory muscles ranged from 41 to 57 cmH₂O, whereas the mean baseline strength of the expiratory muscles ranged from 50 to 63 cmH₂O.

Table 1
Characteristics of included trials ($n=5$).

Study	Design	Participants	Intervention		Outcome measures
			Frequency and duration	Parameters	
Britto et al. (2011) ⁷	RCT	$n=18$ Age (yr)=54 (SD 11) Time since stroke (mth) ≥ 9 MIP=57 cmH ₂ O MEP=NR	Exp=IMT, 30 min x 5/wk x 8 wk Con=sham, 30 min x 5/wk x 8 wk	Muscles=inspiratory Resistance=30% of MIP Device=threshold Progression=resistance adjusted to 30% of maximal strength every 2 weeks	Strength=MIP (cmH ₂ O) Endurance=IME (cmH ₂ O) Activity=Human Activity Profile (0 to 94) Participation=Nottingham Health Profile (score 0 to 38) Timing=0, 8 wk
Fernandes et al. (2007) ²⁹	QRC	$n=36$ Age (yr)=54 Time since stroke (mth) ≤ 3 MIP=42 cmH ₂ O MEP=50 cmH ₂ O	Exp=EMT, 50 reps x 5/wk x 1 wk Con=nothing	Muscles=expiratory Resistance=40% of MEP Device=threshold Progression=not stated	Strength=MEP (cmH ₂ O) Timing=0, 1 wk
Kulnik et al. (2015) ²⁷	RCT	$n=78$ Age (yr)=64 (SD 15) Time since stroke (mth) ≤ 0.5 MIP=42 cmH ₂ O MEP=61 cmH ₂ O	Exp 1=IMT, 50 reps x 7/wk x 4 wk Exp 2=EMT, 50 reps x 7/wk x 4 wk Con=sham, 50 reps x 7/wk x 4 wk	Muscles=inspiratory and expiratory Resistance=50% of MIP and MEP Device=threshold Progression=resistance adjusted to 50% of maximal strength every week	Strength=MIP, MEP (cmH ₂ O) Respiratory complications=pneumonia incidence ^a Timing=0, 4, 13 wk
Messaggi-Sartor et al. (2015) ⁹	RCT	$n=101$ Age (yr)=66 (SD 11) Time since stroke (mth) ≤ 1 MIP=41 cmH ₂ O MEP=63 cmH ₂ O	Exp=IMT+EMT, 100 reps x 5/wk x 3 wk Con=sham, 100 reps x 5/wk x 3 wk	Muscles=inspiratory and expiratory Resistance=30% of MEP Device=threshold Progression=resistance increased 10 cmH ₂ O every week	Strength=MIP, MEP (cmH ₂ O) Respiratory complications=lung infection and pulmonary thromboembolism ^a Timing=0, 3 wk
Sutbeyaz et al. (2010) ²⁸	RCT	$n=30$ Age (yr)=62 (SD 7) Time since stroke (mth)=5 (SD 1) MIP=50 cmH ₂ O MEP=61 cmH ₂ O	Exp=IMT, 30 min x 3/wk x 6 wk Con=nothing	Muscles=inspiratory Resistance=40% of MIP Device=threshold Progression=resistance increased 5 to 10% every week until 60% of maximal strength	Strength=MIP (cmH ₂ O) Activity=Barthel Index (score 0 to 100) Participation=Medical Outcomes Study Short Form 36 (score 0 to 100) Timing=0, 6 wk

^a Outcome measures listed are only those that were analysed in this systematic review.

Con=control group, EMT=expiratory muscle training, Exp=experimental group, IME=inspiratory muscle endurance, IMT=inspiratory muscle training, MEP=maximal expiratory pressure, MIP=maximal inspiratory pressure, NR=not reported, QRC=quasi-randomised controlled trial, RCT=randomised clinical trial, reps=repetitions.

Table 2
PEDro criteria and scores for the included papers (n=5).

Study	Random allocation	Concealed allocation	Groups similar at baseline	Participant blinding	Therapist blinding	Assessor blinding	< 15% dropouts	Intention-to-treat analysis	Between-group difference reported	Point estimate and variability reported	Total (0 to 10)
Britto et al. (2011) ⁷	Y	Y	Y	N	N	Y	Y	N	Y	Y	7
Fernandes et al. (2007) ²⁹	N	N	N	N	N	N	Y	N	Y	Y	3
Kulnik et al. (2015) ²⁷	Y	Y	Y	N	N	Y	N	Y	Y	Y	7
Messaggi-Sartor et al. (2015) ⁹	Y	Y	Y	N	N	Y	Y	Y	Y	Y	8
Sutbeyaz et al. (2010) ²⁸	Y	Y	Y	N	N	Y	Y	N	Y	Y	7

N=no, Y=yes.

Intervention

In all trials the experimental intervention was respiratory muscle training, which was delivered via threshold devices. The respiratory muscle training targeted the inspiratory muscles,^{7,28} expiratory muscles,²⁹ a combination of inspiratory and expiratory muscles,⁹ or inspiratory and expiratory muscles to separate participants.²⁷ Participants undertook training for 30 minutes (or 50 to 100 repetitions), three to seven times per week, for 1 to 8 weeks.

In all trials, the control intervention was nothing or sham respiratory intervention. Two control groups did not receive any intervention^{28,29} and three control groups received a sham intervention.^{7,9,27} Sham intervention was delivered via a threshold device with a small resistance of 10% of the respiratory muscle strength,²⁷ via a threshold device with a fixed workload of 10 cmH₂O,⁹ and via a threshold device without the resistance valve.⁷ In three trials, usual therapy was delivered to both experimental and control groups.^{9,27,28}

Outcome measures

Respiratory muscle strength was measured as maximum pressure generated during inspiration^{7,9,27,28} or expiration.^{9,27,29}

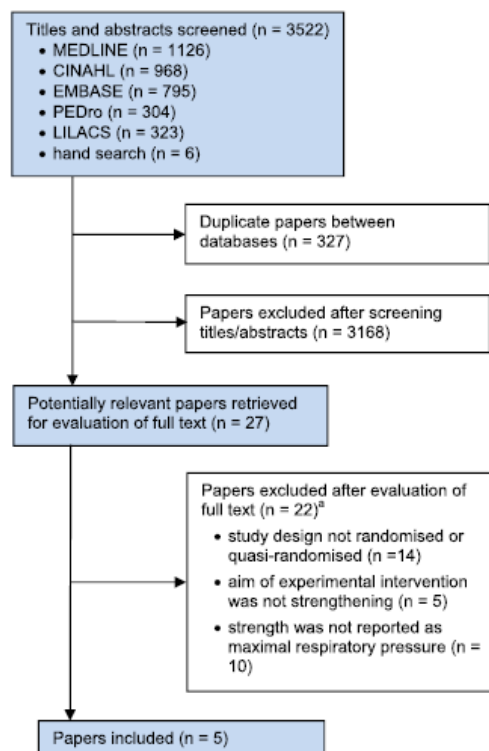


Figure 1. Flow of studies through the review.

^aPapers may have been excluded for failing to meet more than one inclusion criterion.

These pressures were reported in cmH₂O in all trials. Inspiratory muscle endurance was measured in one trial⁷ using the 2-minute incremental load method, which was reported in cmH₂O. Activity was measured in two trials^{7,28} using self-reported questionnaires: Human Activity Profile (0 to 94 points) in one trial⁷ and Barthel Index (0 to 100 points) in the other.²⁸ Participation was measured in two trials^{7,28} using self-reported questionnaires of quality of life: Nottingham Health Profile (0 to 38 points) in one trial⁷ and Medical Outcomes Study Short Form 36 (0 to 100 points) in the other.²⁸ Occurrence of respiratory complications was measured in two trials^{9,27} and reported as number of participants with pneumonia in one trial²⁷ and as number of participants with lung infections or pulmonary thromboembolism in the other,⁹ after the commencement of the training.

Effect of respiratory muscle training

Inspiratory muscle strength

The effect of inspiratory muscle training on inspiratory muscle strength was examined by pooling data from four trials (n = 176 participants) with a mean PEDro score of 7.3, representing moderate quality. When a random effects model was applied, inspiratory muscle training increased maximal inspiratory pressure by 7 cmH₂O (95% CI 1 to 14, I² = 33%), compared with no/sham intervention (Figure 2, see Figure 3 on the eAddenda for the detailed forest plot).

Expiratory muscle strength

The effect of expiratory muscle training on expiratory muscle strength was examined by pooling data from three trials (n = 165 participants) with a mean PEDro score of 6.0, representing moderate quality. When a random effects model was applied, expiratory muscle training increased maximal expiratory pressure by 13 cmH₂O (95% CI 1 to 25, I² = 12%), compared with no/sham respiratory intervention (Figure 4, see Figure 5 on the eAddenda for the detailed forest plot).

Inspiratory muscle endurance

One trial, with a PEDro score of 7, examined the effect of inspiratory muscle training on inspiratory muscle endurance after

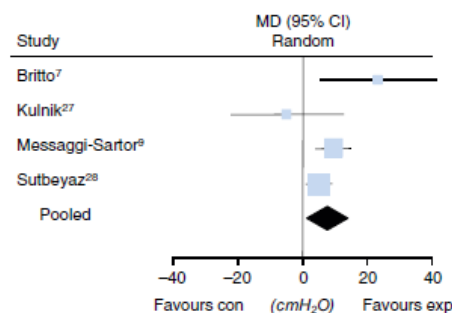


Figure 2. Mean difference (95% CI) of effect of inspiratory muscle training versus no/sham respiratory intervention on maximal inspiratory pressure, in cmH₂O (n = 176).

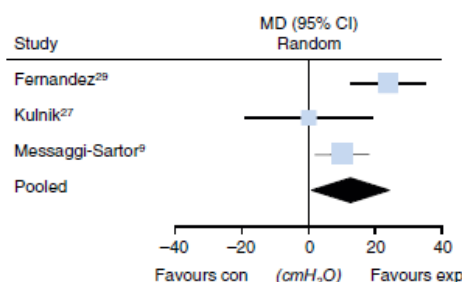


Figure 4. Mean difference (95% CI) of effect of expiratory muscle training versus no/sham respiratory intervention on maximal expiratory pressure, in cmH₂O (n = 165).

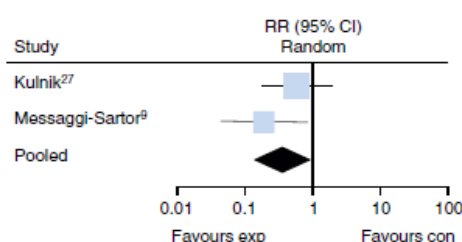


Figure 6. Relative risk (95% CI) of respiratory complications after respiratory muscle training versus no/sham respiratory intervention (n = 179).

stroke.⁷ Inspiratory muscle endurance was measured by using the 2-minute incremental load method⁷ and reported as maximal load in cmH₂O sustained for at least 1 minute. The authors reported a significant between-group difference of 15 cmH₂O (95% CI 2 to 27) in favour of the experimental intervention.

Activity

The effect of respiratory muscle training on activity was examined by two trials^{7,28} with a mean PEDro score of 7. Although both trials measured activity using a self-reported questionnaire, a meta-analysis was not possible because only one trial⁷ reported post-intervention data, with no significant difference in the Human Activity Profile scores between the groups (MD 1, 95% CI -4 to 6). The other trial²⁸ reported that Barthel Index scores improved significantly more in the experimental group than the control group, but did not report numerical data.

Participation

The effect of respiratory muscle training on participation was examined by two trials.^{7,28} Although both trials measured participation using a self-reported questionnaire of quality of life, a meta-analysis was not possible because only one trial⁷ reported post-intervention data, with no significant difference in the Nottingham Health Profile score between the groups (MD -2, 95% CI -5 to 2). The other trial²⁸ reported that the domains of physical role, general health, and vitality of the Medical Outcomes Study Short Form 36 improved significantly more in the experimental group than the control group, but did not report numerical data.

Respiratory complications

The effect of respiratory muscle training on respiratory complications was examined by pooling the data from two trials^{9,27} (n = 179 participants) with a mean PEDro score of 7.5, representing good quality. The likelihood of respiratory complications was significantly lower after respiratory muscle training (RR 0.38, 95% CI 0.15 to 0.96, I² = 0%), compared with no/sham respiratory intervention (Figure 6, see Figure 7 on the eAddenda for the detailed forest plot).

Discussion

This systematic review found that respiratory muscle training can increase respiratory muscle strength and decrease the risk of

respiratory complications after stroke. However, the evidence about whether the benefits are carried over to activity and participation remains unclear.

This review set out to answer three questions. The first examined whether *respiratory muscle training increases respiratory muscle strength and/or endurance after stroke*. The meta-analyses showed that the implementation of respiratory muscle training had a small positive effect on inspiratory and expiratory muscle strength. The pooled effect indicated that inspiratory muscle training resulted in 7 cmH₂O greater maximal inspiratory pressure, compared with no/sham inspiratory intervention. Although the dataset doubled in size, this estimate remained remarkably similar to that reported in a previous systematic review (MD 7 cmH₂O, 95% CI 3 to 11).⁵ The pooled data indicated that expiratory muscle training resulted in 13 cmH₂O greater maximal expiratory pressure, compared with no/sham expiratory intervention.

This is the first systematic review to include only randomised or quasi-randomised clinical trials and to examine the effects of respiratory muscle training on the expiratory muscles. A previous systematic review,³⁰ which included uncontrolled clinical trials, did not demonstrate an improvement of expiratory strength after respiratory muscle training (MD -1 cmH₂O, 95% CI -2 to 1). Therefore, the present review strengthens the evidence regarding the efficacy of respiratory muscle training for increasing respiratory muscle strength, because the conclusion was based on meta-analyses of randomised and quasi-randomised trials with reasonable quality (mean PEDro Score of 6.7 out of 10).

The significant but small increase in strength found in the present review has important clinical implications. According to the 2002 American Thoracic Society/European Respiratory Society statement on respiratory muscle testing,³¹ a maximal inspiratory pressure of 80 cmH₂O is required to exclude clinically important inspiratory muscle weakness. In trials examining the effect of respiratory muscle training in patients with neuromuscular or pulmonary obstructive disease, a threshold of 60 cmH₂O has been used to differentiate weak and healthy participants.^{32,33} Since the average maximal inspiratory pressure of the participants in the present review was 46 cmH₂O (SD 7), these participants could be considered very weak. In this context, an increase of 7 cmH₂O represents a 16% increase, which is sufficient to be considered clinically meaningful. Although there are no reference values that indicate how much expiratory strength is necessary to exclude clinically important expiratory muscle weakness, an increase of 13 cmH₂O in participants with an average maximal expiratory pressure of 58 cmH₂O (SD 6) represents a 22% increase, which is also sufficient to be considered clinically meaningful.

After stroke, strength may be increased even more if training is of sufficient duration and intensity. Most of the adaptations in respiratory muscle strength are typically apparent after 6 weeks of strength training;³⁴ the minimal recommended duration is 8 weeks.³⁵ Only one trial has investigated 8 weeks of strengthening⁷ and the result was considerably higher (MD 23 cmH₂O, 95% CI 1 to 46), compared with the pooled effects found in the present review.

In addition, the exact amount of improvement in respiratory muscle strength may not be important if the primary physiological mechanism by which the training improves clinical outcomes is via improved respiratory muscle endurance.¹⁴ Only one included trial examined the effect of inspiratory muscle training on muscle endurance after stroke. The results were significantly higher in favour of the experimental group (MD 15 cmH₂O). A mechanism involving endurance would be consistent with all the training regimens used, but more clinical trials investigating the effect of respiratory muscle training to increase endurance after stroke are necessary.

The second question examined whether *the benefits of the respiratory muscle training are carried over to activity and participation*. There were insufficient data to determine whether the benefits of respiratory strength are carried over to activity or participation after stroke. Only two trials investigating this question were included and meta-analyses could not be performed. Therefore,

further trials should measure the effects of respiratory muscle training on activity and participation. If benefits are carried over to an activity, such as walking capacity, the findings may have broader implications. For example, walking capacity has been shown to predict physical activity levels and community participation after stroke.^{36,37}

The third question examined whether *respiratory muscle training reduces the occurrence of respiratory complications after stroke*. The meta-analysis showed that respiratory muscle training reduced the relative risk of respiratory complications immediately and 6 months after the commencement of the intervention. A retrospective observational cohort study indicated that pneumonia and respiratory illness are the most common reasons associated with hospital readmissions after stroke, accounting for 15% of the readmissions.³⁸ Pneumonia is described as the leading cause of non-vascular death in acute¹² and chronic³⁹ phases after stroke. The adoption of interventions capable of preventing the occurrence of respiratory complications may substantially improve the long-term outcomes of patients with stroke.⁴⁰ However, although respiratory muscle training reduced the occurrence of respiratory complications after stroke in the present review, the results were based on two trials with small-to-medium sample sizes.^{9,27} Furthermore, the procedures for detecting and excluding lung infection and pneumonia reported by the trials were not sufficiently robust. First, in both studies, occurrences of lung infection or pneumonia between the end of the intervention period and the final follow-up were captured retrospectively with some loss to follow-up. Robust assessment methods would include prospective data collection in shorter intervals, an independent review of each diagnosis by a blinded assessor, and possibly stratification into 'definite' and 'suspected' pneumonia. Second, any definitive study of outcome lung infection and pneumonia after stroke will need to apply a statistical model that adjusts for potential confounders, since it is well established that there are several independent risk factors for post-stroke pneumonia.^{41,42} Therefore, the conclusions regarding the effect of the respiratory muscle training to reduce the occurrence of respiratory complications should be interpreted with caution, and further studies with better methodological quality are warranted.

This review had both strengths and limitations. Given that a score of 8 was likely to be the maximum achievable PEDro score, because it was usually impossible to blind therapists or participants, the mean PEDro score of 6.4 for the included trials represented moderate quality, suggesting that the findings were credible. Another source of bias was lack of reporting whether an intention-to-treat analysis was undertaken. Additionally, the number of participants per group (mean 22, range 9 to 39) was quite low, opening the results to small-trial bias. On the other hand, heterogeneity among the trials pooled in the meta-analysis, based on a random-effects model, was low. Overall, the included trials were similar regarding their clinical characteristics. Most of the trials included participants in the sub-acute phase of rehabilitation (four out of five trials), with a mean baseline inspiratory muscle strength of 46 cmH₂O (SD 7) and expiratory muscle strength of 59 cmH₂O (SD 6), suggesting that most of the participants could be classified as weak. Although the program duration varied between trials (mean 4.4 weeks, SD 2.7, range 1 to 8 weeks), the trials had similar session durations (mean 30 minutes, or 50 to 100 repetitions) and session frequencies (mean 5.0 per week, SD 1.4, range 3 to 7). Another strength of the present review, which is unusual in rehabilitation studies, was that the outcome measures were the same, with respiratory muscle strength always measured via maximal pressures and reported in cmH₂O. Finally, publication bias inherent to systematic reviews was avoided by including studies published in languages other than English.²⁹

In conclusion, this systematic review provides evidence that respiratory muscle training is effective (ie, results in greater increase in inspiratory and expiratory muscle strength, compared with no/sham intervention) after stroke. The results of meta-analyses

based on five trials indicated that 30 minutes of respiratory muscle training, five times per week, for 5 weeks can be expected to increase respiratory muscle strength in very weak individuals after stroke. In addition, respiratory muscle training is expected to reduce the risk of respiratory complications (eg, pneumonia and lung infections) after stroke. Further studies are warranted to investigate whether the benefits of respiratory muscle training are carried over to activity and participation.

What is already known on this topic: Respiratory muscle weakness is common after stroke and is associated with activity limitation and respiratory complications.

What this study adds: Respiratory muscle training increases inspiratory and expiratory muscle strength and reduces the risk of respiratory complications. It remains uncertain whether the benefits carry over to benefits in activity and participation.

Footnotes: ^a Comprehensive Meta-Analysis program Version 3.0, Biostat, Englewood, USA.

eAddenda: Figures 3, 5 and 7, and Appendices 1 and 2 can be found online at doi:10.1016/j.jphys.2016.05.014.

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Websites

www.pedro.org.au

3.3 Search strategy

Appendix 1: Search strategy

Respiratory muscle training increases strength of respiratory muscles and reduces the occurrence of respiratory complications after stroke: a systematic review.

Kênia KP Menezes, Lucas R Nascimento, Louise Ada, Janaine C Polese,
Patrick R Avelino, Luci F Teixeira-Salmela

Databases: MEDLINE, LILACS, PEDro, EMBASE CINAHL

MEDLINE

1. cerebrovascular disorders/ or exp basal ganglia cerebrovascular disease/
or exp brain ischemia/ or exp carotid artery diseases/ or exp intracranial
arterial diseases/ or exp "intracranial embolism and thrombosis"/ or exp
intracranial hemorrhages/ or stroke/ or exp brain infarction/ or vertebral
artery dissection/
2. (stroke or poststroke or post-stroke or cerebrovasc\$ or brain vasc\$ or
cerebral vasc\$ or cva\$ or apoplex\$ or SAH).tw.
3. ((brain\$ or cerebr\$ or cerebell\$ or intracran\$ or intracerebral) adj5
(isch?emi\$ or infarct\$ or thrombo\$ or emboli\$ or occlus\$)).tw.
4. ((brain\$ or cerebr\$ or cerebell\$ or intracerebral or intracranial or
subarachnoid) adj5 (haemorrhage\$ or hemorrhage\$ or haematoma\$ or
hematoma\$ or bleed\$)).tw.
5. hemiplegia/ or exp paresis/
6. (hemipleg\$ or hemipar\$ or paresis or paretic).tw.
7. or/1-6
8. breathing exercises/
9. respiratory therapy/
- 10.respiration/ or inhalation/ or exhalation/
- 11.exp inspiratory capacity/
- 12.exp respiratory muscles/

- 13.((respirat\$ or inspirat\$ or expirat\$ or ventilat\$ or pulmonary) adj5 (therap\$ or train\$ or retrain\$ or exercise\$ or resist\$ or conditioning or strength\$ or weakness or endurance or muscle\$)).tw.
- 14.((breathing or inhalation or exhalation) adj5 (exercise\$ or therap\$ or train\$ or retrain\$)).tw.
- 15.or/8-14
- 16.7 and 15
- 17.exp animals/ not humans.sh.
- 18.16 not 17
- 19.Randomized Controlled Trials as Topic/
- 20.random allocation/
- 21.Controlled Clinical Trials as Topic/
- 22.control groups/
- 23.clinical trials as topic/ or clinical trials, phase i as topic/ or clinical trials, phase ii as topic/ or clinical trials, phase iii as topic/ or clinical trials, phase iv as topic/
- 24.double-blind method/
- 25.single-blind method/
- 26.Placebos/
- 27.placebo effect/
- 28.cross-over studies/
- 29.Therapies, Investigational/
- 30.Research Design/

- 31.evaluation studies as topic/
- 32.randomized controlled trial.pt.
- 33.controlled clinical trial.pt.
- 34.(clinical trial or clinical trial phase i or clinical trial phase ii or clinical trial phase iii or clinical trial phase iv).pt.
- 35.(evaluation studies or comparative study).pt.
- 36.random\$.tw.
- 37.(controlled adj5 (trial\$ or stud\$)).tw.
- 38.(clinical\$ adj5 trial\$).tw.
- 39.((control or treatment or experiment\$ or intervention) adj5 (group\$ or subject\$ or patient\$)).tw.
- 40.(quasi-random\$ or quasi random\$ or pseudo-random\$ or pseudo random\$).tw.
- 41.((multicenter or multicentre or therapeutic) adj5 (trial\$ or stud\$)).tw.
- 42.((control or experiment\$ or conservative) adj5 (treatment or therapy or procedure or manage\$)).tw.
- 43.((singl\$ or doubl\$ or tripl\$ or trebl\$) adj5 (blind\$ or mask\$)).tw.
- 44.(coin adj5 (flip or flipped or toss\$)).tw.
- 45.versus.tw.
- 46.(cross-over or cross over or crossover).tw.
- 47.placebo\$.tw.
- 48.sham.tw.

49.(assign\$ or alternate or allocat\$ or counterbalance\$ or multiple baseline).tw.

50.controls.tw.

51.or/19-50

52.18 and 51

LILACS

5. AVC OR “acidente vascular” OR AVE OR derrame OR hemiparesia OR hemiparéticos OR hemiparético OR paresia OR parético OR paréticos OR hemiplegia OR hemiplégico OR hemiplégicos OR isquêmico OR hemorrágico
6. Respiratório OR respiratórios OR respiração OR inspiração OR inspiratório OR inspiratórios OR expiração OR expiratório OR expiratórios OR ventilatório OR ventilatórios OR ventilação OR pulmonar OR diafragma OR abdominais
7. treino OR treinamento OR força OR fraqueza OR fortalecimento OR exercícios OR exercício OR condicionamento OR terapia OR retreino OR resistência OR endurance
8. 1 and 2 and 3

PEDro

2) Abstract & Title: Stroke OR Hemiparetic OR Hemiparesis

Therapy: respiratory therapy OR Strength Training

Problem: no selection

Body part: no selection

Subdiscipline: no selection

Method: Clinical Trial

EMBASE

1. 'cerebrovascular disease'/exp or 'stroke'/exp or 'cerebrovascular accident'/exp or 'brain hemorrhage'/exp or 'brain ischemia'/exp or 'stroke unit'/exp or 'basal ganglion hemorrhage'/exp or 'brain infarction'/exp or 'occlusive cerebrovascular disease'/exp or 'carotid artery disease'/exp or 'cerebral artery disease'/exp or 'intracranial aneurysm'/exp or 'hemiplegia'/exp or 'paresis'/exp or 'hemiparesis'/exp
2. (stroke or poststroke or 'post stroke' or cerebrovasc\$ or 'brain vasc\$' or 'cerebral vasc\$' or cva\$ or apoplex\$ or sah).ab.
3. (brain\$ or cerebr\$ or cerebell\$ or intracran\$ or intracerebral).ab.
4. (isch?emi\$ or infarct\$ or thrombo\$ or emboli\$ or occlus\$).ab.
5. 3 and 4
6. (brain\$ or cerebr\$ or cerebell\$ or intracerebral or intracranial or subarachnoid).ab.
7. (haemorrhage\$ or hemorrhage\$ or haematoma\$ or hematoma\$ or bleed\$).ab.
8. 6 and 7
9. (hemipleg\$ or hemipar\$ or paresis or paretic).ab.
- 10.1 or 2 or 5 or 8 or 9
- 11.'breathing exercise'/exp or 'breathing'/exp or 'inhalation'/exp or 'exhalation'/exp or 'inspiratory capacity'/exp or 'breathing muscle'/exp
- 12.(respirat\$ or inspirat\$ or expirat\$ or ventilat\$ or pulmonary).ab.
- 13.(therap\$ or train\$ or retrain\$ or exercise\$ or resist\$ or conditioning or strength\$ or weakness or endurance or muscle\$).ab.
- 14.12 and 13

15.(breathing or inhalation or exhalation).ab.

16.(exercise\$ or therap\$ or train\$ or retrain\$).ab.

17.15 and 16

18.11 or 14 or 17

19.'randomized controlled trial'/exp or 'clinical trial'/exp or 'controlled clinical trial'/exp or 'controlled study'/exp or 'randomization'/exp or 'single blind procedure'/exp or 'double blind procedure'/exp or 'parallel design'/exp or 'crossover procedure'/exp or 'placebo'/exp or 'control group'/exp

20.(random\$ or placebo\$ or control\$ or 'clinical trial').ab.

21.19 or 20

22.10 and 18 and 21

23.22 and [humans]/lim

CINAHL

1. (MH "Cerebrovascular Disorders+") or (MH "stroke patients") or (MH "stroke units")
2. TI (stroke or poststroke or post-stroke or cerebrovasc* or brain vasc* or cerebral vasc or cva or apoplex or SAH) or AB (stroke or poststroke or post-stroke or cerebrovasc* or brain vasc* or cerebral vasc or cva or apoplex or SAH)
3. TI (brain* or cerebr* or cerebell* or intracran* or intracerebral) or AB (brain* or cerebr* or cerebell* or intracran* or intracerebral)
4. TI (ischemi* or ischaemi* or infarct* or thrombo* or emboli* or occlus*) or AB (ischemi* or ischaemi* or infarct* or thrombo* or emboli* or occlus*)
5. S3 and S4
6. TI (brain* or cerebr* or cerebell* or intracerebral or intracranial or subarachnoid) or AB (brain* or cerebr* or cerebell* or intracerebral or intracranial or subarachnoid)
7. TI (haemorrhage* or hemorrhage* or haematoma* or hematoma* or bleed*) or AB (haemorrhage* or hemorrhage* or haematoma* or hematoma* or bleed*)
8. S6 and S7
9. (MH "Hemiplegia")
10. TI (hemipleg* or hemipar* or paresis or paretic) or AB (hemipleg* or hemipar* or paresis or paretic)
11. S1 or S2 or S5 or S8 or S9 or S10
12. (MH "Breathing Exercises (SabaCCC)") OR (MH "Breathing Exercises+")

- 13.(MH "Education, Respiratory Therapy") OR (MH "Home Respiratory Care") OR (MH "Inspiration, Respiratory") OR (MH "Respiratory Muscles+") OR (MH "Respiratory Nursing") OR (MH "Respiratory Nursing Society") OR (MH "Respiratory Therapists") OR (MH "Respiratory Therapy+") OR (MH "Respiratory Therapy Equipment and Supplies+") OR (MH "Respiratory Therapy Service")
- 14.(MH "Respiration (Omaha)") OR (MH "Respiration (Saba CCC)") OR (MH "Respiration Alteration (Saba CCC)")
- 15.(MH "Respiration+") and (MH "Muscle Strengthening")
- 16.TI (respirat* or inspirat* or expirat* or ventilat* or pulmonary) OR AB (respirat* or inspirat* or expirat* or ventilat* or pulmonary)
- 17.TI (therap* or train* or retrain* or exercise* or resist* or conditioning or strength* or weakness or endurance or muscle*) OR AB (therap* or train* or retrain* or exercise* or resist* or conditioning or strength* or weakness or endurance or muscle*)
- 18.S16 and S17
- 19.TI (breathing or inhalation or exhalation) OR AB (breathing or inhalation or exhalation)
- 20.TI (exercise* or therap* or train* or retrain*) OR AB (exercise* or therap* or train* or retrain*)
- 21.S19 and S20
- 22.S12 or S13 or S14 or S15 or S18 or S21
- 23.S11 and S22
- 24.PT randomized controlled trial or clinical trial
- 25.(MH "Random Assignment") or (MH "Random Sample+")

- 26.(MH "Crossover Design") or (MH "Clinical Trials+") or (MH "Comparative Studies")
- 27.(MH "Control (Research)") or (MH "Control Group")
- 28.(MH "Factorial Design") or (MH "Quasi-Experimental Studies") or (MH "Nonrandomized Trials")
- 29.(MH "Placebo Effect") or (MH "Placebos") or (MH "Meta Analysis")
- 30.(MH "Clinical Research") or (MH "Clinical Nursing Research")
- 31.(MH "Community Trials") or (MH "Experimental Studies") or (MH "One-Shot Case Study") or (MH "Pretest-Posttest Design+") or (MH "Solomon Four-Group Design") or (MH "Static Group Comparison") or (MH "Study Design")
- 32.PT systematic review
- 33.TI random* or AB random*
- 34.TI (singl* or doubl* or tripl* or trebl*) or AB (singl* or doubl* or tripl* or trebl*)
- 35.TI (blind* or mask*) or AB (blind* or mask*)
- 36.S34 and S35
- 37.TI (crossover or cross-over or placebo* or control* or factorial or sham) or AB (crossover or cross-over or placebo* or control* or factorial or sham)
- 38.TI (clin* or intervention* or compar* or experiment* or preventive or therapeutic) or AB (clin* or intervention* or compar* or experiment* or preventive or therapeutic)
- 39.TI trial* or AB trial*
- 40.S38 and S39

41. TI (counterbalance* or multiple baseline* or ABAB design) or AB (counterbalance* or multiple baseline* or ABAB design)
42. TI (meta analysis* or metaanalysis or meta-analysis or systematic review*) or AB (meta analysis* or metaanalysis or meta-analysis or systematic review*)
43. PT meta analysis
44. S24 or S25 or S26 or S27 or S28 or S29 or S30 or S31 or S32 or S33 or S34 or S35 or S36 or S37 or S38 or S39 or S40 or S41 or S42 or S43
45. S23 and S44

3.4 Excluded papers

Appendix 2: Excluded papers

Respiratory muscle training increases strength of respiratory muscles and reduces the occurrence of respiratory complications after stroke: a systematic review.

Kênia KP Menezes, Lucas R Nascimento, Louise Ada, Janaine C Polese, Patrick R Avelino, Luci F Teixeira-Salmela

Studies	Reasons for exclusion		
	1	2	3
Aziz et al. (2008)	✓	✓	
Cuezy et al. (2010)		✓	✓
Harraf et al. (2008)	✓		
Jo et al. (2014)	✓		
Jung et al. (2014)			✓
Kim et al. (2011)			✓
Kim et al. (2014)		✓	✓
Kim et al. (2015)	✓		✓
Kulnik et al. (2014)	✓		
Meireles et al. (2012)			
Narain and Puckree (2002)	✓	✓	✓
Nuzzo et al. (1999)	✓	✓	✓
Ocko and Costa (2014)	✓		
Ovando et al. (2010)	✓	✓	✓
Pollock et al. (2013)	✓		
Queiroz et al. (2014)	✓		
Rimmer et al. (2000)		✓	✓
Seo et al. (2012)			✓
Seo et al. (2013)			✓
Veerbeek et al. (2014)	✓		
Xiao et al. (2012)	✓		
Yamashita et al. (2010)	✓		

1 = Research design not RCT or quasi-randomised

2 = Aim of experimental intervention is not strengthening

3 = Strength measure is not an outcome measure or is not reported as maximal respiratory pressure

Aziz NA, Leonardi-Bee J, Phillips M, Gladman JR, Legg L, Walker MF (2008). Therapy-based rehabilitation services for patients living at home more than one year after stroke. *Cochrane Database Syst Rev.* 16;(2). Art No: CD005952. DOI: 10.1002/14651858.CD005952.pub2.

Cuesy PG, Sotomayor PL, Piña JO (2010). Reduction in the incidence of poststroke nosocomial pneumonia by using the "turn-mob" program. *J Stroke Cerebrovasc Dis.* 19(1): 23-28.

Harraf F, Ward K, Man W, Rafferty G, Mills K, Polkey M, Moxham J, Kalra L (2008). Transcranial magnetic stimulation study of expiratory muscle weakness in acute ischemic stroke. *Neurology.* 9(24):2000-2007.

Jo M, Kim N, Jung J (2014). The effects of respiratory muscle training on respiratory function, respiratory muscle strength, and cough capacity in stroke patients. *J Korean Soc Phys Med.* 9(4): 399-406.

Jung JH, Shim JM, Kwon HY, Kim HR, Kim BI (2014). Effects of abdominal stimulation during inspiratory muscle training on respiratory function of chronic stroke patients. *J Phys Ther Sci.* 26(1):73-76.

Kim K, Fell WD, Lee JH (2011). Feedback respiratory training to enhance chest expansion and pulmonary function in chronic stroke: A double-blind, randomized controlled study. *J Phys Ther Science.* 23(1):75-79.

Kim J, Park JH, Yim J (2014). Effects of respiratory muscle and endurance training using an individualized training device on the pulmonary function and exercise capacity in stroke patients. *Med Sci Monit.* 5(20):2543-2549.

Kim CB, Shin JH, Choi JD (2015). The effect of chest expansion resistance exercise in chronic stroke patients: a randomized controlled trial. *J Phys Ther Sci.* 27(2):451-453.

Kulnik ST, Rafferty GF, Birring SS, Moxham J, Kalra L (2014). A pilot study of respiratory muscle training to improve cough effectiveness and reduce the incidence of pneumonia in acute stroke: study protocol for a randomized controlled trial. *Trials.* 12;15:123.

Meireles ALF, Meireles LCF, Queiroz JCES, Tassitano RM, Soares FO, Oliveira AS (2012). Effectiveness of electrical stimulation in expiratory muscle on cough of patients after stroke. *Fisioter Pesqui.* 19(4):314-319.

Narain S, Puckree T (2002). Pulmonary function in hemiplegia. *Int J Rehabil Res.* 25(1):57-59.

Nuzzo NA; Bronson LA, McCarthy T, Massery M (1999). Respiratory muscle strength and endurance following at CVA. *J Neuro Phys Ther.* 23(1):25-27.

Ocko R, Costa MC (2014). Respiratory Changes in Patients with Stroke. *Biomed Biopharm Res.* (11)2:141-150.

Ovando AC, Michaelsen SM, Dias JA, Herber V (2010). Gait training, cardiorespiratory training and strength training after stroke: strategies, dose and outcomes. *Fisioter mov.* 23(2):253-269.

Pollock RD, Rafferty GF, Moxham J, Kalra L (2013). Respiratory muscle strength and training in stroke and neurology: a systematic review. *Int J Stroke.* 8(2):124-130.

Queiroz AGC, Silva DD, Lira RAC, Bassini SRF, Uematsu ESC. Respiratory muscle training associated with electrical stimulation diaphragmatic in hemiparesis. *Rev Neurocienc.* 22(2):294-299.

Rimmer JH, Riley B, Creviston T, Nicola T (2000). Exercise training in a predominantly African-American group of stroke survivors. *Med Sci Sports Exerc.* 32(12):1990-1996.

Seo KC, Kim Ha, Lim SW. Effects of feedback respiratory exercise and diaphragm respiratory exercise on the pulmonary function of chronic stroke patients. *J Int Acad Phys Ther Res.* 3(2): 413-478.

Seo KC, Lee HM, Kim HA (2013). The effects of combination of inspiratory diaphragm exercise and expiratory pursed-lip breathing exercise on pulmonary functions of stroke patients. *J. Phys. Ther. Sci.* 25: 241–244.

Veerbeek JM, Wegen E, Peppen R, Wees PJ, Hendriks E, Rietberg M, Kwakkel G (2014). What is the evidence for physical therapy poststroke? A systematic review and meta-analysis. *PLoS One*. 9(2):1-33.

Xiao Y, Luo M, Wang J, Luo H (2012). Inspiratory muscle training for the recovery of function after stroke. *Cochrane Database Syst Rev*. 16:5. Art No:CD009360. DOI: 10.1002/14651858.CD009360.pub2.

Yamashita K, Kikuchi N, Ito K (2010). Effects of expiratory muscle training on respiratory muscle strength and cough intensity of stroke patients. *Rigakuryoho Kagaku*. 25(6):849-853.

3.5 Detailed forest plots

Figures 3, 5 and 7: Detailed forest plots

Respiratory muscle training increases strength of respiratory muscles and reduces the occurrence of respiratory complications after stroke: a systematic review.

Kênia KP Menezes, Lucas R Nascimento, Louise Ada, Janaine C Polese, Patrick R Avelino, Luci F Teixeira-Salmela

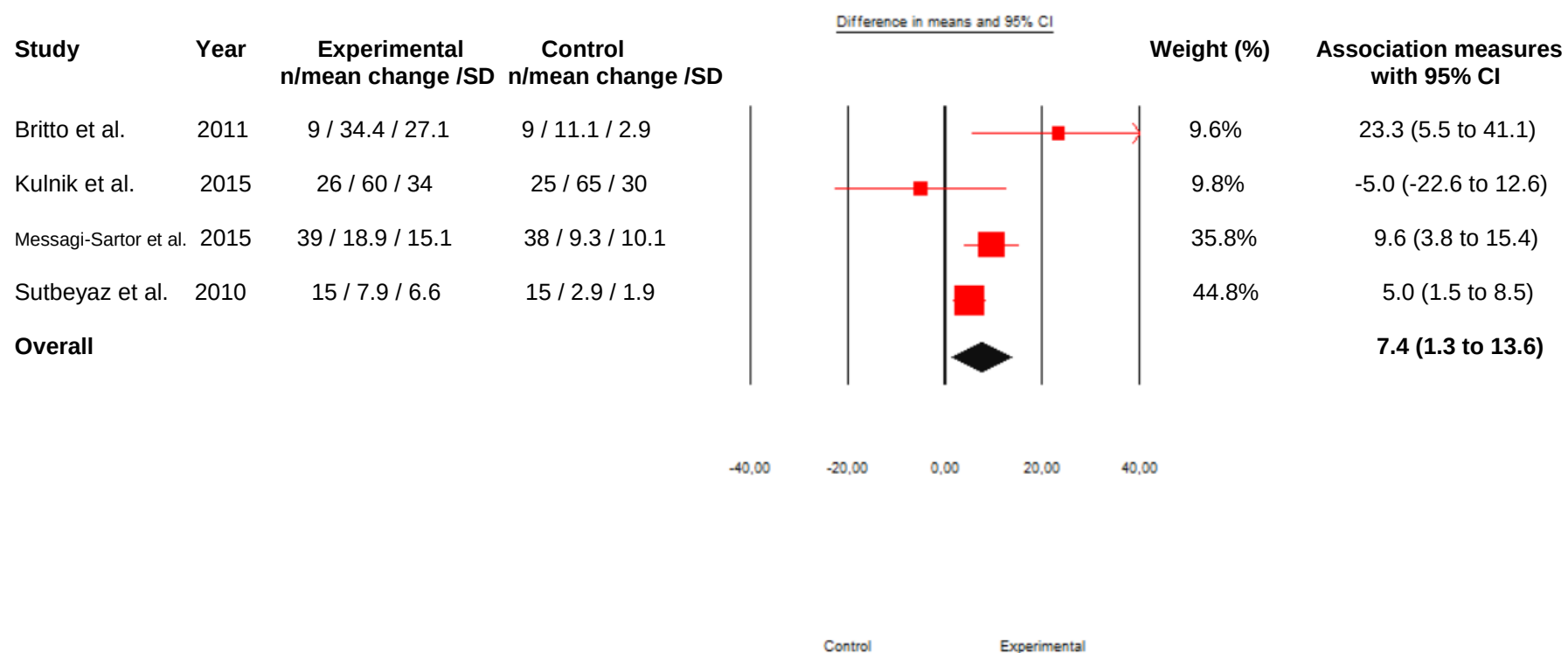


Figure 3. Mean difference (95% CI) of effect of inspiratory strength training versus nothing/placebo respiratory intervention on strength of inspiratory muscles, in cmH₂O (n = 176), with a random-effects model, $I^2 = 33\%$.28

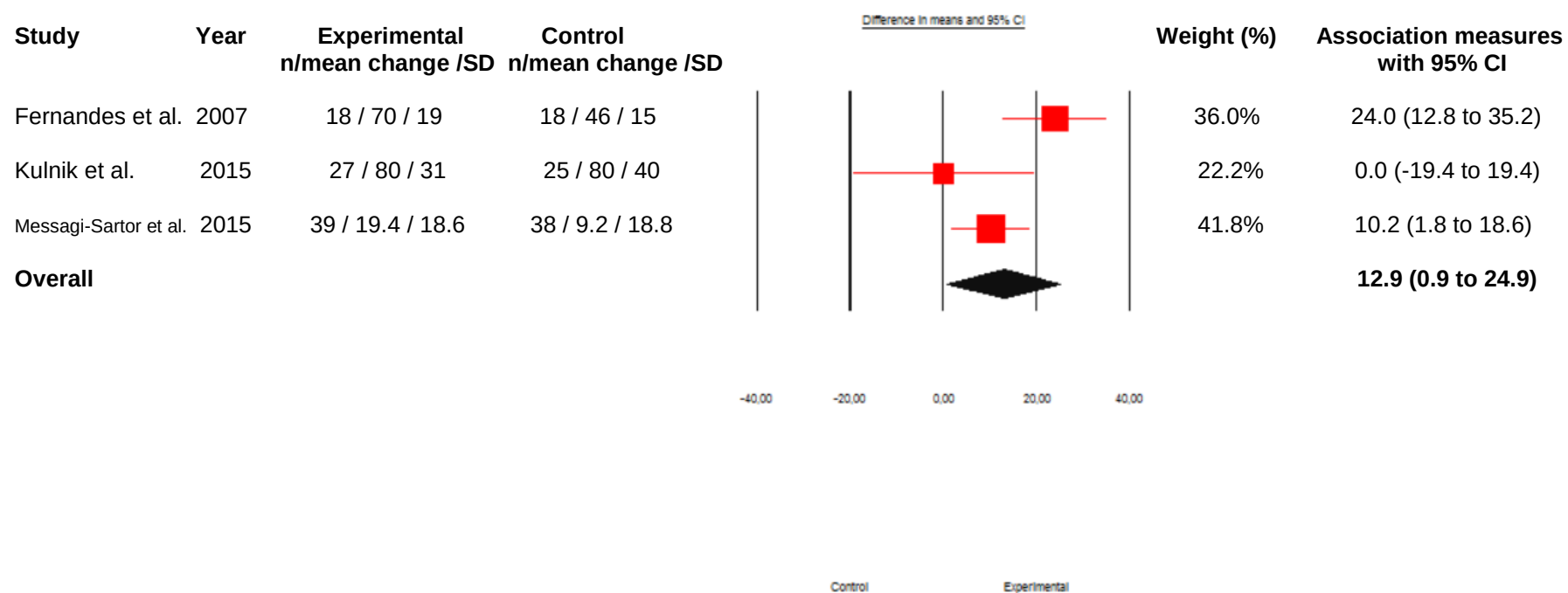


Figure 5. Mean difference (95% CI) of effect of expiratory strength training versus nothing/placebo respiratory intervention on strength of expiratory muscles, in cmH₂O (n = 165). Random effect / I² = 12%

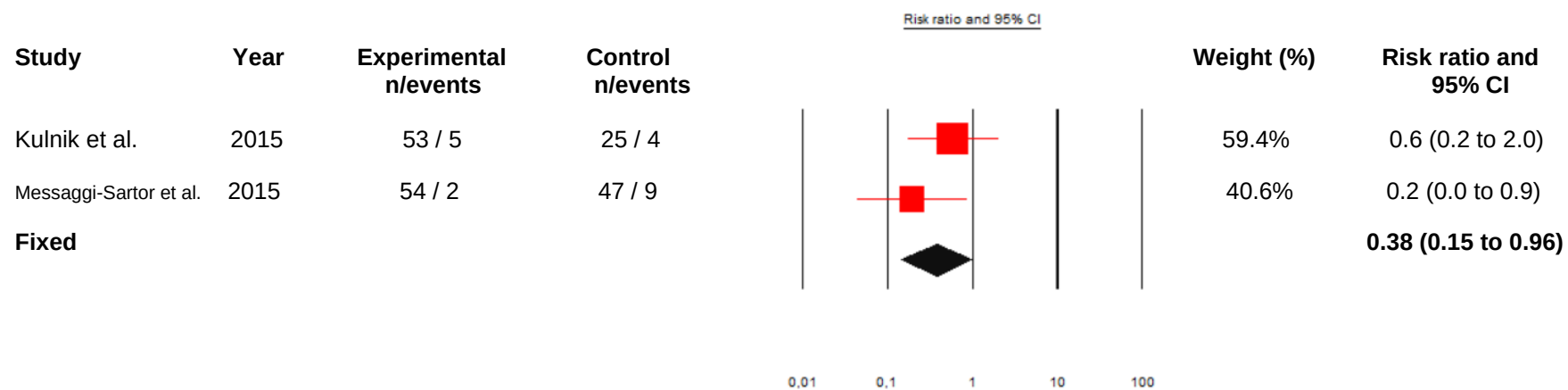


Figure 7. Risk ratio (95% CI) of respiratory complications after respiratory strength training versus nothing/placebo respiratory intervention (n = 179).

Capítulo 4

ARTIGO 3

A review on respiratory muscle training devices

4.1 ABSTRACT

There are currently many devices on the market, which have been used for training of the respiratory muscles. The knowledge of these devices may help professionals to carefully select the best one to be used. However, due to the numerous available devices available, this selection represents a challenge. Although previous studies have attempted to describe all respiratory muscle training devices, important ones with proven efficacy were not included. Therefore, the purpose of this review was to describe the mechanisms and characteristics of all available respiratory muscle training devices, and discuss their merits and limitations. The present review included 14 devices currently available on the market and reported by published studies. However, three could not be described in details, due to lack of information. Amongst the 11 evaluated devices, all of them showed positive aspects and limitations, that should be considered. Although some devices appear to be more advantageous than others, it is not possible to choose the best one, based only upon their technical information and clinical utility. To select the most appropriate one, it is also necessary to consider the specific health condition, the nature of the impairments, the purpose of the training, and whether it is for use within research or clinical contexts.

Key words: Respiratory Muscles; Equipment and Supplies; Resistance Training; Breathing Exercises; Rehabilitation; Review.

[Menezes KKP, Nascimento LR, Avelino PR, Polese JC, Teixeira-Salmela LF (submitted). A review on respiratory muscle training devices. *The Clinical Respiratory Journal*].

4.2 INTRODUCTION

The respiratory muscles are unique amongst the skeletal muscles, since they must work without sustained rest throughout life [1]. However, conditions, such as respiratory diseases, neurological lesions, electrolyte disturbances, blood gas abnormalities, intense weight loss, and cardiac decompensation, may affect these muscles [2]. Weakness of the respiratory muscles is defined as a reduction in muscle contractility, resulting in the inability of the respiratory muscles to generate normal levels of pressure and air flow during inspiration and expiration [3]. This strength could compromise exercise performance in healthy individuals [4, 5] and in those with stroke [6], chronic obstructive pulmonary disease [7], and heart failure [8]. Thus, the implementation of interventions, which has the potential to increase the strength of the respiratory muscles and, consequently, improve exercise performance and functional capacity is vindicated, since deconditioning is one of the most common preventable causes of morbidity and mortality [9].

One approach that has the potential to increase the function of the respiratory muscles is respiratory muscle training [10-12]. This intervention consists of repetitive breathing exercises against an external load, which can be controlled by factors, such as time, intensity, and/or frequency of the training [10, 13, 14]. However, to obtain a training response, the muscle fibers must be overloaded, by requiring them to work for longer, at higher intensities and/or more frequently, than they are accustomed to. Most training regimens combine two or three of these factors, to achieve adequate overload [14]. Furthermore, the adaptations elicited by the training depend upon the type of the stimulus, to which the muscle is subjected. The muscles tend to respond to strength-training stimuli (high intensity and short duration) by improving strength and to endurance-training stimuli (low intensity and long duration) by improving endurance [14]. Thus, when their fibers are overloaded, the respiratory muscles respond to training stimuli, by undergoing adaptations to their structure in the same manner, as any other skeletal muscles.

There are, currently, many devices on the market, which can be used for respiratory muscle training. The respiratory devices fall into two main

categories: devices that impose a resistance-training stimulus and those that impose an endurance-training stimulus [14]. The resistance-training devices subject the muscles to an external load, that is akin to lift a weight, and fall into three main categories, based on how the load is generated: passive flow-resistance, dynamically adjusted flow-resistance, and pressure threshold valve. The endurance-training devices (or require that the respiratory muscles work at high shortening velocities for prolonged periods of time (30 minutes) and the only load imposed on the muscles is that of the inherent flow-resistance and elasticity of the respiratory system [14]. All the devices described by their commercial product brands belong to one of these two categories and each has specific mechanical principles and characteristics. Thus, the knowledge of these devices may help professionals to carefully select the best one to be used with each patient, to align the goals of the intervention with the mechanisms (flow-dependent resistance or pressure thresholds) and characteristics, such as overload range, portability, usability, and cost. However, due to the high number of available devices on the market, this selection represents a challenge for the professionals. Thus, although previous studies have attempted to describe all the respiratory muscle training devices [14-17], some devices with proven efficacy were not included.

Therefore, the purpose of this review was to describe the mechanisms and characteristics of all respiratory muscle training devices, currently available on the market, and discuss their merits and limitations.

4.3 METHODS

Searches were conducted in databases, books, website selling products related to rehabilitation, and reference lists of the retrieved papers. This review provides a list of the devices currently available on the market, and an evaluation of their characteristics, based upon their technical information and clinical utility. Dichotomous responses, based on “yes/no” responses, were chosen to evaluate the devices and, therefore, facilitate reading and, consequently, the choice by the professionals. The “yes” responses for each

topic were: adequate load range: devices clearly stated in the literature with sufficient training load amplitude; portability: devices that can be easily carried in a pocket or in a small bag; usability: devices that do not need the help of a therapist to be handled; adequate mouthpiece sealing: devices with a flexible flanged mouthpiece, that is both comfortable and airtight; possibility of home-based training: devices that are portable and do not require the help of a therapist to be handled; easy/fast adjustment: devices that need less than one minute to be adjusted and connected (in the case of electronic ones); allows inspiratory and expiratory training: devices that allow for the training of both inspiratory and expiratory muscles; cost: devices that are inexpensive, i.e., cost less than 100 dollars. The characteristics of the devices were evaluated by collecting information from the literature and by the authors, who are physiotherapists with clinical experience in the area of neurological and respiratory rehabilitation.

4.4 RESULTS

The present review included 14 devices, currently available on the market and reported by published studies. Overall, most of the devices can be easily carried-out (91%), are easy to use or can be used at home (88%), provide adequate load ranges, mouthpiece sealing, or are easy/fast to adjust (77%), and are inexpensive (66%). On the other hand, only three of the available devices allow both inspiratory and expiratory training. Table 1 summarizes their main technical characteristics, to facilitate comparison and selection by the professionals, according to the patients' conditions and training objectives.

4.4.1 Resistance-training devices

The resistance-training devices fall into the following three main categories, based upon how the load is generated: passive flow-resistance, dynamically adjusted flow-resistance, and pressure threshold valve

4.4.1.1 *Passive flow-resistance devices*

In these devices, the load is given by a previously selected variable diameter orifice, so that for a given flow, the narrower the orifice is, the greatest is the resistive load [15]. However, these devices show an important limitation, because the load is passively generated by the respired air flow, i.e., if there is no flow, there is no load. Thus, they are highly sensitive to the influence of respiratory flow rate, which makes loading unreliable [14].

Pflex

Clinical applicability: The Pflex® (Respironics Inc., Murrysville, PA, USA) is an inexpensive inspiratory muscle trainer (costs less than 20 dollars), commonly used for strength training [18, 19]. This plastic device is 5.7cm long and has a cylindrical shape and an opening at one end for the insertion of a removable plastic mouthpiece and is sealed at the other end by a one-way valve. The breathing resistance is controlled by an adjustable dial-like mechanism with six fixed orifice settings located on the shaft of the device [20]. This device is mainly used in patients with chronic obstructive pulmonary disease, however, it can be used in several other conditions, such as the elderly and neurological or cardiac conditions.

Positive aspects: The Pflex® has an adequate mouthpiece sealing and is easily adjustable and inexpensive.

Limitations: Since that the training load varies with the flow and not just with the orifice size, it is impossible to quantify the training load and progression, without providing simultaneous feedback of the respiratory flow rate [14]. It is possible to adapt another piece, so-called 'targeted flow-resistive training', to control the flow and make the loading reliable [14]. However, this adaptation adds considerably to the cost and bulk of the device.

TrainAir

Clinical applicability: The TrainAir® (Project Electronics Ltd., Kent, ENG, UK) is also an inspiratory muscle trainer used for strength training [21, 22]. This device has a passive flow-resistance mechanism with the addition of pressure

measurement, making load setting reliable and quantifiable. This device may be used in patients, who have respiratory muscle weakness, such as chronic obstructive pulmonary disease, and neurological or cardiac conditions.

Positive aspects: The TrainAir® has an adequate mouthpiece sealing. Furthermore, as an advantage, this device enables continuous biofeedback of the training intensity and built-in assessment of inspiratory muscle function [14].

Limitations: The required laptop and other pieces increase its cost and bulk (about 600 dollars), makes it the preserve of specialist clinics, besides the training being also very time consuming and strenuous [14].

4.4.1.2 Dynamically adjusted flow resistance devices

The mechanism of these devices, although similar to that of the passive flow-resistance ones, allows continuous and dynamic adjustments of the flow resistance. This adjustment allows that the surface area of the flow orifice vary within a breath, according to the prevailing respiratory flow rate [14]. Furthermore, the controlled variable can be either the pressure load or the respired flow rate [14].

POWERbreathe K-Series

Clinical applicability: The POWERbreathe® K-Series (POWERbreathe International Ltd., Southam, ENG, UK), an inspiratory muscle trainer with a response valve electronically controlled to generate the resistance, is a new approach to respiratory training that was launched in 2010, with few publications to date [23, 24]. The index of the display of strength ranges from 10 to 240 cmH₂O and the battery life is about 60 minutes on the training mode. Although the published studies reported its use mainly with patients with chronic obstructive pulmonary disease, it can be used in any condition, as long as the patients have respiratory muscle weakness.

Positive aspects: The POWERbreathe® K-Series is programmable by the user and provides real-time computer-based biofeedback during training [14]. Furthermore, a history of use is recorded in the memory of the device, allowing for real-time training.

Limitations: This device has a high cost (300 to 600 dollars), which makes this method the preserve of specialist clinics.

4.4.1.3 Pressure threshold devices

These devices require individuals to produce a respiratory pressure, sufficient to overcome a pressure load and, thereby, initiate the respiration [14, 15]. The thresholds permit loading at a quantifiable, variable intensity, by providing near-flow-independent resistance to respiration [14, 15].

EMST 150

Clinical applicability: The EMST 150 (Aspire Products, Gainesville, FL, USA) is a recently developed expiratory muscle trainer [25], that costs about 50 dollars and has been successfully used in previous studies [25-27]. This device uses a calibrated, one-way, spring-loaded valve, to mechanically overload the expiratory muscles [25]. The valve blocks the air flow, until a sufficient expiratory pressure is produced. The EMST 150 provides workloads up to 150 cmH₂O, with regular intervals of 30 cmH₂O. Although this device has been mainly used in healthy patients or with neurological conditions, it can also be used in any other condition, to increase the strength of the expiratory muscles, including healthy individuals.

Positive aspects: The EMST 150 is easily adjustable and inexpensive.

Limitations: This device provides only a hard-plastic tube mouthpiece, that makes it challenging for some users to maintain an airtight sealing.

Orygen Dual Valve

Clinical applicability: The Orygen-Dual Valve® (Forumed S.L., Barcelona, CAT, ESP) is a relatively inexpensive (costs about 60 dollars) and portable respiratory trainer, that also allows patients to simultaneously work the inspiratory and expiratory muscles [28]. Furthermore, the Orygen-Dual Valve provides workloads up to 70 cmH₂O, with regular intervals for both cases of 10 cmH₂O [28]. Although it has been recently developed, studies have proven its efficacy in patients with chronic heart failure [28] and stroke [29].

Positive aspects: This device has two opposite chambers, an inspiratory and an expiratory, and these coupled mechanisms in a single device allow both simultaneous and sequential dual-training (inspiratory and expiratory), which has given its name to the valve itself [28].

Limitations: Once the Orygen-Dual Valve® was developed by a group of Spanish researchers, it is available for internet sale only in Spain, with an estimated delivery time of three months.

Powerbreathe

Clinical applicability: The POWERbreathe® (POWERbreathe International Ltd., Southam, ENG, UK) is an inexpensive inspiratory muscle trainer (costs about 40 dollars), whose efficacy has been supported by previous studies [30-32]. This device is supplied in a range of models (POWERbreathe classic and POWERbreathe plus), with load setting spans of 17–98 cmH₂O, 23–186 cmH₂O, and 29–274 cmH₂O. Furthermore, it has a flexible mouthpiece that better fits the patient's mouth, making it more comfortable and airtight [14]. Similar to the POWERbreathe® K-Series, although the published studies reported its use mainly with patients with chronic obstructive pulmonary disease, it can be used in any condition, as long as the patients have respiratory muscle weakness.

Positive aspects: The POWERbreathe® has an adequate mouthpiece sealing, is easily adjustable and inexpensive. In addition, it separates inspiratory and expiratory flow paths, such that the inspiratory valve is protected from expiration [14].

Limitations: It allows just inspiratory training.

PowerLung

Clinical applicability: The PowerLung ® (Powerlung Inc., Houston, TX, USA) is a recent hand-held respiratory muscle device developed for healthy people [33-35]. This device can control both inspiratory and expiratory airflow, by using a spring-loaded valve mechanism, that has separate controls for inspiration and expiration [36]. The PowerLung has the following four models

(about 120 dollars each), that produce varying levels of resistance: AireStream: indicated for healthy lifestyle people, who are moderately active and not involved in athletics or exercise programs; BreatheAir: indicated for people, who are moderately active, exercise at least 2 to 3 days per week, and are engaged in low-intensity activities, such as walking, swimming, or practicing yoga; Sport: indicated for people, who are looking to improve their performance in sports or other rigorous activity; and Trainer: specifically designed for elite athletes and strenuous competitive training activities.

Positive aspects: The PowerLung ® has an adequate mouthpiece sealing and is easily adjustable. In addition, this device allows for varying resistance on inhalation and exhalation via hand-adjusted knobs [36].

Limitations: This device is relatively expensive, which makes this method the preserve of specialist clinics.

Respifits-S

Clinical applicability: The Respifit-S (Biegler GmbH, Mauerbach, NOE, AUT) is an individualized respiratory muscle training device used to strengthen the inspiratory muscles of different populations, such as chronic obstructive pulmonary disease, stroke, and Parkinson disease [37-39]. This device is composed of a main shaft, into which a program card is inserted; a handle mouthpiece, to adjust the exhalation and inhalation volumes and modules; a program card, which is adjusted by the breathing capacity of each patient; and a transparent tube, that connects the main body to the mouthpiece [39]. The therapist operates the main shaft to initiate the training, which is displayed like a game on the main screen [39].

Positive aspects: The graphical display provides feedback of workloads up to 200 cmH₂O for the patient. Furthermore, the Respifit-S is also an endurance trainer.

Limitations: This device is relatively expensive (costs about 1,000 dollars), which also makes this method the preserve of specialist clinics.

Threshold IMT (inspiratory muscle training)

Clinical applicability: The Threshold® IMT (Respironics Inc., Murrysville, PA, USA) is an inexpensive inspiratory muscle trainer (costs about 30 dollars), which has been widely used with various health conditions [40-42]. This device contains, at its end, a valve closed by the positive pressure of a spring, which can be graded from 9 to 41 cmH₂O and allows resistance changes by 2 cmH₂O increments. The Threshold IMT has a one-way spring-loaded valve, that closes during inspiration and requires that participants inhale hard enough, to open the valve and let the air enter. This device provides constant pressure for inspiratory muscle training, regardless of how quickly or slowly the participants breathe, and the optimal loading pressure can be adjusted, based upon the individual characteristics of the participants [43].

Positive aspects: The Threshold® IMT is easily adjustable, inexpensive, and allows increments in resistance by 2cmH₂O. Furthermore, its use has been supported by the most extensive and high-quality published research.

Limitations: This device provides only a hard-plastic tube mouthpiece, that makes it challenging for some users to maintain an airtight sealing. In addition, its small maximal load makes it difficult to achieve adequate levels of training.

Threshold PEP (positive expiratory pressure)

Clinical applicability: The Threshold™ PEP (Respironics Inc., Murrysville, PA, USA), which has been used in previous studies [42, 44, 45] also with various health conditions, has the same mechanism and cost of the Threshold IMT, but was developed for expiratory muscle training and can be graded from 5 to 20 cmH₂O. For this, the subjects have to overcome the resistance of the expiratory flow spring.

Positive aspects: The Threshold™ PEP is easily adjustable, inexpensive, and allows changes in resistance by 1cmH₂O increments.

Limitations: Similar to the Threshold® IMT, this device provides only a hard-plastic tube mouthpiece, that makes it challenging for some users to maintain an airtight seal [14]. Furthermore, the small maximal load of this device makes it difficult to achieve adequate levels of expiratory muscle training. To

overcome this limitation, a possible option is the reverse use of the Threshold IMT device, which has twice the upper load limit [46, 47]. For this, another plastic mouthpiece needs to be adapted at the end of the inspiratory trainer, enabling its use for both inspiratory and expiratory training with the same device [46]. However, even so, the loading range of the Threshold IMT renders it unusable by anyone, whose baseline maximal inspiratory pressure exceeds 60 cmH₂O. Considering a training load of 50%, someone starting training with a maximal inspiratory pressure of 60 cmH₂O and improving by 30%, will rapidly reach the limits of the spring [14].

Other respiratory muscle training devices

Other devices that have pressure threshold mechanisms can be found on the market, although they have been little used within clinical and research contexts. These devices are:

- Expand-a-Lung (Expand-a-Lung Inc, Miami, FL, USA): an inspiratory and expiratory muscle trainer, that costs about 30 dollars [48];
- Sports Breather® (Health Fitness Center, Rockport, TX, USA): an inspiratory and expiratory muscle trainer, that costs about 35 dollars [49];
- Ultrabreathe® (Tangent Healthcare Ltd., Basingstoke, ENG, UK): an inspiratory muscle trainer, that costs about 30 dollars [50, 51].

4.4.2 Endurance-training devices

Endurance training, also named as voluntary isocapnic hyperpnea training, is time consuming and extremely strenuous, requiring a very high level of the user commitment, to achieve and sustain the prescribed training intensity [14]. This type of training requires individuals to maintain high target levels of ventilation for up to 30 minutes, needing a high degree of motivation [14]. The sessions are typically conducted 3 to 5 times per week at about 60 to 90% of maximum voluntary ventilation [14].

Respifits-S

The clinical applicability, positive aspects, and limitations of The RespiFit-S were previously described, since this device allows both strength and endurance training.

SpiroTiger

Clinical applicability: The SpiroTiger® (Idag AG, Volketswill, ZH, CHE) is an electronic-endurance trainer, that had its efficacy supported by previous studies [52-54], and also may be used with various health conditions. This device consists of a hand-held unit with a respiratory pouch and a base station [52]. While sitting, the subjects are asked to hold the mouthpiece to their mouth, while watching the monitor. The base station is manipulated by the therapist, who pushes the start button. While watching the monitor, the subjects start the inspiration and expiration.

Positive aspects: The device 's display and auditory feedback are very important for constraining the subjects' breathing within the threshold value of isocapnia [52]. The SpiroTiger is the only commercial product that provides this type of y training.

Limitations: This device is relatively expensive (costs about 700 dollars), which also makes this method the preserve of specialist clinics.

4.5 DISCUSSION

This review aimed at describing the mechanisms and characteristics of all respiratory muscle training devices, currently available on the market and discuss their merits and limitations. Although 14 available devices were found, lack of information prevented a detailed description of three devices (Expand-a-Lung, Sports Breather, and Ultrabreathe). Thus, this review described 11 devices, which has been frequently used within research contexts, considering eight characteristics: cost, adequate load range, portability, usability, adequate mouthpiece sealing, possibility of home-based training, easy/fast adjustment, and provision of both inspiratory and expiratory training.

It is well known that the POWERbreathe and IMT/PEP Thresholds are the two devices most supported by extensive and high-quality published research [14]. However, the POWERbreathe only allows inspiratory training. Already the IMT and PEP Thresholds have insufficient training load range and a hard-plastic tube mouthpiece, which makes it challenging for some users to maintain an airtight seal. Furthermore, to train both inspiratory and expiratory muscles with the Threshold devices, it is necessary to acquire both models or to adapt the Threshold IMT, which adds to the cost of the device. To resolve these problems, the recent developed Orygen-Dual Valve, that received “yes” in all characteristics, that is, besides showing all the advantages of the other devices, it has sufficient training load range, a flexible flanged mouthpiece, and is able to simultaneously train both inspiratory and expiratory muscles. However, once it has been recently developed, more studies are needed to prove its efficacy in different health conditions. Furthermore, the Orygen-Dual Valve and the most of the reported respiratory trainers are based on mechanical threshold loading. A recent study compared the effects of an inspiratory muscle training protocol on inspiratory function in patients with chronic obstructive pulmonary disease using either a traditional mechanical threshold (IMT Threshold and POWERbreathe) and an electronic-tapered flow-resistive loading (POWERbreathe K-Series) [24]. The results showed that the participants, who were trained using the electronic device, tolerated higher training loads and achieved larger improvements in inspiratory function, than those, who trained with the mechanical device [24]. Thus, although the electronic technology has made the POWERbreathe K-Series an expensive device, this change has apparently also made it more effective. However, this new device, similar to the previous model, only allows inspiratory muscle training.

It is important to address that all mentioned devices have the potential to be used in several healthy conditions. However, the mechanisms behind the respiratory muscle weakness of a patient with chronic obstructive pulmonary disease may be completely different from those with stroke, for example. Therefore, the selection of the devices should not only rely on their technical characteristics, but also on the health condition, the nature of the impairments,

and the purpose of the training. Consequently, although some devices appear to be more advantageous than others, it is not possible to make a general recommendation of the most suitable ones.

Finally, although these devices were developed to increase strength and endurance of the respiratory muscles, they also have shown to be effective in improving other clinical outcomes, such as pulmonary function (forced vital capacity, forced expiratory volume in the first second, peak expiratory flow, maximum voluntary ventilation, forced expiratory flow between 25% and 75% of vital capacity, vital capacity, tidal volume, expiratory reserve volume, inspiratory reserve volume, and inspiratory capacity), dysphagia, perceived exertion, cough, swallow, diaphragm thickness, chest expansion, respiratory complications, and levels of activity and participation [10-13, 18-47]. These findings demonstrate the importance of respiratory muscle training for various health conditions and clinical outcomes. Thus, respiratory muscle training could influence not only strength and endurance measures, but also other clinical outcomes.

Besides the 14 devices reported in the present review, many other can be found on the market, such as the Inflex® (Respironics Inc., Murrysville, PA, USA) inspiratory trainer; The Breather® (PN Medical, Orlando, FL, USA) inspiratory and expiratory trainer; the Portex IMT (Smiths Medical, St Paul, MN, USA) inspiratory trainer; the ECHOTM Expiratory Muscle Trainer (Galemed, Fenjiu, TW, TW); the DHD IMT (DHD Medical Products, Canastota, NY, USA) inspiratory trainer; the ProO2TM (DeVilbiss UK Ltd, Stourbridge, ENG, UK) inspiratory trainer; the Eolos (Aleas Europe, Miami, FL, USA) inspiratory and expiratory muscle trainer; the Dofin™ Breathing Trainer (Galemed, Fenjiu, TW, TW) inspiratory and expiratory trainer; the Bravo Breathing Strength Builder (BreatheHome, Taipei, TW, TW) inspiratory and expiratory trainer; the Breath Builder™ (Windsong, Gurnee, IL, USA) inspiratory trainer; the Bas Rutten O2 Trainer (BRK Inc, Las Vegas, NV, USA) inspiratory trainer; and the Pulmo-Gym/Luft (Pulmo-gym, Alberton, GT, ZA) inspiratory and expiratory trainer. However, since their mechanisms and effectiveness were not investigated, these devices were not included in this review.

This review has both strengths and limitations. The first limitation is that, although there were found 14 available devices reported by the literature, three were not described in detail. Besides the absence of information due to the low number of studies related to these three devices, these studies had low-to-moderate methodological quality, which make it difficult to discuss their effectiveness. Furthermore, 12 others devices also available on the market were not included in this review, due to lack of information. The second limitation is that some studies reported the use of incentive spirometers, such as the Voldyne, for respiratory muscle training [55], which were not considered in the present review. However, this decision was based upon the fact that these devices are not recommended for respiratory muscle training. In addition, previous findings demonstrated that training with the threshold devices is more effective in increasing strength, compared with training with incentive spirometers [56]. On the other hand, the main strength of this review is that it is the first to include a substantial number of respiratory muscle training devices. Furthermore, besides the description, this review summarized the main characteristics of the evaluated devices and provided detailed technical information, regarding their operating mechanisms, loading ranges, musculature to be trained, mouthpiece, besides other characteristics related to their clinical utility, such as cost, portability, usability, amongst others.

4.6 CONCLUSIONS

There were found 14 respiratory training devices available on the market and reported by published studies. However, three were not described in detail, due to lack of information. Amongst the 11 evaluated devices, all of them showed positive aspects and limitations, that should be considered. Although some devices appear to be more advantageous than others, it is not possible to choose the best one, based only upon their technical information and clinical utility. To select the most appropriate one, it is also necessary to consider the specific health condition, the nature of the impairments, and the purpose of the training. Furthermore, the professionals should also consider the purpose of the device, including whether it is for use within research or clinical contexts.

Future studies with good methodological quality should investigate the efficacy of the other devices, which were not described in detail in the present review.

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4.8 Table

Table 1. Characteristics of the evaluated respiratory muscle training devices.

Device	Adequate load range	Portability	Usability	Adequate mouthpiece sealing	Possibility of home-based training	Easy/fast adjustment	Allows inspiratory and expiratory training	Cost effectiveness (inexpensive)
<u>Resistance-training devices</u>								
Pflex®	No	Yes	Yes	No	Yes	Yes	No	Yes
TrainAir®	Yes	No	No	Yes	No	No	No	No
POWERbreathe® K-Series	Yes	Yes	Yes	Yes	Yes	Yes	No	No
EMST 150	Yes	Yes	Yes	No	Yes	Yes	No	Yes
Orygen-Dual Valve®	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes
POWERbreathe®	Yes	Yes	Yes	Yes	Yes	Yes	No	Yes
PowerLung®	-*	Yes	Yes	Yes	Yes	Yes	Yes	No
Respifit-S	Yes	Yes	No	Yes	No	Yes	No	No
Threshold® IMT	No	Yes	Yes	No	Yes	Yes	No	Yes
Threshold™ PEP	No	Yes	Yes	No	Yes	Yes	No	Yes
<u>Endurance-training device</u>								
SpiroTiger®	Yes	Yes	No	Yes	No	No	Yes	No

* Not reported.

Capítulo 5

ARTIGO 4

Prevalence of dyspnea after a stroke: A telephone-based survey

5.1 ABSTRACT

Introduction: Although dyspnea seems to be a clinically relevant outcome to be taken into consideration during stroke rehabilitation, its prevalence, severity, and effects on this population remain uncertain. Thus, the aim of the present study was to investigate the prevalence and severity of dyspnea after stroke, as well the associations between dyspnea, activity limitations, and participation restrictions. **Methods:** A 23-question telephone-based survey was developed by the research team. The survey consisted of a series of questions regarding demographics, characteristics of the stroke and the onset of dyspnea, severity of dyspnea, activity limitations and participation restrictions. Additional questions included the frequency, use of medications, and number of hospital admissions. The prevalence of dyspnea was reported as the percentage of individuals, who reported having dyspnea. Chi-square tests were employed to investigate the associations between dyspnea, activity limitations, and participation restrictions. Relative risks and respective 95% confidence intervals were provided. **Results:** The prevalence of dyspnea was 44% and severe symptoms were reported by 51% of the participants. In addition, dyspnea limited activity and restricted social participation in 85% and 49%, respectively. Dyspnea was significantly correlated with activity limitations ($r=0.87$; 95% CI 0.82 to 0.92; $p<0.01$) and participation restrictions ($r=0.53$; 95% CI 0.46 to 0.62; $p<0.01$). The analyses indicated that individuals, who had dyspnea, were more likely to report that it limited their activities (RR: 6.5; 95% CI 4.3 to 9.9) and restricted social participation (RR: 1.7; 95% CI 1.5 to 2.0). **Conclusions:** Dyspnea is an important symptom after stroke and showed to be associated with activity limitations and restrictions in community participation. An early detection of dyspnea in people with stroke, followed by appropriate management, is strongly recommended and has the potential to improve activity and social participation.

Key words: Prevalence, dyspnea, stroke, activities of daily living, social participation, cross-sectional studies.

[Menezes KKP, Nascimento LR, Alvarenga MTM, Avelino PR, Teixeira-Salmela LF (*submitted*) Prevalence of dyspnea after a stroke: A telephone-based survey. *Topics in Stroke Rehabilitation*].

5.2 INTRODUCTION

Stroke is the second leading global cause of death and the main cause of disability worldwide [1]. Previous studies have demonstrated that stroke affects not only the muscles of the upper and lower limbs, but also those of the respiratory system [2-4]. Patients with stroke typically demonstrate atypical breathing patterns [4,5], decreased ventilatory function [6,7], weakness of the respiratory muscles [2,8], and reduced diaphragmatic activity [9,10]. This abnormal respiratory function may lead to dyspnea in conditions of high and even under low effort demands, which in turn, may interfere with the performance of daily activities and community participation [2-4,8,11].

Dyspnea is defined by the American Thoracic Society as “a subjective experience of breathing discomfort that consists of qualitatively distinct sensations that vary in intensity” [12]. Although dyspnea is seldom the predominant complaint in patients with primary neuromuscular diseases [12], it may be a significant symptom in patients, who show generalized muscle weakness, such as people who suffered a stroke. Furthermore, weakness of the respiratory muscles, associated with sedentary lifestyles and deconditioning, may increase dyspnea after stroke, creating a vicious cycle [13]. This combination of factors may also increase the risk of hospital admissions, due to respiratory complications, which are the leading causes of non-vascular deaths after stroke [14].

Multiple aspects related to dyspnea, such as the prevalence, severity, and frequency have been investigated in the general community and in several health conditions, such as lung diseases and heart failure [15-18]. Quoted prevalence rates for dyspnea vary widely for the general community (1 to 32%) [15], lung diseases (55%) [16], chronic obstructive pulmonary disease (82%) [17], and heart failure (47%) [18]. This variability suggests that dyspnea may be influenced by characteristics, such as age, clinical diagnosis, comorbidities, levels of physical activity, and, therefore, investigation of this relevant symptom should be, at least, disease-specific. It is also known that dyspnea negatively interferes with the ability to perform everyday activities and reduces the perceived quality of life of older individuals and people with respiratory diseases

[15, 19, 20]. Although dyspnea seems to be a clinically relevant outcome to be taken into consideration during rehabilitation [21-23], its prevalence, severity, and effects on the stroke population remain unclear. This information is required to help planning effective interventions, which could help minimizing the effects of dyspnea on daily activity and social participation. Due to the respiratory muscle weakness and sedentary lifestyles adopted by most individuals with stroke [13], it was expected that the prevalence of dyspnea would be high in individuals with stroke, compared to those of the general population

Therefore, the aims of the present study were to investigate the prevalence and severity of dyspnea after stroke, as well the associations between dyspnea, activity limitations, and participation restrictions. The specific research questions were:

1. What is the prevalence and level of severity of dyspnea in people, who suffered a stroke?
2. Is dyspnea associated with activity limitations and/or participation restrictions?

5.3 METHOD

A telephone-based survey was conducted with individuals with stroke. Participants were recruited from the admission lists of stroke care units of two major public hospitals, from March, 2016 to June, 2017 and were included if they were ≥ 20 years of age, at least three months after the onset of stroke, and able to answer simple questions via telephone. Individuals, who were screened to participate in a randomized clinical trial on the effects of respiratory muscle training after stroke [24], were also recruited. This study was approved by the Institutional Research Ethical Committee Review Board (CAAE: 40290114.8.0000.5149) and all participants provided consent.

5.3.1 Survey questionnaire

A telephone-based survey, comprised of 23 questions, was developed by the research team. Two researchers (M.T.M.A. and P.R.A) were trained to

conduct the telephone interviews from a script, to ensure consistency, since dyspnea is often thought of as a sensation similar to pain, which avoids an objective definition assessment, depending of patient self-reports [25]. The survey consisted of a series of questions regarding demographics, characteristics of the stroke and the onset of dyspnea. Specific questions included the severity of dyspnea, which was measured using the Medical Research Council scale. The Medical Research Council is a five-point rating scale, simple to administer, based upon the patient's perceptions of dyspnea while walking distances on level or climbing stairs [26], and significantly correlated with other dyspnea scales [27]. Participants were asked to rate the severity of their dyspnea symptoms, which were categorized as mild (score=1), moderate (scores 2 and 3), and severe (scores 4 and 5) [28]. Additional questions included the frequency, use of medications, and number of hospital admissions. Lastly, participants were asked to inform whether dyspnea limited their activity performance and /or social participation.

5.3.2 Statistical analysis

Descriptive statistics, tests for normality (Kolmogorov-Smirnov), and homogeneity of variance (Levene) were carried out for all outcomes. The prevalence of dyspnea was calculated as the percentage of individuals, who reported having dyspnea. Severity of dyspnea was based upon the Medical Research Council scale and was categorized into mild, moderate, and severe. Dyspnea, activity limitations, and participation restrictions were dichotomized. Chi-square tests were employed to investigate the directions and magnitudes of the correlations, as well as the relative risks, along with respective 95% confidence intervals. All analyses were performed with the SPSS statistical software 23.0 for Windows, with a significance level of 5%.

5.4 RESULTS

5.4.1 Participant's characteristics

A total of 285 individuals, 155 men, participated. Their characteristics are reported in Table 1. The mean age of the participants was 65 years (SD 14) and

the mean time since the onset of the stroke was 15 months (SD 12). The majority of the participants reported more than one episode of stroke (70%) and the most common type of stroke was ischemic (81%).

5.4.2 Incidence and severity of dyspnea

Out of the 285 participants, 124 (44%) reported having dyspnea after the stroke. Out of the 124 participants, who had dyspnea 16 (13%) reported mild, 45 (36%) moderate, and 63 (51%) severe dyspnea. In addition, 105 participants (85%) informed that dyspnea limited their daily activities, whereas 51 (49%) informed that dyspnea restricted social participation.

5.4.3 Association between dyspnea and activity limitations and/or participation restrictions

Dyspnea was significantly correlated with activity limitations ($r=0.87$; 95% CI 0.82 to 0.92; $p<0.01$) and participation restrictions ($r=0.53$; 95% CI 0.46 to 0.62; $p<0.01$). The analyses indicated that individuals, who had dyspnea, were more likely to report activity limitations (RR: 6.5; 95% CI 4.3 to 9.9) and restricted social participation (RR: 1.7; 95% CI 1.5 to 2.0).

5.5 DISCUSSION

This study aimed at investigating the prevalence and severity of dyspnea, as well as the associations between dyspnea, activity limitations, and participation restrictions in people, who had a stroke, through a telephone-based survey. The prevalence of dyspnea was 44%. The majority of the respondents reported having moderate to severe dyspnea, which was associated with activity limitations and participation restrictions.

This study was the first to investigate the prevalence of dyspnea in people with stroke. The present results indicated that almost half of the individuals remain with some degree of dyspnea after the stroke. Furthermore, 51% of the respondents reported severe dyspnea, which indicates the need to stop for breathing after few minutes of walking or breathless sensation during usual everyday activities, such as dressing. [26]. The high prevalence of

dyspnea in people with stroke is worrying, since dyspnea has been shown to be a predictor of mortality related to heart attacks and stroke [29, 30]. Moreover, the high percentage of respondents with severe dyspnea turns on a warning signal, as the risk of deaths significantly increases in people, who have dyspnea of moderate and severe intensities [29, 30]. The results suggested that early detection and management of dyspnea in people with stroke requires attention and should not be under looked.

The present results also demonstrated that 85% and 50% of the participants, who had dyspnea, informed that it limited their activities and restricted their social participation, respectively. Participants, who had dyspnea, were six times more likely to report activity limitation and two times more likely to report restrictions in social participation. This vicious cycle, i.e., reduced activity and deconditioning, may result in increased dyspnea, which is recognized as a key contributor to functional decline, since dyspneic patients are frequently unable to perform their daily life activities, such as walking, due to the discomfort associated with breathing [31].

As dyspnea interferes with many everyday activities involving both the lower and upper limbs, it is not a surprise that perceived community participation is restricted. For instance, if walking ability is poor (particularly walking speed, walking capacity, and ability to manage stairs) after stroke, community participation, which includes leisure activities and social interactions, is expected to be limited, and people may become housebound and isolated from society [32]. Therefore, an early detection of dyspnea in people with stroke, has the potential to improve daily activities and social participation, and reduce the risk of recurrent stroke and deaths [29,30,32,33].

The major strength of the present study is the innovation, since is the first to investigate dyspnea after stroke in a large sample. However, although the sample was broad and drawn from various settings, it was not randomly selected and may not, therefore, be fully representative of the stroke population. Since the recruitment was conducted on a volunteer basis, the volunteers, who agreed to participate, may differ from those of the general community. In addition, a telephone-based survey may also hold some sources of bias.

However, amongst numerous technological advances in medical care, the use of telephone for health care management has increased in scope and application [28], being the telephone-based surveys appropriate for many chronic disorders, including stroke [34]. Furthermore, the Medical Research Council proved to be highly suitable for telephone-based surveys [28].

5.6 CONCLUSIONS

In conclusion, severe dyspnea is an important symptom in people with stroke. The presence of dyspnea was associated with activity limitations and restrictions in community participation. An early detection of dyspnea in people with stroke, followed by appropriate management, is strongly recommended and has the potential to improve daily activities and social participation.

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5.8 Table

Table 1. Characteristics of the participants.

Characteristic		<i>n</i> =285
Age (years), mean (SD)		65 (14)
Sex, men, number (%)		155 (54)
Time since stroke (months), mean (SD)		15 (12)
Number of episodes, number (%)	1	82 (29)
	>1	201 (70)
	Unknown	2 (1)
Type of stroke, number (%)	Ischemic	232 (81)
	Hemorrhagic	21 (8)
	Unknown	32 (11)
Side of weakness, number (%)	Right	109 (38)
	Left	118 (42)
	Both	3 (1)
	Unknown	55 (19)
Associated diseases, number (%)*	Hypertension	229 (80)
	Diabetes	91 (32)
	Hypercholesterolemia	69 (24)
	Other	73 (26)
Number of medications, mean (SD)		4 (3)
Smoking, yes, number (%)		28(10)
Smoking time (years), mean (SD)		38 (18)
No longer smoking, number (%)		127 (45)
Quitted smoking (years), mean (SD)		17 (16)

* Some participants had more than one disease.

Capítulo 6

MÉTODOS E ARTIGO 5

6.1 MÉTODOS

6.1.1 Design

Trata-se de um estudo prospectivo randomizado, com alocação oculta, avaliadores cegados e análise por intenção de tratar em indivíduos pós AVE (Figura 1). Este estudo foi realizado entre março de 2016 a maio de 2017. Os participantes foram alocados aleatoriamente, por meio de um processo de randomização de blocos fixos e ocultos gerados por computador, para os grupos experimental ($n=19$) ou controle ($n=19$). Os participantes do grupo de experimental receberam um treinamento muscular respiratório domiciliar de alta intensidade, enquanto os participantes do grupo controle receberam uma intervenção placebo. As medidas de desfecho foram coletadas no início do estudo (Semana 0), ao final da intervenção (Semana 8) e um mês após o término do treinamento (Semana 12), por avaliadores cegados (Figura 1).

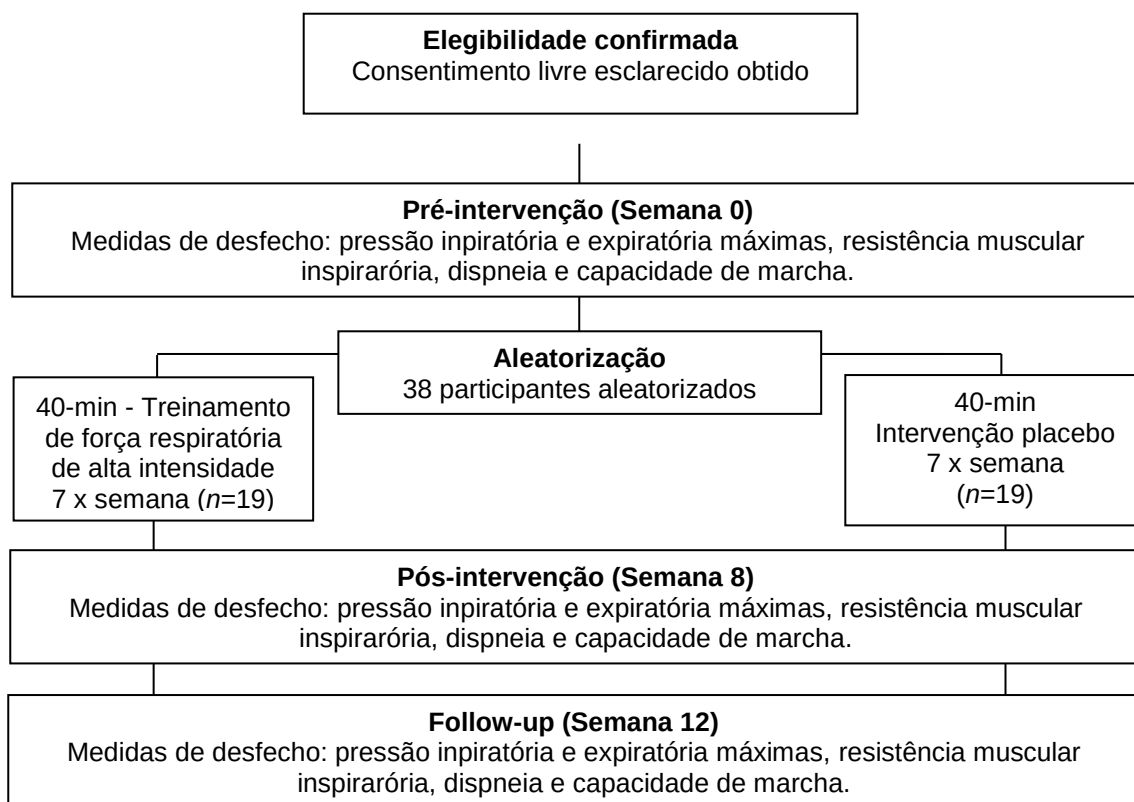


Figura 1. Diagrama de fluxo de coletas.

O estudo obteve aprovação ética do Comitê Ética em Pesquisa (CAAE: 40290114.8.0000.5149) da Universidade Federal de Minas Gerais, Belo

Horizonte, Brasil (ANEXO V). Todos os participantes foram informados sobre o propósito do estudo e forneceram autorização por escrito antes da coleta de dados (APÊNDICE A). O estudo foi registrado no www.ClinicalTrials.gov (NCT02400138) (ANEXO VI).

6.1.2 Participantes, terapeutas e centros

Todos os participantes foram recrutados na comunidade geral da cidade de Belo Horizonte, Brasil, por meio de anúncios publicitários, listas de serviços públicos de reabilitação e listas de projetos de pesquisa anteriores. Os critérios de inclusão foram: tempo pós lesão >3 meses e <5 anos, após o último episódio; idade >20 anos; pressão inspiratória máxima <80 cmH₂O ou pressão expiratória máxima <90 cmH₂O (FARRERO *et al.*, 2013); não estar realizando treinamento respiratório; e capacidade para fornecer o consentimento. Os participantes foram excluídos se apresentassem déficits cognitivos, paralisia facial, doenças respiratórias associadas, condições instáveis, ou quaisquer outras que impedissem ou influenciassem na avaliação ou treinamento.

Um pesquisador independente gerou a sequência de alocação aleatória por computador, usando blocos de permutação de quatro participantes. Para assegurar uma distribuição uniforme entre os grupos, a randomização foi estratificada de acordo com a pressão inspiratória máxima (≥ 45 cmH₂O - fraqueza muscular respiratória leve; <45 cmH₂O - fraqueza muscular respiratória grave). As alocações para cada participante foram colocadas em envelopes opacos, numerados sequencialmente e selados. Após a análise dos critérios de inclusão e a realização da avaliação inicial, um envelope foi aberto e a alocação foi revelada.

Embora não seja possível cegar os participantes devido ao perfil da intervenção, precauções foram tomadas, afim de não revelar detalhes em relação à intervenção aplicada nos dois grupos. No momento do recrutamento, os participantes só receberam a informação de que realizariam um treinamento dos músculos respiratórios, com ou sem progressão de carga, sem informações relacionadas à superioridade de um método em relação ao outro. Além disso, todos os dispositivos de treinamento foram cobertos com material

opaco, de modo que os participantes não tinham acesso aos valores das cargas de treinamento.

6.1.3 Intervenção

Os participantes foram submetidos a um treinamento muscular respiratório de alta intensidade, durante oito semanas, ou a uma intervenção placebo. As intervenções foram realizadas por dois fisioterapeutas com quatro anos (DP 1,4) de experiência profissional na área de reabilitação neurológica. Todos os participantes receberam um dispositivo *Orygen-Dual Valve*, que permite o treinamento simultâneo dos músculos inspiratórios e expiratórios, com ajustes de cargas independente (Fig. 2). O dispositivo fornece cargas de trabalho até 70 cmH₂O e um bocal flexível, confortável, que fornece vedação adequada (MARCO *et al.*, 2013). A única diferença entre os dois grupos foi a carga de treinamento ajustada nos dispositivos.



Figura 2. Orygen Dual Valve, um dispositivo de treinamento de força respiratória, composto de duas câmaras separadas: inspiratória (à direita) e expiratória (à esquerda).

O treinamento foi realizado no ambiente doméstico dos participantes, o que significa que não foi diretamente supervisionado. Assim, para incentivar os participantes a cumprir o protocolo, ambos os grupos assinaram um contrato simbólico de compromisso com o programa de treinamento (APÊNDICE B). Para monitorar a adesão dos participantes ao protocolo proposto, ambos os grupos receberam um diário para registrar os dias e o tempo de cada sessão de treinamento realizado (APÊNDICE C). Quando necessário, um

cuidador/familiar foi instruído a ajudar os participantes no preenchimento do diário.

6.1.3.1 Grupo experimental

Os participantes alocados no grupo experimental receberam treinamento dos músculos respiratórios, 40 minutos por dia, sete vezes por semana, ao longo de oito semanas. O treinamento diário de 40 minutos foi dividido em duas sessões diárias (manhã e tarde). Cada sessão diária foi composta por quatro blocos de treinamento respiratório de quatro minutos, seguido de um minuto de descanso após cada bloco. A carga de treinamento foi adaptada e ajustada individualmente, sendo a carga inicial fixada em 50% da pressão inspiratória e expiratória máximas iniciais, e ajustadas semanalmente por um fisioterapeuta, em uma visita domiciliar, para 50% dos novos valores para cada pressão.

6.1.3.2 Grupo controle

Os participantes alocados no grupo controle receberam uma intervenção placebo. O treinamento muscular respiratório foi administrado usando o mesmo dispositivo, no entanto, sem resistência (0 cmH₂O) ou progressão, também ao longo de oito semanas, durante 40 minutos por dia (divididos em duas sessões), sete vezes por semana,. O grupo controle recebeu os mesmos procedimentos de treinamento e avaliações realizados no grupo experimental, incluindo as visitas domiciliares dos fisioterapeutas, a fim de evitar viés relacionado a quantidade de atenção dada aos participantes.

6.1.4 Medidas de desfecho

As medidas de desfecho foram coletadas no início do estudo (Semana 0), ao final da intervenção (Semana 8) e um mês após o término do treinamento (Semana 12), por avaliadores cegados. Todas as medidas foram realizadas em laboratório, e incluíram uma medida de desfecho primária e cinco secundárias. Os participantes foram instruídos a não fazer comentários sobre o treinamento respiratório recebido.

6.1.4.1 Primária

A medida de desfecho primária foi a força muscular inspiratória ou seja, a pressão inspiratória máxima gerada durante a inspiração, medida por um manovacuômetro digital (UFMG) e reportada em cmH₂O, de acordo com diretrizes prévias (PESSOA *et al.*, 2014; PESSOA *et al.*, 2015). Este instrumento apresenta adequadas propriedades de medidas (PESSOA *et al.*, 2014). A coleta foi realizada com o participante posicionado confortavelmente sentado em uma cadeira, com os pés apoiados no chão, com suporte para as costas e tronco em um ângulo 90 graus em relação ao quadril. Uma boquilha convencional e clipe nasal foram utilizados (PESSOA *et al.*, 2015). Os participantes foram instruídos a respirar tranquilamente, de acordo com o comando verbal "Ponha o ar para fora, ponha o ar para dentro". Duas a três respirações a nível de volume corrente precederam o teste. Para registrar a pressão inspiratória máxima, os participantes realizaram inspirações contra uma via aérea obstruída dentro do bocal (PESSOA *et al.*, 2015). Os indivíduos foram autorizados a praticar duas vezes e, logo em seguida, solicitados a executar pelo menos cinco manobras aceitáveis, com duração de pelo menos um segundo. Foram registrada e armazenadas para análise a maior pressão de três medidas reproduzíveis, com menos de 20% de variabilidade, sendo que a maior medida não deveria ser a última (PESSOA *et al.*, 2015).

6.1.4.2 Secundárias

A força muscular expiratória (ou seja, a pressão expiratória máxima gerada durante a expiração) também foi medida por um manovacuômetro digital (UFMG) e reportada em cmH₂O, seguindo as diretrizes recomendadas para o uso do manovacuômetro (PESSOA *et al.*, 2014; PESSOA *et al.*, 2015). O protocolo de coleta foi o mesmo descrito anteriormente para a pressão inspiratória máxima, exceto que para esta medida os participantes realizaram expirações contra uma via aérea obstruída dentro do bocal (PESSOA *et al.*, 2015).

A resistência muscular inspiratória foi medida através do dispositivo *POWERbreathe KH1*, e reportada pelo número de respirações. Os

participantes foram instruídos a respirar contra uma carga inspiratória sub-máxima (ou seja, 50% de sua pressão inspiratória máxima medida na avaliação inicial), o máximo de tempo possível ou até um limite de sete minutos, seguindo as diretrizes recomendadas para o uso do dispositivo (CHARUSUSIN *et al.*, 2013).

A dispneia foi medida através da *Medical Research Council*, uma escala de cinco pontos, com escores variando de zero a quatro. O escore é dado pelo valor que melhor representa a dispneia do participante, em que quanto maior a pontuação, maior a dispneia em atividades leves. Assim, zero indica "falta de ar ao realizar exercício intenso" e quatro indica "tanta falta de ar, que o indivíduo não sai mais de casa" (KOVELIS *et al.*, 2008). A *Medical Research Council* já foi traduzida e validada para a população brasileira, com adequadas propriedades de medidas (KOVELIS *et al.*, 2008).

A incidência de complicações respiratórias foi mensurada semanalmente, perguntando aos participantes se eles foram hospitalizados, devido a causas respiratórias (por exemplo, pneumonia). O número de internações hospitalares foi registrado.

A capacidade de marcha foi medida através do Teste de Caminhada de 6 Minutos, e reportada como a distância percorrida, em metros. Os participantes foram instruídos a andar a maior distância possível, contornando dois cones distanciados a 30 metros, podendo fazer uso de suas órteses e realizar pausas, conforme necessário, de acordo com o protocolo padronizado (ATS/ERS, 2002). Os indivíduos tiveram a sua pressão arterial, frequência cardíaca, saturação periférica e sensação de esforço (Escala de Borg Modificada) avaliados no início e término do teste. Instruções padronizadas por meio de comando verbal foram dadas aos indivíduos por avaliadores treinados, de acordo com critérios estabelecidos previamente (BRITTO; SOUZA, 2006; BRITTO *et al.*, 2013). O TC6min possui propriedades de medida adequadas para indivíduos pós-AVE (FULK *et al.*, 2008; SALBACH *et al.*, 2011).

Por fim, a eficácia das precauções em relação ao "cegamento" dos participantes foi avaliada após a conclusão de todas as avaliações, perguntando aos avaliadores se os participantes haviam revelado sua

alocação, ou qualquer outra informação, que evidenciasse o grupo em que estavam alocados. Além disso, após as avaliações, os participantes foram indagados sobre o treinamento, com a seguinte pergunta: "Você participou de um teste com dois grupos que receberam treinamento muscular respiratório. Em um grupo, as cargas de treinamento foram ajustadas semanalmente, enquanto que no outro grupo, as cargas de treinamento não foram alteradas. Você sabe para qual grupo você foi alocado?" Foram dadas três opções de respostas possíveis: i) grupo com progressão de cargas de treinamento, ii) grupo sem progressão de cargas de treinamento, ou iii) não sabe. Os avaliadores também foram indagados se saberiam dizer em qual grupo cada participante foi alocado. Foram dadas três opções de respostas possíveis: i) grupo experimental, ii) grupo controle, ou iii) não sabe.

6.1.5 Cálculo amostral

O número de participantes foi calculado para detectar, de forma confiável, uma diferença entre grupos de 15 cmH₂O na força dos músculos inspiratórios, com um *power* de 80%, nível de significância de 0,05, e considerando uma taxa de abandono dos participantes de 15%. Em um ensaio clínico aleatorizado, com uma população similar (BRITTO *et al.*, 2011), a força média dos músculos inspiratórios na avaliação inicial foi de 57 cmH₂O (SD 15), usando os mesmos procedimentos de medição. Assim, o número de participantes necessários para detectar uma diferença de 15 cmH₂O entre dois grupos independentes foi de 15 participantes por grupo. No entanto, com base no pressuposto de que cerca de 15% dos participantes poderiam abandonar o estudo durante o seu desenvolvimento, o número mínimo de participantes considerado necessário foi 18 participantes por grupo ($n=36$) (MENEZES *et al.*, 2017).

6.1.6 Análise dos dados

Um pesquisador independente, cegado, em relação à alocação dos grupos, realizou a análise estatística. Todas as análises foram realizadas com intenção de tratar. A coleta de dados resultou em seis variáveis, que refletem

deficiências e limitações de atividade: força muscular inspiratória e expiratória (cmH₂O), resistência muscular inspiratória (número de respirações), dispneia (*Medical Research Council*, 0-4), complicações respiratórias (número de internações hospitalares) e capacidade de marcha (metros). Uma vez que existem dois fatores (tempo x grupo), com medidas repetidas no fator de tempo (Semana 0, Semana 8 e Semana 12), ANOVA de medidas repetidas (2*3) foi utilizada para avaliar as diferenças entre grupos para as variáveis força inspiratória e expiratória, resistência inspiratória e capacidade de caminhada. O teste *Mann-Whitney U* foi utilizado para avaliar a diferença entre grupos para as variáveis dispneia e complicações respiratórias. A diferença média entre os grupos e os intervalos de confiança de 95% foram reportados para todos os resultados. Todas as análises foram realizadas com o programa estatístico SPSS 17.0.

6.2 RESULTADOS

6.2.1 Recrutamento

De uma lista inicial de 355 indivíduos, 54 não atenderam aos critérios de inclusão e 31 faleceram. Dos 270 restantes, 135 indivíduos não puderam ser contactados (número errado, número ocupado, não atendeu, não estava em casa) e 65 se recusaram a participar do estudo. Daqueles que foram agendados para a avaliação inicial ($n=70$), 15 não compareceram e 17 apresentaram valores elevados de pressão inspiratória máxima (> 80 cmH₂O) e/ou pressão expiratória máxima (> 90 cmH₂O). Desta forma, 38 indivíduos foram recrutados e participaram do presente estudo (Figura 3).

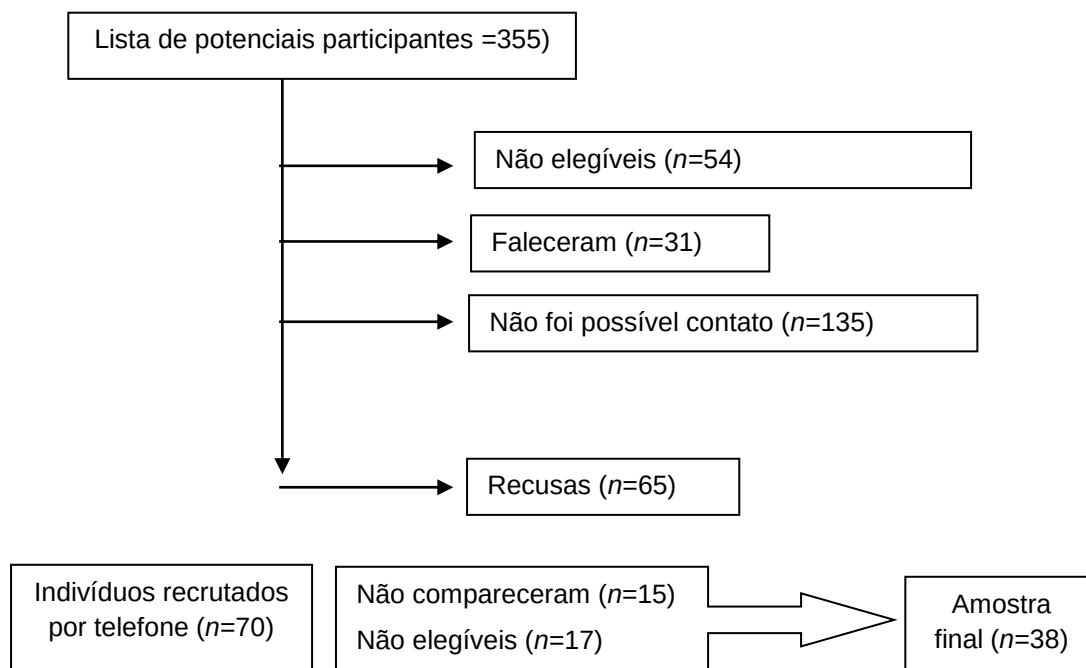


Figura 3. Fluxograma do recrutamento do estudo.

Os 71 indivíduos, que não foram elegíveis a participar do presente estudo, foram excluídos devido às seguintes razões: não haviam sofrido AVE, tempo pós-lesão inferior a três meses ou superior a cinco anos, tinham afasia de expressão, condições cardíacas instáveis, pós-cirúrgico, ou apresentaram valores elevados de pressão inspiratória e/ou expiratória máximas. Todas essas informações foram obtidas através do prontuário dos indivíduos dos hospitais os quais foram atendidos, através de contato telefônico, ou pela avaliação inicial para análise dos critérios. Em relação às recusas, as principais razões apresentadas foram desinteresse, falta de tempo, e dificuldade em sair de casa.

6.2.2 Participantes

Trinta e oito participantes, 16 homens, foram elegíveis e incluídos no estudo, sendo randomizados em dois grupos semelhantes. A média de idade dos participantes foi de 63 (SD 13) anos e do tempo de evolução foi de 20 (SD 17) meses. Suas características estão descritas na Tabela 1.

Tabela 1. Características dos participantes.

Características		Intervenção <i>n</i> =19	Controle <i>n</i> =19
Idade (anos), média (DP)		60 (14)	67 (11)
Sexo, homem, número (%)		8 (42)	8 (42)
Tempo pós lesão (meses), média (DP)		24 (20)	16 (12)
Número de episódios, número (%)	1	13 (68)	14 (74)
	>1	6 (32)	5 (26)
Tipo de AVE, número (%)	Isquêmico	12 (63)	15 (79)
	Hemorrágico	3 (16)	3 (16)
	Desconhecido	4 (21)	1 (5)
Lado parético, número (%)	Direito	12 (63)	6 (32)
	Esquerdo	6 (32)	11 (58)
	Desconhecido	1 (5)	2 (10)

6.2.3 Adesão

Dentre os 38 participantes incluídos, 36 realizaram todo o protocolo de treinamento e 37 realizaram todas as avaliações. Um participante do grupo experimental interrompeu os exercícios, após duas semanas de treinamento relatando dor torácica. Um participante do grupo controle abandonou o estudo após iniciar a intervenção, relatando motivos profissionais. Assim, os dados das medidas de pós-intervenção e *follow-up* foram perdidos para o participante do grupo controle, que abandonou o estudo. Além disso, seis participantes (três do grupo intervenção) se recusaram a retornar para a medida de *follow-up*. Os dados faltosos foram substituídos pela medida mais próxima de cada participante. A avaliação de oito semanas foi realizada uma semana depois do previsto em seis participantes. Os motivos relatados incluíram: viagem do participante (*n*=1), falta de tempo dos participantes ou cuidadores (*n*=3) ou o pesquisador não conseguiu contatar o participante (*n*=2). O único evento adverso relatado foi dor torácica durante o exercício (*n*=1), relatado pelo paciente do grupo controle, que interrompeu os exercícios após duas semanas de treinamento.

Cinco participantes (14%) (dois do grupo intervenção) perderam seus diários de treinamento, e 10 (28%) (cinco do grupo intervenção) retornaram os

diários com informações incompletas. As análises dos 21 diários com informações completas e corretas revelaram que todos os participantes incluídos realizaram, pelo menos, 80% do protocolo de treinamento domiciliar proposto. Os principais motivos relatados quando houve falha no treinamento (não realizou todos os dias ou não treinou por 40 minutos) foram falta de tempo, esquecimento e doença (como gripe, por exemplo). Em relação às sete visitas domiciliares propostas durante as oito semanas de treinamento, a média de visitas foi de 5,8. Os principais motivos que impediram essas visitas foram: viagem do participante, falta de tempo do participante ou cuidador para receber o pesquisador, mal-estar (gripe, dor ortopédica, etc.), o pesquisador não conseguiu contatar o participante, e recusa a receber o pesquisador.

Em relação ao cegamento dos avaliadores, estes conseguiram inferir corretamente a alocação de 11 participantes. Em relação aos participantes, 58% do grupo experimental e 47% do grupo controle indicaram que acreditavam estar no grupo superior, ou seja, o grupo com ajuste de carga semanal, com a maioria dos demais participantes indicando que não tinham certeza em relação à alocação.

6.3 Artigo 5:

Effect of high-intensity home-based respiratory muscle training on strength of respiratory muscles following a stroke: a protocol for a randomized controlled trial

O presente artigo trata-se do protocolo, com a descrição detalhada da metodologia utilizada no ensaio clínico aleatorizado, produto principal desta tese. Quando apresentam propostas de protocolos de intervenção inéditos, a publicação deste tipo de estudo é fundamental, pois permite uma exposição mais minuciosa de todos os métodos utilizados durante a pesquisa, o que geralmente não é possível na publicação do estudo final, devido à restrição de caracteres/palavras exigidos pelos periódicos. Assim, uma vez que o presente estudo trata-se de um protocolo inédito de treinamento muscular respiratório em indivíduos pós AVE, com proposta de treino domiciliar, com intensidade, duração, e frequência acima dos valores já descritos na literatura, com acompanhamento e ajuste de carga semanal, este foi publicado no *Brazilian journal of Physical Therapy*. Esta publicação se encontra a seguir, seguida do ensaio clínico aleatorizado, a ser submetido no periódico *Journal of Physiotherapy*.

Trial registration: Clinical Trials, NCT02400138. Registrado em 23 de março de 2015 (<https://clinicaltrials.gov/show/NCT02400138>).0.

[Menezes KKP, Nascimento LR, Polese JC, Ada L, Teixeira-Salmela LF (2017) Effect of high-intensity home-based respiratory muscle training on strength of respiratory muscles following a stroke: a protocol for a randomized controlled trial. *Brazilian Journal of Physical Therapy* 21(5):372-377].

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CLINICAL TRIAL PROTOCOL

Effect of high-intensity home-based respiratory muscle training on strength of respiratory muscles following a stroke: a protocol for a randomized controlled trial[☆]



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KEYWORDS

Clinical trial;
Stroke;
Breathing exercises;
Gait;
Muscle strength;
Rehabilitation

Abstract

Background: Respiratory muscle training has shown to increase strength of the respiratory muscles following a stroke. However, low duration and/or intensity of training may be responsible for the small effect size seen and/or absence of carry-over effects to an activity, e.g., walking. Therefore, an investigation of the effects of long-duration, high-intensity respiratory muscle training is warranted.

Objective: This proposed protocol for a randomized clinical trial will examine the efficacy of high-intensity respiratory muscle training to increase strength and improve activity following a stroke.

Methods: This study will be a two-arm, prospectively registered, randomized controlled trial, with blinded assessors. Thirty-eight individuals who have suffered a stroke will participate. The experimental group will undertake a 40-min of respiratory muscle training program, seven days/week, for eight weeks in their homes. Training loads will be increased weekly. The control group will undertake a sham respiratory muscle training program with equivalent duration and scheduling of training. The primary outcome will be the strength of the inspiratory muscles, measured as maximal inspiratory pressure. Secondary outcomes will include expiratory muscle strength, inspiratory muscle endurance, dyspnea, respiratory complications, and walking capacity. Outcomes will be collected by a researcher blinded to group allocation at baseline (Week 0), after intervention (Week 8), and one month beyond intervention (Week 12).

[☆] **Trial registration:** Clinical Trials, NCT02400138. Registered on March 23rd, 2015 (<https://clinicaltrials.gov/show/NCT02400138>).

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Conclusion: High-intensity respiratory muscle training may have the potential to optimize the strength of the respiratory muscles following a stroke. If benefits are carried over to activity, the findings may have broader implications, since walking capacity has been shown to predict physical activity and community participation on this population.

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Introduction

Following a stroke, the loss of the ability to generate normal amounts of force also affects the respiratory muscles.¹ Mean inspiratory muscle strength has been reported as ~51 cmH₂O in stroke patients, compared with ~92 cmH₂O in healthy adults, and expiratory strength as 67 cmH₂O, compared to ~117 cmH₂O.² That is, respiratory muscle strength in people suffering from a stroke is half of that expected in healthy adults. Weakness of the respiratory muscles has been related to decreased walking capacity,^{3,4} which, in turn, has been related to restrictions in community participation. Additionally, respiratory muscle weakness may limit participation in community exercise programs, due to the reduced capacity to walk long distances.⁵

Respiratory muscle training has the potential to increase the strength of the respiratory muscles,⁶ and its effect has been previously examined in people with acute and chronic respiratory conditions,^{7,8} heart failure,⁹ and stroke.^{1,10,11} With this type of training, patients are asked to perform repetitive breathing exercises against an external load (e.g., using a flow-dependent resistance device or a pressure threshold device^{8,10}), in order to increase muscle strength and/or endurance. There have been four systematic reviews^{1,10–12} with meta-analysis of randomized trials examining the effect of respiratory muscle training on measures of respiratory muscle strength following a stroke. However, two reviews included only two trials of inspiratory training with substantial statistical heterogeneity ($I^2 = 95\%$), leading to inconclusive findings.^{1,11} More recent systematic reviews^{10,12} examined the effect of both inspiratory and expiratory muscle training following a stroke. Gomes-Neto et al.¹² included seven randomized trials of reasonable quality and reported increases of 7 cmH₂O in inspiratory strength (95%CI: 3–12; $I^2 = 45\%$) and forced vital capacity (MD 2 L, 95%CI: 1–3, $I^2 = 86\%$), forced expiratory volume at 1 second (MD 1.2 L, 95%CI: 1–2; $I^2 = 51\%$), and exercise tolerance (SMD 0.7, 95%CI: 0.2–1.2; $I^2 = 0$). However, the results were not significant for expiratory strength (MD 6 cmH₂O, 95%CI: –4 to 15; $I^2 = 57\%$). Menezes et al.¹⁰ included five randomized trials of reasonable quality and reported increases of 7 cmH₂O in inspiratory strength (95%CI: 1–14; $I^2 = 33\%$) and 13 cmH₂O for expiratory strength (95%CI: 1–25; $I^2 = 12\%$). However, the results were inconclusive regarding inspiratory endurance, occurrence of respiratory complications, and carry-over to everyday activity. Furthermore, only one of the trials included combined training (i.e., inspiratory plus

expiratory training), a combination which has the potential to optimize the effects of training.

Although evidence appears to recommend respiratory muscle training to increase the strength of the respiratory muscles, the magnitude of the effect was small and the effect size may potentially be increased if training is of appropriate duration and/or intensity. The majority of the trials, which were included in the reviews, targeted only inspiratory or expiratory muscles, had a mean training duration of four weeks, and did not systematically progress training. As respiratory muscles respond to training stimuli in a similar fashion to other skeletal muscles, they can be overloaded by requiring them to work longer, at high intensities, and/or more frequently, than they are normally accustomed to.² Thus, the effect of respiratory muscle training on strength and activity following a stroke may be increased with higher intensity training (i.e., increased frequency, duration and training of both muscle groups).

Therefore, this protocol for a randomized clinical trial will examine whether high-intensity respiratory muscle training is effective in increasing strength and endurance of the respiratory muscles, decreasing dyspnea sensation and respiratory complications, and improving walking capacity following a stroke.

Methods

Study design

A prospective, randomized trial with concealed allocation, blinded assessors, and intention-to-treat analysis will be carried-out (Fig. 1). Community-dwelling people who have suffered a stroke will be recruited and randomly allocated to either a respiratory muscle training (experimental) group or a sham training (control) group. Outcome measures will be collected by trained researchers at baseline (Week 0), at the end (Week 8), and one month after the cessation of the training (Week 12). Data collection and analysis will be carried-out by a researcher blinded to the group allocation. Participants will be informed about the study and will provide consent before participating in the trial. The study obtained ethical approval from the Institutional Research Ethical Committee (CAAE: 40290114.8.0000.5149) of the *Universidade Federal de Minas Gerais*, Belo Horizonte, Brazil. The trial was prospectively registered at the ClinicalTrials.gov (NCT02400138).

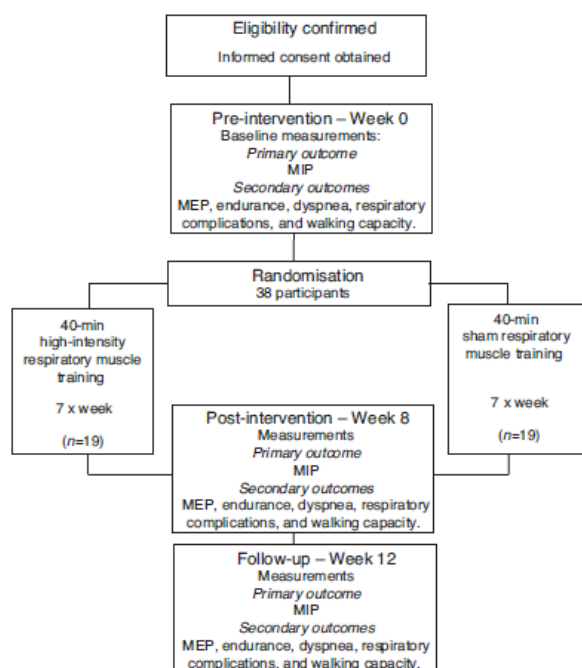


Figure 1 Flow diagram of the planned protocol pathway. MIP, maximal inspiratory pressure; MEP, maximal expiratory pressure.

Patient population – inclusion and exclusion criteria

Participants will be people who have suffered a stroke, who will be eligible if they:

- are >3 months and <5 years after their last stroke episode;
- are >20 years of age;
- have maximal inspiratory pressure <80 cmH₂O or maximal expiratory pressure <90 cmH₂O¹³;
- have not undertaken any respiratory training;
- have provided written consent.

Participants will be excluded if they have:

- cognitive deficits, which might prevent them from following instructions;
- facial palsy, associated respiratory diseases, or unstable conditions, which might prevent testing or training;
- undergone thoracic or abdominal surgery.

Physical therapists, who will deliver both interventions (experimental and control), will be eligible to work with the participants if they have at least two years of professional experience in the area of neurological or pulmonary rehabilitation.

Randomization

The randomization method will be computer-generated, independent, using random permutation blocks of four

participants, and stratified according to the maximal inspiratory pressure (≥ 45 cmH₂O – respiratory muscle weakness; <45 cmH₂O – severe respiratory muscle weakness), to ensure an even spread between the groups. The participant allocation will be concealed in sequentially numbered and sealed opaque envelopes, prepared prior to the study by a research assistant, who will not be involved in the study. After the baseline measures have been collected, participants will be randomly allocated to the experimental or control groups by the intervention therapist, using the content in the sealed opaque envelopes.

Intervention

The respiratory muscle training will be carried-out using an Orygen Dual Valve device (Forumed S.L., Barcelona, CAT, ESP). This respiratory device allows patients to train the inspiratory and expiratory muscles simultaneously and to adjust the loads independently. The Orygen Dual Valve is a relatively cheap, portable, easy to use piece of equipment and provides workloads up to 70 cmH₂O with load adjustments of 10 cmH₂O.¹⁴

The experimental group will receive home-based respiratory muscle training, totaling 40 min per day, seven days per week, over eight weeks. The 40-min daily training will be split into two daily sessions (i.e., morning and afternoon). Each daily session will be comprised of 4 four-minute sets of respiratory training with one-minute rest intervals between each set. The resistance will be provided by the Orygen Dual Valve, which allows individuals to exercise the inspiratory and expiratory muscles simultaneously during the training session.¹⁵ Training will be individually tailored for each participant. The initial training load for each participant will be set at 50% of his/her maximal baseline inspiratory and expiratory strength for both inspiratory and expiratory strength training. The participants will be trained and instructed to do the exercise program on their own with no supervision. Once a week, during the physical therapist's home visit, the clinician will determine the new values for maximal inspiratory and expiratory strength, and will adjust the load to 50% of the new values. The device will be covered with opaque material, so that participants will be blinded to the training load.

The control group will receive a sham intervention. Sham respiratory muscle training will be delivered using a Orygen Dual Valve with no resistance (0 cmH₂O) or progression, over the 8 week period, 40 min per day, seven days per week. The device will be covered with opaque material, so that participants will be blinded to the fact that they are receiving no training load. The control group will receive the same training and testing schedule as the experimental group. This will avoid bias related to amount of attention given to participants. If training proves to be effective, the control group may receive the experimental training program after the experiment is complete and if it proves to be effective.

The respiratory muscle training will be undertaken in the participant's home environment, which will reduce the cost of the intervention and may result in good compliance.¹⁶ On the other hand, this means that the training will not be directly supervised. To record the compliance, participants will receive a diary to register the time and days

of each training session and their daily training volume. When required, a caregiver will be instructed how to help them. To encourage the participants to comply with the protocol, both groups will be asked to sign a contract of commitment to the training program. All the participants will be evaluated and receive all the information regarding the home-based training in a research laboratory.

Primary outcome

The primary outcome to be measured is strength of the inspiratory muscles (i.e., maximal inspiratory pressure generated during maximum resistance of inspiration, measured using a digital manovacuometer¹⁷), and reported as pressure (cmH₂O), following the recommended guidelines for the use of the manovacuometer.¹⁸

Secondary outcomes

Secondary outcomes to be measured are the strength of the expiratory muscles, inspiratory endurance, dyspnea, respiratory complications, and walking capacity.

Strength of the expiratory muscles (i.e., maximal expiratory pressures generated during maximum resistance of expiration), will be measured using a digital manovacuometer,¹⁷ and reported as pressure (cmH₂O), following the recommended procedures for the use of the manovacuometer.¹⁸

Inspiratory endurance will be measured using a flow-resistive loading device (POWERbreathe KH1) and reported as the number of breaths. Participants will be asked to breathe against a sub-maximal inspiratory load (i.e., 50% of their maximal inspiratory pressure measured at baseline, until task failure), following the recommended guidelines for the flow-resistive loading device.¹⁹

Dyspnea will be measured using the Medical Research Council Scale, which is a 5-point scale, in which 0 indicates 'breathless only with strenuous exercise' and 4 indicates 'too breathless to leave the house'.²⁰

The incidence of respiratory complications will be measured weekly during the 12 weeks of the study by asking the participants whether they were admitted to a hospital and how often for respiratory causes (e.g., pneumonia or lung infections).

Walking capacity will be measured using the 6-min Walk Test and reported as distance (m) covered in 6 min. Using a standardized protocol for the 6-min Walk Test,²¹ participants will be instructed to cover the maximum distance possible in 6 min, taking rests as needed.

Data monitoring

An independent researcher, who will be blind to the group allocations, will monitor any adverse effects and perform database management and statistical analyses. The treating physical therapists will be responsible for the monitoring of exercise doses and participants program compliance.

Sample size estimates

Thirty-eight participants will be recruited, using strength of inspiratory muscles as the primary outcome. The sample size was calculated to reliably detect a between-group difference of 15 cmH₂O, with 80% power, at a two-tailed significance level of 0.05, and an expected drop-out rate of 15%. In a randomized trial with a similar population,²² the strength of the inspiratory muscles was 57 cmH₂O (SD 15) using the same measurement procedures. The least number of participants needed to detect a 15 cmH₂O difference between two independent groups in that study was 16 subjects per group. Based on the assumption that about 15% of the participants might drop-out during the course of the study, a target of 38 participants in total is set.

Statistical analyses

Data collection will return six variables, which reflect impairments and activity limitations: inspiratory and expiratory strength (cmH₂O), inspiratory endurance (i.e., number of breaths), dyspnea (Medical Research Council scale 0–4), respiratory complications (i.e., number of hospital admissions), and walking capacity (i.e., meters in 6 min). There are two factors (group × time), with repeated measures on the time factor. Two-way analyses of variance with repeated measures at all time-points for all outcomes will be reported to evaluate the statistical significance of between-group differences. The mean between-group difference and 95% confidence intervals will be reported for all outcomes. The effect of the intervention will be calculated based on intention-to-treat analyses.

Discussion

Significance of the study

The proposed clinical trial will examine the efficacy of a high-intensity respiratory muscle training protocol delivered to people following a stroke. Although previous systematic reviews have shown positive effects of respiratory muscle training on strength of the respiratory muscles, the effect sizes were too small and insufficient to provide carry-over effects to everyday activities.^{10,12} In response to this challenge, a higher intensity training (i.e., increased frequency, duration, and targeting both inspiratory and expiratory muscles), which may result in relevant increases in respiratory muscle strength. Since respiratory muscle training not only imposes a resistance to the respiratory muscles, but also causes hyperventilating for prolonged periods of time, it may have an additional effect on respiratory muscle endurance,^{2,23,24} which could translate into a more efficient use of the respiratory muscles in activities of daily living. Furthermore, if benefits are carried over to activity, the findings may have broader implications, since walking capacity has been shown to predict physical activity and community participation following a stroke.⁵

In addition, a previous systematic review¹⁰ has indicated that respiratory muscle training has the potential to decrease the risk of respiratory complications after stroke.

It is well known that pneumonia and respiratory illness are the most common reasons associated with hospital admissions and death following a stroke, responding for 15% of the readmissions.²⁵ The adoption of interventions capable of preventing the occurrence of respiratory complications may substantially improve the long-term outcomes of patients following a stroke.²⁶ Our clinical trial aims to clarify the evidence regarding the effects of a respiratory muscle training on the occurrence of respiratory complications. If training benefits will lead to decreases number of readmissions/deaths due to respiratory complications, the findings may have broader implications, such as reduced costs arising from immediate and long-term health care, increased production due to reduced sick leave, and early retirements.

The experimental intervention will be delivered via the Oxygen-Dual Valve®. This device is a relatively inexpensive (costs about 60 US dollars) and portable respiratory trainer that also allows patients to simultaneously work both the inspiratory and expiratory muscles.¹⁴ Although it has been recently developed, studies have proven its efficacy in patients with chronic heart failure¹⁴ and stroke.¹⁵ If the intervention provides better results than the sham treatment, this device could be a good option for patients with respiratory muscle weakness.

In conclusion, the results of the trial may result in an important advance in neurological/pulmonary rehabilitation. First, the magnitude of effect may be higher than previous trials, due to the increased intensity of training. Second, if benefits are carried over to activity, community participation may be enhanced, given that the 6-min Walk Test is a strong predictor of community walking in people following a stroke.²⁷ Third, if the results lead to a reduction in hospital admissions, respiratory muscle training could help reducing direct and indirect costs associated with a stroke.

Strengthens and weakness of the proposed protocol

The strength of the proposed protocol is that it is a randomized controlled trial that has been prospectively registered. The trial also includes concealed allocation and an intention-to-treat approach. The sample size has been calculated to provide appropriate statistical power to detect between-group differences in the primary outcome. The assessor responsible for collecting the outcome data will be blind to group assignment. The physical therapist, who delivers the training, has clinical experience and a masters degree in neurological rehabilitation. This trial has some limitations, since participants and therapist cannot be really blinded, which is impractical during the delivery of complex interventions. The experimental and control interventions consist of home exercises, which depend on participants' motivation. It is not possible to predict the amount of home exercises that will be performed. Strategies to encourage participants to comply with the protocol, such as contract of commitment to the training, phone calls, and weekly visits, are planned.

Conflicts of interest

The authors declare no conflicts of interest.

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Capítulo 7

ARTIGO 6

High-intensity home-based respiratory muscle training increases strength and endurance of respiratory muscles and reduces dyspnea after stroke: a randomized-controlled trial

7.1 ABSTRACT

Question: Does high-intensity home-based respiratory muscle training increase strength and endurance of respiratory muscles and decrease dyspnea and occurrence of respiratory complications after stroke? Are the effects maintained beyond the training and/or carried-over to walking capacity? **Design:** Two-arm, prospectively registered, randomized trial, with blinded measurers. **Participants:** Thirty-eight individuals with respiratory muscle weakness, following stroke. **Intervention:** High-intensity home-based respiratory muscle training. The experimental group received 40-min home-based respiratory muscle training, seven days/week, for eight weeks. Training loads were increased weekly. The control group received sham respiratory muscle training with an equivalent schedule. **Outcome measures:** Primary outcome was strength of the inspiratory muscles, measured as maximal inspiratory pressure. Secondary outcomes were strength of the expiratory muscles, endurance of the inspiratory muscles, dyspnea, occurrence of respiratory complications, and walking capacity. Outcomes were measured by a researcher blinded to group allocation at baseline (Week 0), after training (Week 8), and one month beyond training (Week 12). **Results:** Compared to the control, the experimental group showed increased inspiratory (27 cmH₂O; 95% CI 15 to 39) and expiratory (42 cmH₂O; 95% CI 25 to 59) strength, inspiratory endurance (34 breathes; 95% CI 21 to 47) and reduced dyspnea (-1.3 out of 5.0; 95% CI -2.1 to -0.5) and the benefits were maintained at one month beyond training. There was no significant between-group difference for walking capacity. There was one respiratory complication could per group. **Conclusion:** High-intensity home-based respiratory muscle training was effective in increasing strength and endurance of the respiratory muscles and reducing dyspnea after stroke, was

maintained beyond the intervention, but did not carry over to increased walking capacity.

Key-words: clinical trial; stroke; respiratory muscle training; strength; gait; rehabilitation.

Trial registration: Clinical Trials, NCT02400138. Registered on March 23rd, 2015 (<https://clinicaltrials.gov/show/NCT02400138>)

[Menezes KKP, Nascimento LR, Avelino PR, Alvarenga MTM, Ada L, Polese JC, Barbosa MH, Teixeira-Salmela LF. High-intensity home-based respiratory muscle training increases strength and endurance of respiratory muscles and reduces dyspnea after stroke: a randomized controlled trial. *A ser submetido à revista Journal of Physiotherapy*].

7.2 INTRODUCTION

Stroke is the second leading global cause of death and the leading cause of disability [1]. Recent data indicated that 30 million people in the world have experienced and survived a stroke [2]. After a stroke, muscle weakness is the most prominent motor impairment, which affects not only the upper and lower limb muscles, but also the respiratory ones [3]. Respiratory strength in people with stroke is, approximately, half of that expected for healthy adults [3], resulting in atypical breathing patterns and decreased respiratory function [4]. Furthermore, individuals with stroke typically report dyspnea in conditions of high and even under low effort demands, which in turn, may interfere with the performance of daily activities and limit community participation [5-8].

Respiratory muscle training has been employed to increase the strength of the inspiratory and expiratory muscles in people with stroke [3,6,8-10]. This type of training consists of repetitive breathing exercises against an external load, using a flow-dependent resistance or a pressure threshold, which can be controlled by parameters, such as time, intensity, and/or frequency of the training [4,6]. Respiratory muscle training is based upon the premise that respiratory muscles respond to training stimuli, by undergoing adaptations to their structure in the same manner, as any other skeletal muscles, when their fibers are overloaded, increasing both the proportion of type I fibers and the size of type II fibers [11]. Thus, to obtain a training response, the muscle fibers should be overloaded, by requiring them to work for longer, at higher intensities and/or more frequently, than they are accustomed to. Furthermore, because respiratory muscle training not only imposes a resistance to the respiratory muscles, but also consists of hyperventilating for prolonged periods of time, it may have an additional effect on respiratory endurance [4,12] and could translate into a more efficient use of the respiratory muscles in activities of daily living.

Four systematic reviews with meta-analysis, of randomized trials, examined the effects of respiratory muscle training in individuals with stroke

[6,10]. However, two reviews included only two trials of inspiratory training with substantial statistical heterogeneity ($I^2 = 95\%$), leading to inconclusive findings [3,13]. More recent, Gomes-Neto et al. [10] included seven randomized trials of reasonable quality, and reported increases of 7 cmH₂O in inspiratory strength (95%CI: 3 to 12; $I^2 = 45\%$), forced vital capacity (MD 2 L, 95%CI: 1 to 3, $I^2 = 86\%$), forced expiratory volume at 1 sec (MD 1.2 L, 95%CI: 1 to 2; $I^2 = 51\%$), and exercise tolerance (SMD 0.7, 95%CI: 0.2 to 1.2; $I^2 = 0$). However, the results indicated that respiratory muscle training was not effective for increasing expiratory strength (MD 6 cmH₂O, 95%CI: -4 to 15; $I^2 = 57\%$). Menezes et al. [6] included five randomized trials of reasonable quality and reported increases of 7 cmH₂O in inspiratory strength (95%CI: 1 to 4; $I^2 = 33\%$) and 13 cmH₂O in expiratory strength (95%CI: 1 to 25; $I^2 = 12\%$). However, the results were inconclusive regarding inspiratory endurance, occurrence of respiratory complications, and carry-over effects to everyday activities.

Although there is evidence regarding increases in strength associated with respiratory muscle training after stroke, some questions remain unclear. First, only one of the included studies on the systematic reviews combined inspiratory and expiratory training [9]. Since inspiratory and expiratory weakness is associated with symptoms, such as dyspnea, and ineffective cough with increased risk of aspiration pneumoniae [4], training both muscles could have the potential to optimize the effects. Furthermore, studies are still warranted, to investigate whether the benefits of respiratory muscle training are carried over to endurance and activity. Moreover, although previous trials found significant results, the magnitude of the effect may be considered clinically small [14,15]. Possible explanations for these findings, previously pointed-out by Menezes et al. [6], could be that the majority of the trials did not systematically progress training and had a mean training duration of only four weeks. Therefore, it is possible that with a training targeted to require both inspiratory and expiratory muscles to work longer, at high intensities, and/or more frequently, than they are normally accustomed to, the effects on strength and activity would be higher. For instance, the effects of high-intensity training on

strength, endurance, and dyspnea have already been demonstrated in patients with heart failure [16]. There were not found any studies, which applied high-intensity training after stroke. Furthermore, if benefits are carried over to activity, community participation may be enhanced, given that walking capacity is a strong predictor of community walking in people following a stroke [17].

Therefore, this randomized clinical trial examined whether high-intensity respiratory muscle training is effective in increasing strength and endurance of the respiratory muscles, decreasing dyspnea and respiratory complications, and improving walking capacity after stroke. The specific questions were:

1. Does high-intensity home-based respiratory muscle training increase the strength and endurance of the respiratory muscles and decrease dyspnea and respiratory complications after stroke?
2. Are the effects maintained beyond the training and/or carried-over to walking capacity?

7.3 METHOD

7.3.1 Design

A prospective randomized trial, with concealed allocation, blinded assessors, and intention-to-treat analysis was undertaken, between March, 2016 and May, 2017 (Figure 1). Participants were randomly allocated, via a computer-generated, concealed, fixed blocked randomization procedure to either experimental ($n=19$) or control ($n=19$) groups. The experimental group received a home-based respiratory muscle training of high intensity, and the control group received a sham training. Outcome measures were collected at baseline (Week 0), at the end of the training (Week 8), and one month after the cessation of the training (Week 12), by blinded assessors.

This trial obtained ethical approval from the Research Ethical Committee (CAAE: 40290114.8.0000.5149) of the Universidade Federal de Minas Gerais, Belo Horizonte, Brazil. All participants were informed about the purpose of the study and provided written consent, prior to data collection. The trial was registered at the www.ClinicalTrials.gov (NCT02400138).

7.3.2 Participants, therapists and centers

Participants with stroke were recruited from the general community of the city of Belo Horizonte, Brazil, by means of advertisements and by screening public rehabilitation services and lists of previous research projects. Participants were eligible, if they: were >3 months and <5 years after their last episode of stroke and >20 years of age; had maximal inspiratory pressure <80 cmH₂O or maximal expiratory pressure <90 cmH₂O [18]; were not undertaking any respiratory training; and were able to provide informed consent. Participants were excluded from the trial if they had cognitive deficits, facial palsy, associated respiratory diseases, unstable conditions, which might prevent testing or training, or undergone thoracic or abdominal surgery.

A research assistant, who was not involved with recruitment, compiled a computer-generated, random allocation schedule, using permutation blocks of four participants. In order to ensure an even spread between the groups, the randomization was stratified according to the participants' maximal inspiratory pressures (≥ 45 cmH₂O – weak and <45 cmH₂O – very weak). Participants' allocations were placed in opaque, sequentially numbered, and sealed envelopes, which were held offsite by an independent researcher, to ensure concealed allocation. Upon successful patient screening and completion of the baseline assessments, the envelope was opened and the group allocation was revealed. At this point, the participant was considered to have entered the trial.

Whilst it was not possible to blind participants, efforts were made to keep them naïve to detailed information on the two groups. At the time of recruitment,

participants were only told that they would receive a respiratory muscle training device, with or without load progression, but no information whether a method was deemed superior to the other was provided. In addition, all the training devices were covered with opaque material, so that the participants were blind to the training loads.

7.3.3 Intervention

Participants were submitted to an eight-week high intensity home-based respiratory muscle training or to a sham training. The training was carried-out by two physiotherapists, who had at least four years of clinical and research experience in the area of neurological rehabilitation. All participants received an Orygen-Dual Valve device, which allows simultaneous training of the inspiratory and expiratory muscles, and has independent load adjustment. This device allows workloads up to 70 cmH₂O and has a flexible, comfortable, and airtight-flanged mouthpiece [16]. The only difference between the two groups was the training load specified on the device.

The training was undertaken in the participants' home environment, which means it was not directly supervised. To record the compliance, participants from both groups, received a diary, to register the time and days of all training sessions and their daily training volume. When required, a proxy was instructed to help them. To encourage the participants to comply with the protocol, both groups signed a symbolic contract of commitment to the training program.

Experimental group

Participants allocated to the experimental group received high intensity home-based respiratory muscle training, 40 min per day, seven times per week, over eight weeks. The 40-min daily training was split into two daily sessions (morning and afternoon). Each daily session was comprised of four-minute sets

of respiratory training, followed by one-minute rest between the sets. The training load was individually tailored and adjusted, as follows: The initial training load was set at 50% of the participants' maximal baseline inspiratory and expiratory strength, for both inspiratory and expiratory training. Once a week, the treating physiotherapist performed a home visit, measured the current values of inspiratory and expiratory strength, and re-adjusted the load.

Control group

Participants allocated to the control group received a sham training. Sham respiratory muscle training was delivered using the same device, without any resistance (0 cmH₂O) or progression, 40 min per day, seven times per week, over eight weeks. The control group received the same training and testing schedule, as the experimental group, including the home visits, to avoid bias related to the amount of attention.

7.3.4 Outcome measures

Outcome measures were collected at baseline (Week 0), at the end of the training (Week 8), and one month after the cessation of the training (Week 12), by well-trained and blinded researchers. All measures were collected in a laboratory setting and included one primary and five secondary outcomes. Participants were instructed to not reveal their allocation or make any comments regarding their training.

Primary outcome

Primary outcome was inspiratory muscle strength, i.e., maximal inspiratory pressure, which was measured by a digital manovacuometer (developed by UFMG researches) and reported in cmH₂O, following recommended guidelines [19,20].

Secondary outcomes

Expiratory muscle strength, i.e., maximal expiratory pressure, was measured by the same digital manovacuometer, and reported in cmH₂O, following recommended guidelines [19,20].

Inspiratory endurance was measured using a flow-resistive loading device (POWERbreathe KH1) and reported as number of breaths. Participants were asked to breathe against a sub-maximal inspiratory load, i.e., 50% of their maximal inspiratory pressure measured at baseline, until task failure or up to maximum seven minutes, following recommended procedures [21].

Dyspnea was measured using the Medical Research Council scale. This is a five-point scale and scores range from zero to four, in which zero indicates 'breathless only with strenuous exercise' and four 'too breathless to leave the house or when dressing or undressing' [22].

The occurrence of respiratory complications was weekly measured, by asking the participants, whether and how often they were admitted to a hospital, due to respiratory reasons (e.g., pneumonia or lung infections). The number of hospital admissions was registered.

Walking capacity was measured by the distance covered during the six-minute Walk Test, and reported in meters. Participants were instructed to walk along a 30-m hallway and cover maximum distance as possible, over six minutes, taking rests as needed, according to standardized protocol [23].

Finally, the success of participants' blinding was determined after the completion of the four-week follow-up measurements, by asking the assessors if the participants had revealed their group allocation or if they had been unblinded in any other way. Additionally, the naivety of the participants to the hypothesis of the trial was also evaluated, after the follow-up measures. Specifically, they were asked: *"You participated in a trial with two groups receiving respiratory muscle training. In one group, the training loads were weekly adjusted, whereas in the other group, the loads did not change. Do you*

know to which group you have been allocated?" They were given three possible answers: *'group with progression of training loads'*, *'group without progression of training loads'*, or *'unsure'* [24].

7.3.5 Sample Size

The number of participants was calculated, to reliably detect a between-group difference of 15 cmH₂O in strength of the inspiratory muscles, with 80% power, at a two-tailed significance level of 0.05, and an expected dropout rate of 15%. In a randomised trial with a similar sample [8], the strength of the inspiratory muscles was 57 cmH₂O (SD 15), using the same measurement procedures. Based upon the assumption that about 15% of participants could dropout during the course of the study, the least number of participants needed to detect a 15 cmH₂O difference between two independent groups was 18 per group. Thus, a target of at least 36 participants in total was set [25].

7.3.6 Data analysis

An independent researcher, blinded to group allocation, performed the statistical analyses. All analyses were conducted on an intention-to-treat basis. Data collection returned six variables, which reflect impairments and activity limitations: inspiratory and expiratory strength (cmH₂O), inspiratory endurance (number of breaths), dyspnea (Medical Research Council scale, 0-4), respiratory complications (number of hospital admissions), and walking capacity (m). There are two factors (group*time), with repeated measures on the time factor (Week 0, Week 8, and Week 12). Thus, two-way analyses of variance with repeated measures at all time-points were performed, to evaluate between-group differences for all outcomes. Mann-Whitney U tests were employed to evaluate the between-group differences for dyspnea, and respiratory complications. The mean differences between the groups and 95% confidence

intervals were reported for all outcomes. All analyses were performed with the SPSS software (17.0 version) [26].

7.4 RESULTS

7.4.1 Flow of trials through the review

Fifty-six individuals were screened for eligibility over the duration of the trial. Of these, 38 (16 men) were eligible/willing to participate, and were randomized to two groups. Eighteen participants were considered ineligible, due to baseline values of either maximal inspiratory pressure (>80 cmH₂O) and/or maximal expiratory pressure (>90 cmH₂O). The flow of participants through the trial is illustrated in Figure 1 and their characteristics are reported in Table 1. The mean age of the participants was 63 (SD 13) years and the mean time since the onset of the stroke was 20 (SD 17) months.

7.4.2 Compliance with the study protocol

Study compliance was excellent, with 18/19 participants of both the experimental and control groups receiving the training. One participant of the experimental group dropped-out training after two weeks, due to pain and one participant of the control group dropped-out of the study before starting training, due to professional reasons. In addition, six participants (three from the experimental group) refused to return for the follow-up measurements. Missing data were interpolated from the nearest measure taken. The eight-week assessment was conducted one week later than intended in six cases, for the following reasons: trip ($n=1$), participants or caregivers' lack of time ($n=3$), and contact problems ($n=2$). The only reported adverse event was chest pain during exercise ($n=1$), reported by the participant of the control group, who dropped-out training after two weeks.

The 36 participants, who completed the study protocol, reported that they performed the home-based training, as recommended. However, five (14%) participants (two from the experimental group) lost their diaries and 10 (28%) (five from the experimental group) returned their diaries with incomplete information. The analyses of the diaries, which had complete information, revealed that all participants of both groups performed, at least, 80% of the proposed training. The main reasons for skipping a training day were lack of time, forgetfulness, and sickness. The mean number of home visits was six out of the seven planned visits.

The assessors were inadvertently unblinded in 11 cases. Regarding the participants' naivety about which intervention was anticipated to be superior, 58% of the experimental group and 47% of the control group indicated that they believed they were in the superior group, with most of the remaining participants (33% of both the experimental and control groups) indicating that they were unsure.

7.4.3 Effects of the high-intensity respiratory muscle training

The results for all outcome measures, including between-group differences, are displayed in Table 2.

Primary outcome

The mean between-group difference for strength of the inspiratory muscles was 27 cmH₂O (95% CI 15 to 39), in favour of the experimental group. The benefits were maintained beyond the intervention period with a mean between-group difference of 24 cmH₂O (95% CI 11 to 37) ($F=9.59$, $p<0.001$).

Secondary outcomes

The mean between-group difference for the strength of the expiratory muscles was 42 cmH₂O (95% CI 25 to 59), in favour of the experimental group. The benefits were maintained beyond the intervention period with a mean between-group difference of 30 cmH₂O (95% CI 15 to 45) ($F=12.10$, $p<0.001$).

The mean between-group difference for the endurance of the inspiratory muscles was 34 breathes (95% CI 21 to 47), in favour of the experimental group. The benefits were maintained beyond the intervention period with a mean between-group difference of 26 breathes (95% CI 10 to 42) ($F=12.77$, $p<0.001$).

The mean between-group difference for dyspnea was -1.3 (0-4) (95% CI -2.1 to -0.5), in favour of the experimental group. The benefits were maintained beyond the intervention period with a mean between-group difference of -1.2 (0-4) (95% CI -2.2 to -0.2) ($p<0.05$).

Regarding respiratory complications, analysis could not be performed, since they were limited to one per group. There was no significant between-group difference for walking capacity (MD 37 m; 95% CI -24 to 98) ($F=0.68$, $p=0.52$).

7.5 DISCUSSION

This was the first randomized controlled trial to deliver high-intensity respiratory muscle training after stroke. This trial demonstrated that a high-intensity home-based respiratory muscle training increased the strength and endurance of the respiratory muscles and reduced dyspnea. The benefits were maintained at one month after the cessation of the training. There was no significant between-group difference for walking capacity and analysis regarding the occurrence of respiratory complications could not be performed, since they were limited to one per group.

Maximal respiratory pressures have been recognized as sensitive measures of strength of the respiratory muscles and are gaining interest as

targets in rehabilitation and therapeutic clinical trial endpoint for neuromuscular diseases [28]. The findings of the present trial showed that the training increased the strength of the inspiratory muscles by 27 cmH₂O and of the expiratory muscles by 42 cmH₂O. These gains are the highest reported in the literature [8,9,29-32]. Previous systematic reviews reported changes in inspiratory strength of 7 cmH₂O [6,10] and in expiratory strength of 13 cmH₂O [6]. The differences may be explained by the combination of three factors: (i) characteristics of the training, which was delivered at higher loads, frequency, and intensity; (ii) characteristics of the device, which allows both inspiratory and expiratory training at higher loads (up to 70 cmH₂O) [16]; and (iii) characteristics of the sample, which was comprised of participants, who had respiratory muscle weakness. In addition, smallest detectable differences for inspiratory and expiratory pressure range from 18-22% [15]. Since the average baseline values of the participants were 55 cmH₂O (SD 15) for inspiratory strength and 76 cmH₂O (SD 22) for expiratory strength, increases of 27 and 42 cmH₂O represent respectively gains of 49 and 55%, which are sufficient to be considered clinically relevant.

The present trial also found significant improvements in endurance of the inspiratory muscles, with a mean increase of 34 breaths, in favour of the experimental group. This means that the individuals were able to recruit the respiratory muscles for a longer time. Only one previous trial investigated the effects of inspiratory muscle training on inspiratory endurance after stroke [8] and reported positive results (MD 15 cmH₂O (95% CI 2 to 27). However, it is not possible to directly compare the results, since inspiratory endurance was reported in cmH₂O, and not in number of breaths [8].

The significantly changes in strength and endurance are important, since weakness of the expiratory muscles leads to ineffective cough and clearance of airway secretions, while decreased strength and endurance of the inspiratory muscles have been associated with dyspnea and/or nocturnal alveolar hypoventilation [33,34]. The results of the present trial indicated that the benefits of respiratory muscle training were carried-over to dyspnea, with a

mean between-group difference of -1.3 on the Medical Research Council scale. The Medical Research Council scale is widely used in the field of rehabilitation, as a discriminative tool, to characterize study populations [36] and changes ≥ 1 point indicate perceived clinical improvements [37]. Similar to the present findings, previous studies with stroke subjects, also found significant improvements in dyspnea, as determined by the Borg scale, after a program of respiratory muscle training [32,38]. It is important to note that 16 participants of the experimental group reported improvements in dyspnea, whereas only two of the control group reported the same.

In this trial, the effects of the training on the occurrence of respiratory complications could not be analyzed, since they were limited to one per group. The reduced occurrence of respiratory complications may be explained by the characteristics of the participants, who were at the sub-acute and chronic phases after the stroke. It is expected that higher occurrence of respiratory complications would occur at the acute stages [39].

Although weakness of the respiratory muscles and dyspnea are commonly associated with limitations in performing daily activities, the benefits were not carried-over to walking capacity. The mean between-group differences observed at post-training (37 m) and follow-up (44 m) suggest that the effects of respiratory training on walking capacity, as primary outcome, should be examined in a larger trial. In the present study, sample size calculation was based upon the primary outcome, i.e., maximal inspiratory pressure, which was sufficient to show the efficacy of the intervention. Furthermore, the participants already walked at high speeds, i.e., had a community ambulation status, which may also have contributed to the absence of significant effects of the intervention on walking capacity.

The main strength of the current study is that it is a randomized controlled trial, which was prospectively registered and strictly followed the Consort guidelines. The trial included concealed allocation, an intense-to-treat approach, and the sample size was calculated to provide appropriate statistical

power to detect between-group differences in the primary outcome. In addition, the intervention proved to be effective and clinically relevant, even though the training was home-based, without direct supervision and used a relatively low-cost device (US\$72).

However, this trial is not without limitations. The effectiveness of keeping participants naïve to the details of the study was not very successful, which may have introduced bias. It is well known that it is difficult or unpractical to blind participants and physiotherapists during the delivery of complex interventions [40].

In summary, the findings of this trial have important implications for the advance of area of neurological rehabilitation. High-intensity home-based respiratory muscle training showed to be effective in increasing strength and endurance of the respiratory muscles and reducing dyspnea after stroke, and the magnitude of the effects were higher than those previously reported.

Ethical approval: The Institutional Research Ethical Committee of the Universidade Federal de Minas Gerais approved this study. All participants gave written informed consent before data collection began. All applicable institutional and governmental regulations concerning the use of human volunteers were followed.

Conflicts of interest: None.

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7.7 Figures

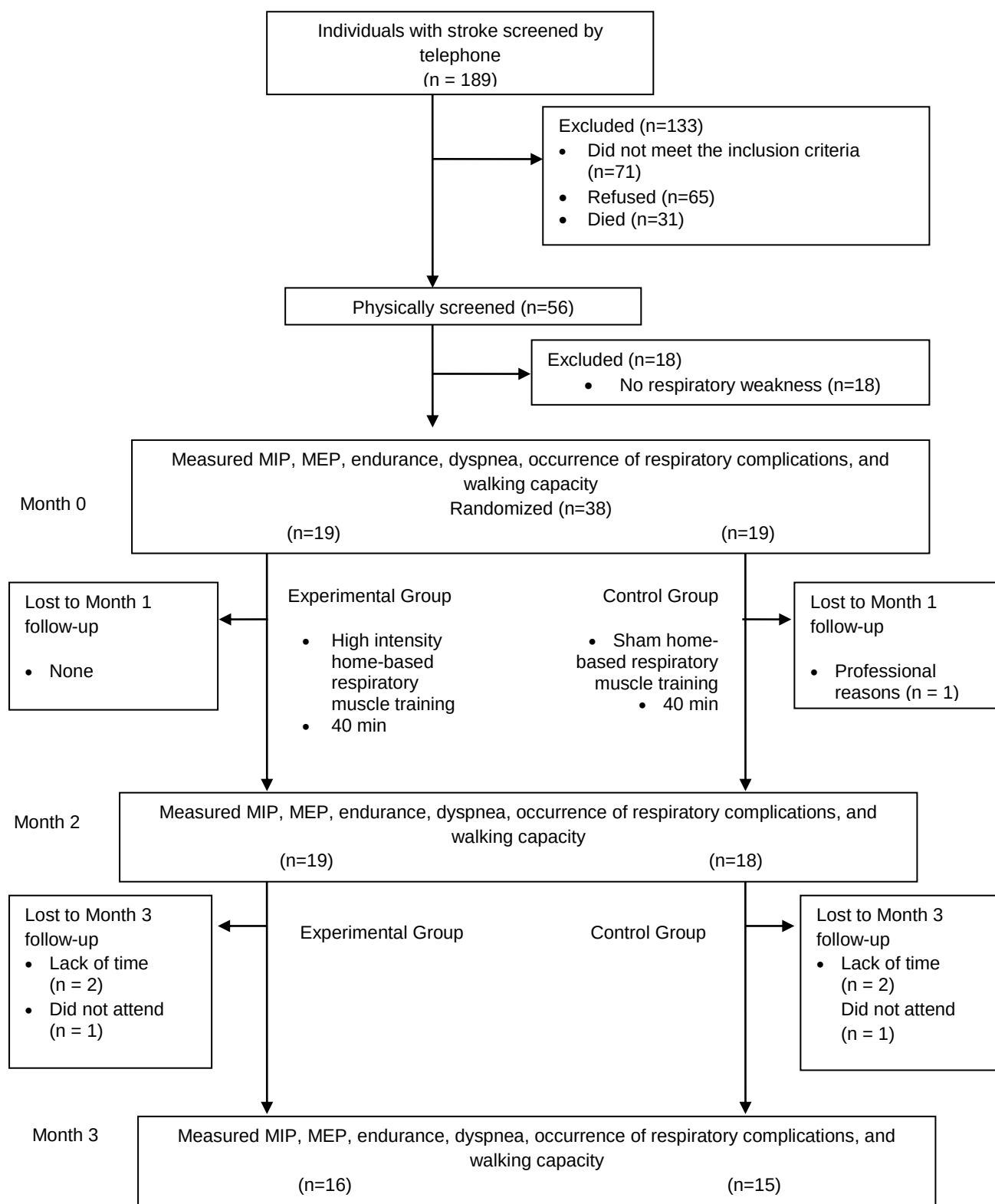


Figure 1. Design and flow of participants through the trial.

7.8 Tables

Table 1. Characteristics of the participants

Characteristic		Intervention <i>n</i> =19	Control <i>n</i> =19
Age (years), mean (SD)		60 (14)	67 (11)
Sex, men, number (%)		8 (42)	8 (42)
Time since stroke (months), mean (SD)		24 (20)	16 (12)
Number of episodes, number (%)	1	13 (68)	14 (74)
	>1	6 (32)	5 (26)
Type of stroke, number (%)	Ischemic	12 (63)	15 (79)
	Hemorrhagic	3 (16)	3 (16)
	Unknown	4 (21)	1 (5)
Side of weakness, number (%)	Right	12 (63)	6 (32)
	Left	6 (32)	11 (58)
	Unknown	1 (5)	2 (10)
Walking speed (m/s), mean (SD)		0.9 (0.3)	0.9 (0.4)

Table 2. Mean (SD) of groups, mean (SD) differences within groups, and mean (95% CI) differences between groups.

Outcome	Groups						Within-group differences				Between-group differences	
	Week 0		Week 8		Week 12		Week 8 minus Week 0		Week 12 minus Week 0		Week 8 minus Week 0	Week 12 minus Week 0
	Exp (n = 19)	Con (n = 19)	Exp (n = 19)	Con (n = 19)	Exp (n = 19)	Con (n = 19)	Exp	Con	Exp	Con	Exp-Con	Exp-Con
Maximal inspiratory pressure (<i>cmH₂O</i>)	58 (17)	52 (14)	94 (24)	61 (21)	95 (23)	65 (25)	36 (23)	9 (13)	37 (20)	13 (18)	27 (15 to 39)	24 (11 to 37)
Maximal expiratory pressure (<i>cmH₂O</i>)	74 (20)	78 (24)	125 (33)	86 (29)	117 (26)	90 (33)	50 (33)	8 (17)	42 (26)	12 (19)	42 (25 to 59)	30 (15 to 45)
Inspiratory endurance (#breaths)	11 (7)	19 (18)	43 (28)	18 (17)	38 (32)	20 (21)	33 (28)	-0.7 (5.3)	27 (32)	1 (11)	34 (21 to 47)	26 (10 to 42)
Medical Research Council scale (0 – 4)	2.1 (1.6)	1.4 (1.5)	0.6 (1.1)	1.3 (1.4)	1.1 (1.4)	1.5 (1.6)	-1.4 (1.6)	-0.1 (0.3)	-1.0 (1.9)	0.2 (1.0)	-1.3 (-2.1 to -0.5)	-1.2 (-2.2 to -0.2)
Occurrence of respiratory complications (<i>n</i>)	-	-	1	1	1	1	1	1	1	1	0	0
Six-minute walk test (<i>m</i>)	338 (125)	329 (143)	375 (141)	328 (162)	369 (121)	316 (150)	36 (90)	-1 (94)	31 (67)	-13 (101)	37 (-24 to 98)	44 (-12 to 100)

Exp = experimental group, Con = control group.

Capítulo 8

CONSIDERAÇÕES FINAIS

A presente tese objetivou evidenciar os efeitos de um programa domiciliar de fortalecimento da musculatura respiratória de alta intensidade em pacientes pós-AVE. Durante a estruturação e realização deste estudo, outros cinco foram desenvolvidos, visando proporcionar contribuições científicas sobre o tema à prática do profissional de reabilitação. Assim, as principais contribuições clínicas da tese foram descritas nos parágrafos seguintes.

Os resultados da primeira revisão sistemática reportaram cinco possibilidades de intervenções, visando melhorar a função respiratória após o AVE, sendo elas o treinamento muscular respiratório, exercícios aeróbicos, respiratórios e posturais, e a adição de estimulação elétrica. O treinamento muscular respiratório, baseado nos resultados de 11 estudos, provou ser eficaz para melhorar a força inspiratória e expiratória, a função pulmonar e a dispneia. No entanto, poucos estudos foram encontrados investigando os efeitos das demais intervenções e, portanto, ainda não há evidências para aceitar ou refutar a eficácia dos exercícios aeróbicos, respiratórios e posturais, ou a adição de estimulação elétrica na função respiratória.

Outra revisão sistemática realizada investigou somente os efeitos do treinamento muscular respiratório em indivíduos pós-AVE e forneceu evidências, baseado em cinco estudos, de que o treinamento muscular respiratório é efetivo nesta população. De acordo com os achados, 30 minutos de treinamento, cinco vezes por semana, durante cinco semanas, podem aumentar a força muscular respiratória e reduzir o risco de complicações respiratórias de indivíduos após o AVE.

Em relação aos vários dispositivos disponíveis atualmente no mercado destinados ao treinamento da musculatura respiratória, a presente tese apresentou 11 dispositivos, descritos detalhadamente e com eficácia comprovada por estudos publicados. Estes foram: *Pflegx*, *TrainAir*, *POWERbreathe K-Series*, *EMST 150*, *Orygen Dual Valve*, *Powerbreathe*, *PowerLung*, *Respifits-S*, *Threshold IMT (inspiratory muscle training)*, *Threshold PEP (positive expiratory pressure)*, and *SpiroTiger*. No entanto, outros 12

dispositivos, também disponíveis no mercado, não foram incluídos nesta revisão, devido à falta de informações e estudos publicados, e outros 3 foram citados, sem descrição detalhada, também devido à falta de informações. Dentre os 11 dispositivos, todos apresentaram aspectos positivos e limitações, que devem ser considerados pelos profissionais. Assim, a escolha do dispositivo mais apropriado deve ser guiada não só baseada nos aspectos clínicos do paciente e no propósito do treinamento, como também pelas informações técnicas e utilidade clínica de cada dispositivo.

Outros resultados do presente trabalho estão relacionados à prevalência da dispneia após o AVE e ao impacto que este sintoma causa nas atividades e participação social destes indivíduos. A prevalência da dispneia foi de 44%. Destes, 51% relataram dispneia severa, 85% informaram que a dispneia limitava suas atividades e 49% que restringia a participação social. Corroborando com tais achados, os resultados estatísticos indicaram que indivíduos com dispneia são mais propensos a relatar limitações em atividades e restrições em participação social. Assim, conclui-se que a dispneia é um sintoma comum em pessoas que sofreram AVE, e está associada a limitações de atividade e restrições na participação social. A detecção precoce da dispneia em indivíduos pós AVE, seguido de um tratamento adequado, é fortemente recomendado e tem potencial para ajudar a melhorar a execução de atividades e a participação social nesta população.

Finalmente, o ensaio clínico aleatorizado, principal produto da presente tese, evidenciou que o treino domiciliar de alta intensidade da musculatura respiratória em pacientes pós-AVE, em comparação com uma intervenção placebo, aumentou a força inspiratória e expiratória, resistência inspiratória e reduziu a dispneia. Além disso, tais benefícios foram mantidos um mês após o término do treinamento. Não houve diferença significativa entre os grupos para a capacidade de marcha e ocorrência de complicações respiratórias. As diferenças médias encontradas entre os grupos para a força da musculatura respiratória foram os maiores já reportadas na literatura. Assim, um treino diário de 40 minutos, com uma carga de 50% da pressão respiratória máxima,

durante oito semanas, é eficaz para aumentar, aproximadamente, 60% da força muscular inspiratória e 70% da força expiratória.

Como conclusão, de forma geral, podemos observar que a dispneia é um sintoma comum em indivíduos pós-AVE, que impacta na atividade e participação social destes indivíduos. Dentre as varias modalidades de intervenção para melhorar a função respiratória nesta população, o treino muscular respiratório é a que apresenta maior eficácia comprovada na literatura, com efeitos significativos sobre a força dos músculos respiratórios, função pulmonar e dispneia, além de reduzir a ocorrência de complicações respiratória. Por fim, o treino muscular respiratório de alta intensidade é capaz de melhorar a função respiratória de indivíduos pós-AVE, superando os valores já reportados previamente pela literatura. Tais resultados contribuíram com achados importantes para a linha de pesquisa de Estudos em Reabilitação Neurológica do Adulto do Programa de Pós-Graduação em Ciências da Reabilitação, apresentando dados de prevalência e de intervenções/dispositivos destinados à melhora da função respiratória em indivíduos com incapacidades decorrentes do AVE.

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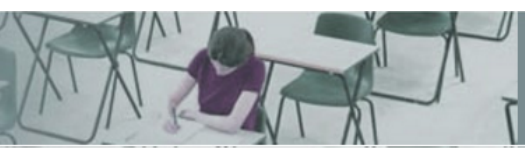
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ANEXOS

ANEXO I



Sistema Acadêmico
Consulta de Informações dos
Alunos da Pós-Graduação



Usuário: Kenia Kiefer Parreiras de Menezes
Número de Matrícula do Aluno: 2014668161
SAIR

Menu	
▼	NÚMEROS DO ALUNO
▶	Selecionar
▼	ALUNO
▶	Dados Pessoais
▶	Dados de Admissão
▶	Situação no Curso
▶	Ocorrências Acadêmicas
▼	HISTÓRICO ESCOLAR
▶	Atividades Coursadas e Em Curso
▼	MATRÍCULA
▶	Oferta de Atividades
▼	CURRÍCULO
▶	Grade Curricular

Consultar Atividades em Curso e Coursadas

[Informação para simples consulta, sem validade oficial]

Aluno **2014668161** **KÊNIA KIEFER PARREIRAS DE MENEZES**Curso **3581** **CIÊNCIAS DA REABILITAÇÃO/D**

Relação de Atividades no Histórico

Periodo	Turma	Nome Atividade	Tipo Mat	Freq	Nota	Conc	Sit Final	Créd	Integr ?
2014/1	DIP FIT810 U	ESTÁGIO EM DOCÊNCIA		S	100	A	A	4	Sim
2014/1	DIP FIT820 U	MEDIDAS E INSTRUMENTOS DE AVALIACAO II		S	86	B	A	04	Sim
2014/1	DIP FIT825 U	ASPECTOS AVAL DESEMP CARDIORRESPIRATORIO		S	75	C	A	03	Sim
2014/2	DIP DTO806 D	TOPICOS ESPECIAIS		S	80	B	A	2	Sim
2014/2	DIP DTO815 U	SEMINARIOS DE DOUTORADO		S	93	A	A	2	Sim
2014/2	DIP FIT833 U	INST.DE MED. E AV.DO IND.COM DISF.NEUR.		S	100	A	A	2	Sim
2015/1	ETF GER000	ELABORACAO DE TRABALHO FINAL						0	Sim
2015/2	ETF GER000	ELABORACAO DE TRABALHO FINAL						0	Sim
2016/1	ETF GER000	ELABORACAO DE TRABALHO FINAL						0	Sim
2016/2	ETF GER000	ELABORACAO DE TRABALHO FINAL						0	Sim
2017/1	ETF GER000	ELABORACAO DE TRABALHO FINAL						0	Sim
2017/2	DCR GER000	DISPENSA DE CREDITO					4	16	Sim
2017/2	ETF GER000	ELABORACAO DE TRABALHO FINAL						0	Sim

LEGENDA		
Tipo Mat	Tipo de Matrícula: Normal ou Eletiva	
Freq	Frequência	S = Suficiente I = Insuficiente
Conc	Conceito	
Sit Final	Situação Final na Atividade	A = Aprovado R = Reprovado 1 = Trancamento Total 2 = Trancamento Parcial sem Justificativa 3 = Trancamento Parcial com Justificativa 4 = Dispensa
Créd	Número de créditos atribuídos	
Integr?	Indica se a atividade será computada ou não na integralização dos créditos exigidos.	

[Informação para simples consulta, sem validade oficial]

 IMPRIMIR

 VOLTAR

ANEXO II

RESPIRATORY CARE

Efficacy of interventions aiming at improving respiratory function after stroke: A systematic review

Journal:	<i>Respiratory Care</i>
Manuscript ID:	Draft
Manuscript Type:	Systematic Review
Date Submitted by the Author:	n/a
Complete List of Authors:	Menezes, Kênia; Universidade Federal de Minas Gerais, Physiotherapy Nascimento, Lucas; Universidade Federal de Minas Gerais, Physiotherapy Avelino, Patrick; Universidade Federal de Minas Gerais, Department of Physical Therapy Alvarenga, Maria; Universidade Federal de Minas Gerais, Fisioterapia Teixeira-Salmela, Luci; Universidade Federal de Minas Gerais, Department of Physical Therapy
Categories:	Rehabilitation, Muscles, respiratory/diaphragm/work of breathing, Neuromuscular disease

SCHOLARONE™
Manuscripts

ANEXO III

The Clinical Respiratory Journal

A review on respiratory muscle training devices

Journal:	<i>The Clinical Respiratory Journal</i>
Manuscript ID	Draft
Manuscript Type:	Review Article
Date Submitted by the Author:	n/a
Complete List of Authors:	Menezes, Kênia; Havaí Nascimento, Lucas Avelino, Patrick Polese, Janaïne Teixeira-Salmela, Luci
Subject Category - Select up to 5 subject categories that best match your manuscript:	Pulmonary Rehabilitation, Critical Care, Environmental & Occupational Lung Disease, COPD Rehabilitation, Interventional Pulmonology
Keywords - keywords may be selected from the supplied list:	Respiratory Muscles, Equipment and Supplies, Resistance Training, Breathing Exercises, Rehabilitation, Review

ANEXO IV

Topics in Stroke Rehabilitation

Prevalence of dyspnea after a stroke: A telephone-based survey

--Manuscript Draft--

Manuscript Number:		
Full Title:	Prevalence of dyspnea after a stroke: A telephone-based survey	
Article Type:	Original Article	
Keywords:	Prevalence; Severity; Dyspnea; Stroke; Activity; Social participation	
Corresponding Author:	Kênia Menezes Universidade Federal de Minas Gerais BRAZIL	
Corresponding Author Secondary Information:		
Corresponding Author's Institution:	Universidade Federal de Minas Gerais	
Corresponding Author's Secondary Institution:		
First Author:	Kênia Menezes	
First Author Secondary Information:		
Order of Authors:	Kênia Menezes Lucas Nascimento Maria Tereza Alvarenga Patrick Avelino Luci Teixeira-Salmela	
Order of Authors Secondary Information:		
Abstract:	Background: Although dyspnea seems to be a clinically relevant outcome to be taken into consideration during stroke rehabilitation, its prevalence, severity, and effects on this population remain uncertain. Objectives: To investigate the prevalence and severity of dyspnea after stroke, as well the associations between dyspnea, activity limitations, and participation restrictions. Methods: A 23-question telephone-based survey was developed by the research team. The survey included information about the onset of dyspnea, severity of dyspnea, activity limitations and participation restrictions. The prevalence of dyspnea was reported as percentage of individuals. Chi-square tests were employed to investigate the associations between dyspnea, activity limitations, and participation restrictions. Relative risks and respective 95% confidence intervals were provided. Results: The prevalence of dyspnea was 44% and severe symptoms were reported by 51% of the participants. In addition, dyspnea limited activity and restricted social participation in 85% and 49%, respectively. Dyspnea was significantly correlated with activity limitations ($r=0.87$; 95% CI 0.82 to 0.92; $p<0.01$) and participation restrictions ($r=0.53$; 95% CI 0.46 to 0.62; $p<0.01$). The analyses indicated that individuals, who had dyspnea, were more likely to report that it limited their activities (RR: 6.5; 95% CI 4.3 to 9.9) and restricted social participation (RR: 1.7; 95% CI 1.5 to 2.0). Conclusions: Dyspnea is an important symptom after stroke and showed to be associated with activity limitations and restrictions in community participation. An early detection of dyspnea in people with stroke, followed by appropriate management, is strongly recommended and has the potential to improve activity and social participation.	
Funding Information:	Conselho Nacional de Desenvolvimento Científico e Tecnológico (304434/2014-0) Fundação de Amparo à Pesquisa do Estado de Minas Gerais (PPM 00006-14)	Not applicable Mrs Kênia Menezes

ANEXO V

UNIVERSIDADE FEDERAL DE
MINAS GERAIS



PARECER CONSUBSTANCIADO DO CEP

DADOS DO PROJETO DE PESQUISA

Título da Pesquisa: EFICÁCIA DO TREINAMENTO MUSCULAR RESPIRATÓRIO EM HEMIPARÉTICOS:
UM ENSAIO CLÍNICO ALEATORIZADO.

Pesquisador: Luci Fuscaldi Teixeira-Salmela

Área Temática:

Versão: 2

CAAE: 40290114.8.0000.5149

Instituição Proponente: Escola de Educação Física da Universidade Federal de Minas Gerais

Patrocinador Principal: Financiamento Próprio

DADOS DO PARECER

Número do Parecer: 986.309

Data da Relatoria: 06/03/2015

Apresentação do Projeto:

O Acidente Vascular Encefálico (AVE) é definido pela Organização Mundial de Saúde como uma síndrome clínica de desenvolvimento rápido de sinais de distúrbios focais ou globais da função cerebral de origem vascular, com sintomas que perduram por um período superior a 24 horas. Este quadro geralmente leva à fraqueza ou paralisia em um lado do corpo, denominada hemiparesia ou hemiplegia, contralateral à lesão encefálica. Indivíduos hemiparéticos apresentam fraqueza de musculatura respiratória, gerando sintomas relacionados a esta disfunção. O trabalho mútuo tanto da musculatura inspiratória como expiratória na biomecânica respiratória tanto no repouso como durante a prática de atividades físicas é importante para estes indivíduos. Será realizado um ensaio clínico aleatorizado, duplo cego. Os indivíduos serão recrutados da comunidade em geral na cidade de Belo Horizonte, Brasil. Dois pesquisadores, cegados em relação à alocação dos sujeitos em cada grupo, irão avaliar as variáveis de desfecho. Os participantes serão distribuídos aleatoriamente no grupo experimental ou um grupo sham, depois de revelar o conteúdo dos envelopes opacos e fechados. Após a oitava semanas de intervenção e após um e três meses de follow-up, as mesmas variáveis de desfecho serão coletadas pelos mesmos assistentes de pesquisa. O treinamento para o grupo experimental será realizado cinco vezes por semana, por 30 minutos diários, sendo três sessões (15 minutos) de TMI e três sessões (15

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Continuação do Parecer: 986.309

minutos) de TME durante oito semanas consecutivas. Cada sessão tem duração de 5 minutos, onde o indivíduo deve respirar com o dispositivo na boca continuamente e descansar, por um minuto, entre as sessões. Após a garantia de aprendizado do treinamento pelos indivíduos, eles serão orientados a realizar os exercícios domiciliarmente. Sessões quinzenais serão realizadas para monitorar a técnica realizada domiciliarmente (que será explicada no tópico "Procedimentos") para assegurar que os indivíduos estão sendo capazes de realizar o treinamento de forma adequada e para esclarecer qualquer dúvida, como tempo de treinamento e/ou posicionamento adequado do threshold. Todos os participantes deste grupo receberão, além do Threshold® IMT, o Threshold™ PEP para realizar o treinamento em casa. Os indivíduos alocados no grupo controle receberão o mesmo treinamento e monitoramento quinzenal do grupo experimental, no entanto, as molas dos aparelhos Threshold® IMT e Threshold™ PEP serão zeradas para que nenhuma resistência seja oferecida. Para que o valor da resistência da mola não seja identificado, todos os instrumentos, de ambos os grupos, serão revestidos com material opaco. Após explicação dos objetivos do estudo, os indivíduos interessados em participar serão avaliados para elegibilidade e submetidos à avaliação física e entrevista, onde serão coletados dados clínicos, antropométricos e demográficos. As medidas de desfecho primário serão a P_{lmáx} e a P_{Emáx}. As medidas de desfecho secundárias incluirão: endurance muscular inspiratória, endurance muscular expiratória, fadiga, capacidade ao exercício e qualidade de vida. Para estimular a adesão, os indivíduos serão convidados a assinar um contrato de comprometimento com o treinamento, onde serão expostas as condições de treinamento e o indivíduo, ao assinar, se compromete a realizar a atividade proposta no tempo e da forma estipulados. Para controlar a adesão, os voluntários também receberão um diário para registrar os dias e o tempo de treinamento total, também como forma de monitorar a adesão ao tempo e à frequência do treinamento realizado pelos participantes. Quando necessário, um acompanhante será instruído a ajudar o indivíduo a preencher o diário. Mínima diferença clinicamente importante A MDCI será avaliada usando o método de classificação global de mudança do paciente. Após oito semanas de treinamento, os pacientes serão questionados sobre a sua percepção da magnitude das mudanças na sensação de dispneia desde sua admissão no estudo. Uma escala de Likert (-5 a +5) será aplicada no pós-treinamento, onde os pacientes serão convidados a responder a seguinte pergunta "em comparação com a condição de quando você iniciou o programa, você percebeu qualquer alteração na sua sensação de dispneia"? Será oferecida 11 categorias de resposta variando de 5 (muito melhor) para +1 (quase nenhuma melhora) para "melhora" e -5 (muito pior) a -1 (quase nenhuma piora) para "piora". Os pacientes serão classificados no grupo MDCI se suas classificações estiverem dentro dos intervalos de +2 a +3 ou

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-2 a -3.

Critério de Inclusão: (1) idade 20 anos, (2) históricos de AVE hemorrágico ou isquêmico, com no mínimo de três meses de evolução, (3) ausência de alterações cognitivas identificadas pelos pontos de corte no Mini-exame do estado mental (MEEM), (4) valores de PImáx e PEmáx inferiores a 90% dos valores preditos para a população saudável, (5) não ter paralisia facial, o que pode evitar a oclusão labial adequada, (6) ausência de disfunções pulmonares, neurológicas ou condições cardíacas instáveis que impeçam ou influenciem na execução dos testes e (7) não serem fumantes há pelo menos 5 anos.

Critério de Exclusão: Serão excluídos indivíduos que apresentarem qualquer condição que possa impossibilitar a execução dos testes.

Objetivo da Pesquisa:

Objetivo Primário: O objetivo deste Ensaio Controlado Aleatorizado (ECA) será investigar a eficácia de um programa de treinamento da musculatura inspiratório e expiratório em medidas motoras e funcionais em indivíduos hemiparéticos e verificar a manutenção destes possíveis efeitos a longo prazo.

Objetivo Secundário: Investigar a mínima diferença clinicamente importante (MDCI) da PImáx e PEmáx para esta população.

Avaliação dos Riscos e Benefícios:

Riscos: O indivíduo poderá sentir dores musculares durante e após os testes, pois os testes exigem um esforço físico maior do que aquele realizado no dia a dia. Para minimizar a ocorrência deste desconforto, será realizado um período de descanso entre as medidas.

Benefícios: Os resultados obtidos irão colaborar com o conhecimento científico, podendo estabelecer novas propostas de tratamento para indivíduos que tenham a mesma condição de saúde.

Comentários e Considerações sobre a Pesquisa:

A pesquisa foi bem delineada e tem potencial para gerar informação científica nova e para contribuir para a melhoria da qualidade de vidas dos pacientes após terem sofrido um acidente vascular encefálico.

Em carta resposta ao COEP, a pesquisadora informa as modificações efetuadas:

Adequações-se o TCLE:

Substituir a palavra parâmetros por outra mais simples;

A palavra "parâmetros" foi substituída por "informações". A frase final ficou escrita da seguinte

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forma: "Inicialmente, serão coletados dados para a sua identificação, além de algumas informações clínicas". Esta alteração será encontrada na primeira frase do tópico do TCLE "DESCRIÇÃO DOS TESTES A SEREM REALIZADOS".

Informar que benefícios poderão vir da participação (observando que os benefícios são diferentes entre casos e controles). Os benefícios foram descritos como consta na frase final seguinte: "Os resultados obtidos irão colaborar com o conhecimento científico, podendo estabelecer novas propostas de tratamento de indivíduos que tenham a mesma doença que você". Os benefícios diretos do tratamento não podem ser descritos uma vez que este é o objetivo de estudo do presente projeto e dessa forma, a última frase foi retirada. Além disso, não é possível discriminar os benefícios entre os indivíduos dos grupos caso e controle uma vez que estes estarão cegados em relação à existência de dois grupos distintos e à alocação dos mesmos. Este cegamento dos voluntários é fundamental para a qualidade metodológica do estudo. Esta alteração será encontrada na única frase do tópico do TCLE "BENEFÍCIOS".

Informar que não serão remunerados e que podem decidir se retirar da pesquisa a qualquer momento e que isto não vai interferir na forma como é assistido no serviço;

Esta informação foi adicionada ao TCLE, conforme a frase seguinte: "Além disso, você não receberá nenhuma remuneração pela sua participação e poderá se retirar da pesquisa a qualquer momento, sem interferência na forma como esta sendo assistido".

Esta alteração será encontrada na segunda frase do tópico do TCLE "NATUREZA VOLUNTÁRIA DO ESTUDO/ LIBERDADE PARA SE RETIRAR".

Informar ao participante que ele receberá uma cópia do TCLE.

Esta informação foi adicionada ao TCLE, conforme a frase seguinte: "Estou assinando as duas cópias deste termo voluntariamente, sendo uma cópia para mim e outra para os pesquisadores e tenho direito de, agora ou mais tarde, discutir qualquer dúvida que venha a ter com relação à pesquisa".

Esta alteração será encontrada na terceira frase do tópico do TCLE "DECLARAÇÃO E ASSINATURA".

Considerando que a assinatura do acompanhante será necessária quando o paciente não puder assinar, coletar dado de parentesco do responsável pelo participante. Esta informação foi adicionada ao TCLE.

Considerações sobre os Termos de apresentação obrigatória:

Presentes: Projeto de Pesquisa Plataforma Brasil, projeto de pesquisa original, folha de rosto (devidamente preenchida e assinada pela coordenadora da pesquisa e pelo diretor da Escola de Educação Física EEFFTO da UFMG), TCLE, parecer consubstanciado com aprovação da Câmara do

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Departamento de Fisioterapia.

Recomendações:

Tendo em vista que a palavra "cópia" refere-se a um documento não original e que não detém, portanto, o mesmo valor legal do documento original, solicita-se sua substituição pela palavra "via" no TCLE, conforme o disposto pela Resolução CNS nº 466 de 2012 itens IV.3.f e IV.5.d.

Sugere-se à pesquisadora repensar sobre a não aplicação do "contrato de comprometimento", por se tratar de pessoas em estado de vulnerabilidade, pois de acordo com a Resolução 466/12:

"II.25 - vulnerabilidade - estado de pessoas ou grupos que, por quaisquer razões ou motivos, tenham a sua capacidade de autodeterminação reduzida ou impedida, ou de qualquer forma estejam impedidos de opor resistência, sobretudo no que se refere ao consentimento livre e esclarecido". Esclarecemos que um "contrato de comprometimento" pode exercer sobre o participante argumento de autoridade. Explicações sobre a importância das anotações diárias seriam suficientes para o comprometimento do paciente. Não deve ser esquecido o princípio de voluntariedade e direito de desistência à participação na pesquisa que versa no TCLE.

Recomenda-se a aprovação do projeto de pesquisa.

Conclusões ou Pendências e Lista de Inadequações:

Somos favoráveis à aprovação do projeto "EFICÁCIA DO TREINAMENTO MUSCULAR RESPIRATÓRIO EM HEMIPARÉTICOS: UM ENSAIO CLÍNICO ALEATORIZADO" da Pesquisadora Profa. Dra. Luci Fuscaldi Teixeira-Salmela.

Situação do Parecer:

Aprovado

Necessita apreciação da CONEP:

Não

Considerações finais a critério do CEP:

Aprovado conforme parecer.

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BELO HORIZONTE, 16 de Março de 2015

Assinado por:
Telma Campos Medeiros Lorentz
(Coordenador)

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ANEXO VI

ClinicalTrials.gov

A service of the U.S. National Institutes of Health

Home-based Respiratory Training After Stroke**This study is not yet open for participant recruitment.** (see [Contacts and Locations](#))

Verified March 2015 by Federal University of Minas Gerais

Sponsor:

Federal University of Minas Gerais

Information provided by (Responsible Party):

Luci Fuscaldi Teixeira-Salmela, Federal University of Minas Gerais

ClinicalTrials.gov Identifier:

NCT02400138

First received: March 23, 2015

Last updated: March 25, 2015

Last verified: March 2015

[History of Changes](#)[Full Text View](#)[Tabular View](#)[No Study Results Posted](#)[Disclaimer](#)[How to Read a Study Record](#)**Purpose**

Weakness of the respiratory muscles demonstrated by individuals with stroke, may generate important symptoms, such as fatigue and dyspnea. Since adequate strength of the inspiratory and expiratory muscles is required, mainly when performing physical activities, rehabilitation interventions for stroke subjects should include respiratory training. This study will test the hypothesis that home-based combined training of the inspiratory and expiratory muscles is effective in improving strength and endurance of the inspiratory and expiratory muscles, fatigue, exercise capacity, and quality of life with stroke subjects. For this clinical trial, people after stroke will be randomly allocated into either experimental or control/sham groups. The experimental group will undertake training of the inspiratory plus expiratory muscles with the Threshold device regulated at 40% of the subjects' maximal inspiratory and expiratory pressure values, five times/week over eight weeks during 30 minutes/day. The control group will undertake the same protocol, but the participants will receive the threshold devices without the resistance valves. At baseline, post intervention, and four and 12 weeks after the cessation of the interventions, researchers blinded to group allocations will collect the following outcome measures: maximal inspiratory and expiratory pressures, endurance, fatigue, dyspnea sensation, exercise capacity, and quality of life.

Condition	Intervention	Phase
Stroke	Other: Respiratory training Other: Control	Phase 0

Study Type: [Interventional](#)Study Design: [Allocation: Randomized](#)[Endpoint Classification: Efficacy Study](#)[Intervention Model: Parallel Assignment](#)[Masking: Double Blind \(Subject, Investigator, Outcomes Assessor\)](#)[Primary Purpose: Treatment](#)Official Title: [Effects of Home-based Respiratory Training After Stroke: A Randomized Controlled Trial](#)

Further study details as provided by Federal University of Minas Gerais:

Primary Outcome Measures:

- Maximal inspiratory and expiratory pressures [Time Frame: up to three-month follow-ups] [Designated as safety issue: No]
Maximal inspiratory and expiratory pressures will be assessed by a digital manovacuometer, following previously described protocols.

Secondary Outcome Measures:

- Inspiratory and expiratory endurance [Time Frame: Baseline, after intervention, and one and three-month follow-ups]
[Designated as safety issue: No]
Inspiratory and expiratory endurance will be assessed by the threshold devices, following previously described protocols.
- Dyspnea sensation [Time Frame: Baseline, after intervention, and one and three-month follow-ups] [Designated as safety issue: No]
Dyspnea sensation will be assessed by the Medical Research Council Scale.
- Exercise capacity [Time Frame: Baseline, after intervention, and one and three-month follow-ups] [Designated as safety issue: No]
Exercise capacity will be evaluated by the six-minute walking test
- Quality of life [Time Frame: Baseline, after intervention, and one and three-month follow-ups] [Designated as safety issue: No]

Quality of life will be assessed by the Brazilian version of the Stroke-specific quality of life scale.

Estimated Enrollment: 20
 Study Start Date: July 2015
 Estimated Study Completion Date: December 2017
 Estimated Primary Completion Date: November 2016 (Final data collection date for primary outcome measure)

Arms	Assigned Interventions
Experimental: Respiratory training Respiratory training will include training of the inspiratory and expiratory muscles five times per week over eight weeks, divided into three five-minute sessions of inspiratory training and the same doses of expiratory training, totaling 30 minutes of training. The training program will follow previously employed protocols for stroke survivors and will be carried-out with the Thresholds regulated at 40% of the subjects' maximal inspiratory and expiratory pressure values.	Other: Respiratory training Respiratory training will include training of the inspiratory and expiratory muscle five times per week over eight weeks, divided into three five-minute sessions of inspiratory training and the same doses of expiratory training, totaling 30 minutes of training. The training program will follow previously employed protocols for stroke survivors and will be carried-out with the threshold regulated at 40% of the subjects' maximal inspiratory and expiratory pressure values. Other: Control The control/sham group will underwent exactly the same protocol and bi-weekly monitoring at home, but the participants will receive the threshold devices with the minimum resistance of the spring.
Sham Comparator: Control The control/sham group will underwent exactly the same protocol and bi-weekly monitoring at home, but the participants will receive the threshold devices with the minimum resistance of the spring, which will be also concealed. The control group will also attend the bi-weekly sessions and undergo the same procedures, except for the load adjustments. If the training proves to be effective, the control subjects will be informed and have the choice to receive the training with proper loads.	Other: Respiratory training Respiratory training will include training of the inspiratory and expiratory muscle five times per week over eight weeks, divided into three five-minute sessions of inspiratory training and the same doses of expiratory training, totaling 30 minutes of training. The training program will follow previously employed protocols for stroke survivors and will be carried-out with the threshold regulated at 40% of the subjects' maximal inspiratory and expiratory pressure values. Other: Control The control/sham group will underwent exactly the same protocol and bi-weekly monitoring at home, but the participants will receive the threshold devices with the minimum resistance of the spring.

Detailed Description:

Rationale: Weakness of the respiratory muscles demonstrated by individuals with stroke, may generate important symptoms, such as fatigue and dyspnea. Since adequate strength of the inspiratory and expiratory muscles is required, mainly when performing physical activities, rehabilitation interventions for stroke subjects should include respiratory training.

Aim: This study will test the hypothesis that home-based combined inspiratory muscular training (IMT) plus expiratory muscular training (EMT) program is effective in improving strength and endurance of the inspiratory and expiratory muscles, fatigue, exercise capacity, and quality of life (QoL) with stroke subjects.

Design: For this prospective, double-blinded, randomized clinical trial, people after stroke will be randomly allocated into either experimental or control/sham groups. The experimental group will undertake training of the inspiratory plus expiratory muscles with the Threshold[®] IMT and the Threshold[™] PEP regulated at 40% of the subjects' maximal inspiratory pressure (MIP) and maximal expiratory pressure (MEP) values, five times/week over eight weeks during 30 minutes/day. The control group will undertake the same protocol, but the participants will receive the threshold devices without the resistance valves. At baseline, post intervention, and four and 12 weeks after the cessation (two follow-ups) of the interventions, researchers blinded to group allocations will collect all outcome measures.

Study outcomes: Primary outcomes will be MIP and MEP. Secondary outcomes will include inspiratory and expiratory endurance, fatigue, dyspnea sensation, exercise capacity, and QoL.

► Eligibility

Ages Eligible for Study: 20 Years and older
 Genders Eligible for Study: Both
 Accepts Healthy Volunteers: No

Criteria

Inclusion Criteria:

Stroke survivors will be eligible if they: are older than 20 years of age; have a mean time since of the onset of a unilateral stroke of at least three months; show no cognitive impairments, identified by the education adjusted cut-off scores on the Mini-Mental State Examination (MMSE)(16); have MIP and MEP values lower than 70% of the predicted ones for the healthy population(17); have no facial palsy, that could prevent proper labial occlusion; be able to use a cycle ergometer; have no restriction in lung function and no other neurologic, orthopedic or unstable cardiac conditions, that could prevent the tests and training; were non-smokers or smoke-free for at least five years; and have not undergone thoracic or abdominal surgery.

Exclusion Criteria:

Subjects will be excluded if they are already performing any type of respiratory training.

► Contacts and Locations

Choosing to participate in a study is an important personal decision. Talk with your doctor and family members or friends about deciding to join a study. To learn more about this study, you or your doctor may contact the study research staff using the Contacts provided below. For general information, see [Learn About Clinical Studies](#).

Please refer to this study by its ClinicalTrials.gov identifier: NCT02400138

Locations

Brazil

Department of Physical Therapy, Universidade Federal de Minas Gerais
Belo Horizonte, MG, Brazil, 31270-901

Sponsors and Collaborators

Federal University of Minas Gerais

Investigators

Study Director: Fatima Rodrigues-de-Paula, Ph.D. Federal University of Minas Gerais

► More Information

Publications:

[Sutbeyaz ST, Koseoglu F, Inan L, Coskun O. Respiratory muscle training improves cardiopulmonary function and exercise tolerance in subjects with subacute stroke: a randomized controlled trial. Clin Rehabil. 2010 Mar;24\(3\):240-50. doi: 10.1177/0269215509358932. Epub 2010 Feb 15.](#)

[Britto RR, Rezende NR, Marinho KC, Torres JL, Parreira VF, Teixeira-Salmela LF. Inspiratory muscular training in chronic stroke survivors: a randomized controlled trial. Arch Phys Med Rehabil. 2011 Feb;92\(2\):184-90. doi: 10.1016/j.apmr.2010.09.029.](#)

Responsible Party:	Luci Fuscaldi Teixeira-Salmela, Titular professor, Federal University of Minas Gerais
ClinicalTrials.gov Identifier:	NCT02400138 History of Changes
Other Study ID Numbers:	RTS-01
Study First Received:	March 23, 2015
Last Updated:	March 25, 2015
Health Authority:	Brazil: Ethics Committee

ClinicalTrials.gov processed this record on March 25, 2015

APÊNDICES

APÊNDICE A

TERMO DE CONSENTIMENTO LIVRE E ESCLARECIDO

Nº _____

Investigadora: Kênia Kiefer Parreiras de Menezes

Orientadora: Prof^a Luci Fuscaldi Teixeira-Salmela, Ph.D.

TÍTULO DO PROJETO

EFEITOS DE UM PROGRAMA DOMICILIAR DE FORTALECIMENTO MUSCULAR RESPIRATÓRIO DE ALTA INTENSIDADE EM HEMIPARÉTICOS: UM ENSAIO CLÍNICO ALEATORIZADO.

INFORMAÇÕES

Você está sendo convidado a participar de um projeto de pesquisa, que tem como objetivo avaliar a força dos seus músculos respiratórios e realizar o efeito de um treinamento específico para verificar se existe uma boa recuperação desta força em pessoas que sofreram Acidente Vascular Encefálico (“derrame”). Este projeto será desenvolvido como tese de doutorado no programa de Pós-graduação em Ciências da Reabilitação do Departamento de Fisioterapia da Escola de Educação Física, Fisioterapia e Terapia Ocupacional da Universidade Federal de Minas Gerais (UFMG).

DESCRIÇÃO DOS TESTES A SEREM REALIZADOS

Inicialmente, serão coletados dados para a sua identificação, além de algumas informações clínicas. Para garantir o seu anonimato, serão utilizadas senhas numéricas. Assim, em momento algum haverá divulgação do seu nome. Você realizará alguns testes para medir sua força muscular, condição física, e algumas medidas pulmonares. Também será aplicado um questionário avaliação da sua fadiga e qualidade de vida. A duração máxima da avaliação é de duas horas, sendo que serão realizados intervalos para repouso. Você também receberá dois aparelhos para treinar seus músculos cinco vezes por semana, durante dois meses. Três avaliações serão realizadas no laboratório de desempenho cardiorrespiratório da UFMG, sendo agendadas de acordo com os objetivos deste estudo e a sua disponibilidade. Além destas, três visitas domiciliares serão realizadas pelas investigadoras, também de acordo com os objetivos deste estudo e a sua disponibilidade.

RISCOS

Você poderá sentir dores musculares durante e após os testes, pois os testes exigem um esforço físico maior do que aquele que você realiza no seu dia a dia. Para minimizar a ocorrência deste desconforto, será realizado um período de descanso entre as medidas.

BENEFÍCIOS

Os resultados obtidos irão colaborar com o conhecimento científico, podendo estabelecer novas propostas de tratamento de indivíduos que tenham a mesma doença que você.

NATUREZA VOLUNTÁRIA DO ESTUDO/ LIBERDADE PARA SE RETIRAR

A sua participação é voluntária e você tem o direito de se recusar a participar por qualquer razão e a qualquer momento. Além disso, você não receberá nenhuma remuneração pela sua participação e poderá se retirar da pesquisa a qualquer momento, sem interferência na forma como esta sendo assistido.

GASTOS FINANCEIROS

Os testes, e todos os materiais utilizados na pesquisa não terão custo para você.

USO DOS RESULTADOS DA PESQUISA

Os dados obtidos no estudo serão para fins de pesquisa, podendo ser apresentados em congressos e seminários e publicados em artigo científico; porém, sua identidade será mantida em absoluto sigilo.

DECLARAÇÃO E ASSINATURA

Eu, _____ li e entendi toda a informação repassada sobre o estudo, sendo os objetivos e procedimentos satisfatoriamente explicados. Tive tempo, suficiente, para considerar a informação acima e, tive a oportunidade de tirar todas as minhas dúvidas. Estou assinando as duas cópias deste termo voluntariamente, sendo uma cópia para mim e outra para os pesquisadores e tenho direito de, agora ou mais tarde, discutir qualquer dúvida que venha a ter com relação à pesquisa com:

Kênia Kiefer Parreiras de Menezes: (031) 9256-0696
Profª Luci Fuscaldi Teixeira-Salmela (031) 3409-7403

Assinando este termo de consentimento, eu estou indicando que eu concordo em participar deste estudo.

Assinatura do Participante

Data

Assinatura do Acompanhante
Parentesco: _____

Data

Assinatura do Pesquisador Responsável

Data

Comitê de Ética em Pesquisa / UFMG: Av. Presidente Antônio Carlos, 6627 – Unidade Administrativa II - 2º andar – Sala 2005. CEP: 31270-901 – BH – MG
Telefax: (31) 3409-4592 E-mail: coep@prpq.ufmg.br

APÊNDICE B**CONTRATO DE COMPROMETIMENTO**

Eu, _____, concordo em realizar o treinamento com o aparelho Orygen Dual Valve. Eu também me comprometo em realizar este treinamento sete vezes por semana, durante oito semanas, por 40 minutos diários, sendo 20 minutos pela manhã e 20 minutos à tarde. Nestes 20 minutos, eu irei utilizar o aparelho durante minha respiração, posicionando o aparelho na boca e tentando vencer a resistência contra minha respiração (inspiração e expiração), em quatro séries de quatro minutos, descansando um minuto entre elas.

Em discussão com o meu terapeuta, _____, eu entendo que posso realizar este treinamento a qualquer hora da manhã ou da tarde, desde que uma vez iniciado, eu deva realizá-lo por completo, sem interrupções. Também me comprometo a realizar o treinamento forma como me ensinaram, sem alterações ou adaptações.

Assim, eu, _____, concordo aceitar e executar os termos acima fielmente como foi descrito.

Assinatura do paciente

Assinatura do terapeuta

Testemunha

Acompanhante/Cuidador

APÊNDICE C

DIÁRIO

VOCÊ DEVE PREENCHER O DIÁRIO TODOS OS DIAS, ANOTANDO SE REALIZOU O TREINAMENTO NO DIA E O TEMPO QUE REALIZOU. É FUNDAMENTAL QUE VOCÊ REALIZE O TREINAMENTO COM O DISPOSITIVO DURANTE AS OITO SEMANAS, SETE DIAS POR SEMANA, DUAS VEZES AO DIA, DURANTE 20 MINUTOS CADA, CONFORME O QUE LHE FOI ORIENTADO E COMBINADO, MEDIANTE O CONTRATO DE COMPROMETIMENTO.

1ª SEMANA:

DIA 1:

Treinou com o Dispositivo pela manhã? () SIM () NÃO Tempo (minutos): _____

Treinou com o Dispositivo pela tarde? () SIM () NÃO Tempo (minutos): _____

DIA 2:

Treinou com o Dispositivo pela manhã? () SIM () NÃO Tempo (minutos): _____

Treinou com o Dispositivo pela tarde? () SIM () NÃO Tempo (minutos): _____

DIA 3:

Treinou com o Dispositivo pela manhã? () SIM () NÃO Tempo (minutos): _____

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MINI CURRICULUM VITAE

1. FORMAÇÃO COMPLEMENTAR

- **2016**
 - "Osteoartrose de joelho - Abordagem contemporânea.
 - Carga horária: 15 horas - *Online*.
 - Instituto CEFISA de Ensino em Saúde, CEFISA, Brasil.
- **2014**
 - *Publications Ethics*.
 - Carga horária: 4 horas.
 - Universidade Federal de Minas Gerais, UFMG, Brasil.

2. VÍNCULO INSTITUCIONAL

UNIVERSIDADE FEDERAL DE MINAS GERAIS

- **2016 – 2017**
 - Aluna de doutorado.
 - Carga horária: 20 horas.
 - Regime: Dedicação parcial.
- **2014 - 2015**
 - Bolsista de Doutorado (FAPEMIG).
 - Carga horária: 40 horas
 - Regime: Dedicação exclusiva.
- **2017/2º**
 - Professora convidada para ministrar aula na disciplina de Cinesiologia Aplicada à Fisioterapia
 - Carga horária: 4 horas
- **2017/1º**
 - Professora convidada do curso de Especialização em Fisioterapia da Universidade Federal de Minas, na área de Fisioterapia Neurofuncional do Adulto.
 - Tema: Instrumentos para avaliação neurofuncinal.
 - Carga horária: 5 horas
- **2015 - Atual**
 - Pesquisadora Colaboradora do grupo de pesquisa em Reabilitação Neurológica no Adulto (*Neurogroup*).

- **2016**
 - Professora convidada para ministrar na disciplina de Cinesiologia Aplicada à Fisioterapia
 - Carga horária: 4 horas.
- **2014 - 2016**
 - Representante discente do programa de Pós-graduação em Ciências da Reabilitação (Conceito CAPES 6).
- **2014 / 1º**
 - Professora convidada para ministrar na disciplina de Cinesiologia Aplicada à Fisioterapia.
 - Carga horária: 8 horas.
- **2014 / 2º**
 - Professora convidada para ministrar na disciplina de Cinesiologia Aplicada à Fisioterapia.
 - Carga horária: 8 horas.

FUNDAÇÃO COMUNITÁRIA DE ENSINO SUPERIOR DE ITABIRA

- **2016 – atual**
 - Professora Adjunta
 - Carga horária: 12 horas (1º semestre /2016); 18 horas (2º semestre/2016); 15 horas (1º semestre /2017); e 12 horas (2º semestre/2017).
 - Disciplinas ministradas:
 - ✓ 2016/1º: Cinesiologia
Próteses e Órteses
 - ✓ 2016/2º: Cinesioterapia
Recursos Terapêuticos Manuais
Estágio Supervisionado II - Neurologia Adulto
 - ✓ 2017/1º: Cinesiologia
Próteses e Órteses
Estágio Supervisionado III - Neuropediatria
 - ✓ 2017/2º: Cinesioterapia
Recursos Terapêuticos Manuais
Trabalho de Conclusão de Curso I
- **2016**
 - Membro do NDE - Fisioterapia / FUNCESI.

3. LINHAS DE PESQUISA

- Desempenho Motor e Funcional Humano
- Estudos em Reabilitação Neurológica no Adulto

4. REVISOR DE PERIÓDICO

- **2013 - Atual**
 - Periódico: Revista Baiana de Saúde Pública
- **2012 - Atual**
 - Periódico: Revista Brasileira de Ciência e Movimento
- **2017 - Atual**
 - Periódico: Journal of Physiotherapy Research

5. PRÊMIOS E TÍTULOS

- **2016**
 - Relevância acadêmica - trabalho apresentado na XXV SIC: CORRELAÇÃO ENTRE MEDIDAS DE FORÇA DA MUSCULATURA MUSCULAR RESPIRATÓRIA, ENDURANCE, DISPNEIA E CAPACIDADE FUNCIONAL EM INDIVÍDUOS HEMIPARÉTICOS. Universidade Federal de Minas Gerais.
- **2016**
 - Relevância acadêmica - trabalho apresentado na XXV SIC: INCIDÊNCIA DE DISPNEIA EM INDIVÍDUOS PÓS ACIDENTE VASCULAR ENCEFÁLICO. Universidade Federal de Minas Gerais.
- **2014**
 - Relevância acadêmica - trabalho apresentado na XXIII SIC: PROPRIEDADES PSICOMÉTRICAS DO LOWER EXTREMITY MOTOR COORDINATION TEST EM INDIVÍDUOS PÓS-AVE. Universidade Federal de Minas Gerais.
- **2014**
 - Menção Honrosa - Trabalho apresentado na XXIII SIC: PROPRIEDADES PSICOMÉTRICAS DO LOWER EXTREMITY MOTOR COORDINATION TEST EM INDIVÍDUOS PÓS-AVE. Universidade Federal de Minas Gerais.

6. ARTIGOS PUBLICADOS

1. **MENEZES, K.K.P.**; FARIA, C.D.C.M.; SCIANNI, A.A.; AVELINO, P.R.; FORTINI, I.F.; TEIXEIRA-SALMELA, L.F. Previous lower limb dominance does not affect measures of impairment and activity after stroke. *European Journal of Physical and Rehabilitation Medicine*, v. 53, p. 24-31, 2017.
2. FORTINI, I.F.; BASILIO, M.L.; POLESE, J.C.; **MENEZES, K.K.P.**; FARIA, C.D.C.M.; SCIANNI, A.A.; TEIXEIRA-SALMELA, L.F. Caracterização da participação social de indivíduos na fase crônica pós-acidente vascular encefálico. *Revista de Terapia Ocupacional da Universidade de São Paulo*, v. 28, p. 71, 2017.
3. AVELINO, P.R.; FORTINI, I.F.; BASILIO, M.L.; **MENEZES, K.K.P.**; TEIXEIRA-SALMELA, L.F. Adaptação transcultural do ABILOCO: uma medida de habilidade de locomoção, específica para indivíduos pós Acidente Vascular Encefálico. *Acta Fisiátrica*, v. 23, p. 161-165, 2017.
4. **MENEZES, K.K.P.**; NASCIMENTO, L.R.; PINHEIRO, M.B.; SCIANNI, A.A.; FARIA, C.D.C.M.; Avelino, P.R.; FORTINI, I.F.; TEIXEIRA-SALMELA, L.F. Lower-limb motor coordination is significantly impaired in ambulatory people with chronic stroke: A cross-sectional study. *Journal of Rehabilitation Medicine*, v. 49, p. 322-326, 2017.
5. MAGALHAES, H.C.G.; **MENEZES, K.K.P.**; AVELINO, P.R. Efeitos do uso do Kinesio® Taping na marcha de indivíduos pós-acidente vascular encefálico: uma revisão sistemática com metanálise. *Revista Fisioterapia e Pesquisa*, v. 24, p. 218-228, 2017.
6. **MENEZES, K.K.P.**; AVELINO, P.R.; SCIANNI, A.A.; FORTINI, I. F.; FARIA, C.D.C.M.; NASCIMENTO, L.R.; TEIXEIRASALMELA, L.F. Learning effects of the lower extremity motor coordination test in individuals with stroke. *Physical Medicine and Rehabilitation - International*, v. 4, p. 1111, 2017.
7. **MENEZES, K.K.P.**; AVELINO, P.R. Grupos operativos na Atenção Primária à Saúde como prática de discussão e educação: uma revisão. *Cadernos Saúde Coletiva*, v. 24, p. 124-130, 2016.
8. **MENEZES, K.K.P.**; NASCIMENTO, L.R.; ADA, L.; POLESE, J.C.; AVELINO, P.R.; TEIXEIRA-SALMELA, L.F. Respiratory muscle training increases respiratory muscle strength and reduces respiratory complications after stroke: a systematic review. *Journal of Physiotherapy*, v. 62, p. 138-144, 2016.

9. FORTINI, I.F.; BASILIO, M.L.; POLESE, J.C.; **MENEZES, K.K.P.**; TEIXEIRA-SALMELA, L.F. Strength deficits of the paretic lower extremity muscles were the impairment variables that best explained restrictions in participation after stroke. *Disability and Rehabilitation*, p. 1-6, 2016.
10. **MENEZES, K.K.P.**; SCIANNI, A.A.; FORTINI, I.F.; AVELINO, P.R.; FARIA, C.D.C.M.; TEIXEIRA-SALMELA, L.F. Measurement properties of the lower extremity motor coordination test in individuals with stroke. *Journal of Rehabilitation Medicine*, v. 47, p. 502-507, 2015.
11. **MENEZES, K.K.P.**; SCIANNI, A.A.; FORTINI, I.F.; AVELINO, P.R.; CARVALHO, A.C.; FARIA, C.D.C.M.; TEIXEIRASALMELA, L.F. Potential predictors of lower extremity impairments in motor coordination of stroke survivors. *European Journal of Physical and Rehabilitation Medicine*, v. 51, p. 1-24, 2015.
12. **MENEZES, K.K.P.** Physical therapy rehabilitation after traumatic brain injury. *Journal of Neurology & Neurophysiology*, v. 06, p. 1-2, 2015.
13. **MENEZES, K.K.P.**; SCIANNI, A.A.; FORTINI, I.F.; AVELINO, P.R.; FARIA, C.D.C.M.; TEIXEIRASALMELA, L.F. Lower limb motor coordination of stroke survivors, based upon their levels of motor recovery and ages. *Journal of Neurology & Neurophysiology*, v. 06, p. 1, 2015.
14. **MENEZES, K.K.P.**; SCIANNI, A.A.; FORTINI, I.F.; AVELINO, P.R.; FARIA, C.D.C.M.; TEIXEIRA-SALMELA, L.F. Motor Recovery, tonus of the plantar flexor muscles, and age are predictors of the lower limb motor coordination in stroke survivors. *Journal of Yoga & Physical Therapy*, v. 05, p. 1-2, 2015.
15. AVELINO, P.R.; **MENEZES, K.K.P.**; CARVALHO, A.C.; HIROCHI, T.L.; TEIXEIRA-SALMELA, L.F. Revisão das propriedades psicométricas de testes de coordenação motora dos membros superiores em hemiparéticos. *Revista de Terapia Ocupacional da Universidade de São Paulo*, v. 24, p. 273, 2014.
16. PINHEIRO, M.B.; **MENEZES, K.K.P.**; TEIXEIRA-SALMELA, L.F. Review of the psychometric properties of lower limb motor coordination tests. *Fisioterapia em Movimento*, v. 27, p. 541-553, 2014.
17. **MENEZES, K.K.P.**; AVELINO, P.R.; COSTA, H.S. Evidence-Based Practice: A Challenge for Professionals and Researchers. *Journal of Physiotherapy Research*, v. 1, p. 1-2, 2017.

18. AVELINO, P.R.; MAGALHAES, L.C.; FORTINI, I.F.; BASILIO, M.L.; **MENEZES, K.K.P.**; TEIXEIRA-SALMELA, L.F. Cross-cultural validity of the ABILOCO questionnaire for individuals with stroke, based on Rasch analysis. *Disability and Rehabilitation, Ahead of print*, 2017.
19. **MENEZES, K.K.P.**; NASCIMENTO, L.R.; POLESE, J.C.; ADA, L.; TEIXEIRA-SALMELA, L. F. Effect of high-intensity home-based respiratory muscle training on strength of respiratory muscles following a stroke: a protocol for a randomized controlled trial. *Brazilian Journal of Physical Therapy, Ahead of print*, 2017.
20. **MENEZES, K. K. P.**; LEITE, D.X.; AVELINO, P.R. Locomoção humana sob a perspectiva dos Sistemas Dinâmicos: teoria e implicações clínicas. *Revista Brasileira de Biomecânica, Ahead of print*, 2017.

7. RESUMOS PUBLICADOS EM ANAIS DE CONGRESSOS

1. CHRISTOVAO, I.S.; **MENEZES, K.K.P.**; NASCIMENTO, L.R.; AVELINO, P.R.; FARIA-FORTINI, I.; BASILIO, M.L.; TENORIO, R.A.; ALVARENGA, M.T.M.; TEIXEIRA-SALMELA, L.F. Reprodutibilidade do questionário ABILOCO-Brasil em indivíduos pós-Acidente Vascular Encefálico. In: XXVI Semana de Iniciação Científica da UFMG, 2017, Belo Horizonte. Anais da XXVI Semana de Iniciação Científica da UFMG, 2017.
2. TENORIO, R.A.; **MENEZES, K.K.P.**; NASCIMENTO, L.R.; AVELINO, P.R.; CHRISTOVAO, I.S.; ALVARENGA, M.T.M.; TEIXEIRA-SALMELA, L.F. Prevalência e impacto da dispneia em indivíduos pós-Acidente Vascular Encefálico. In: XXVI Semana de Iniciação Científica da UFMG, 2017, Belo Horizonte. Anais da XXVI Semana de Iniciação Científica da UFMG, 2017.
3. ALVARENGA, M.T.M.; **MENEZES, K.K.P.**; NASCIMENTO, L.R.; AVELINO, P.R.; POLESE, J.C.; CANDIDO, G.N.; TEIXEIRA-SALMELA, L.F. Treino muscular respiratório de alta intensidade aumenta a força e endurance muscular respiratória e reduz dispneia em indivíduos pós-Acidente Vascular Encefálico: um ensaio clínico aleatorizado. In: XXVI Semana de Iniciação Científica da UFMG, 2017, Belo Horizonte. Anais da XXVI Semana de Iniciação Científica da UFMG, 2017.
4. CANDIDO, G.N.; **MENEZES, K.K.P.**; NASCIMENTO, L.R.; AVELINO, P.R.; ALVARENGA, M.T.M.; TEIXEIRA-SALMELA,

L.F. Eficácia dos exercícios respiratórios na função respiratória após Acidente Vascular Encefálico: uma revisão sistemática. In: XXVI Semana de Iniciação Científica da UFMG, 2017, Belo Horizonte. Anais da XXVI Semana de Iniciação Científica da UFMG, 2017

5. ALVARENGA, M.T.M.; **MENEZES, K.K.P.**; NASCIMENTO, L.R.; AVELINO, P.R.; TEIXEIRA-SALMELA, L.F. Efeitos de um programa domiciliar de fortalecimento muscular respiratório de alta intensidade em pacientes pós-acidente vascular encefálico: ensaio clínico aleatorizado. In: 9º Congresso Internacional de Fisioterapia, 2017, Porto Alegre. Anais do 9º Congresso Internacional de Fisioterapia, 2017.
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8. APRESENTAÇÕES DE TRABALHO

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15. **MENEZES, K. K. P.**; FORTINI, I. F.; AVELINO, P. R.; CARVALHO, A. C.; SCIANNI, A. A.; TEIXEIRA-SALMELA, L. F. Influência da dominância prévia do membro inferior na coordenação motora de hemiparéticos. 2014. (Apresentação de Trabalho/Congresso).
16. **MENEZES, K. K. P.**; FORTINI, I. F.; AVELINO, P. R.; CARVALHO, A. C.; SCIANNI, A. A.; TEIXEIRA-SALMELA, L. F. Fatores relacionados ao Lower Extremity Motor Coordination Test em indivíduos hemiparéticos. 2014. (Apresentação de Trabalho/Congresso).

9. ENTREVISTAS, MESAS REDONDAS, CURSOS, PROGRAMAS E COMENTÁRIOS NA MÍDIA

1. **MENEZES, K.K.P.**; COSTA, H.S. Criatividade e inovação na fisioterapia. 2017 (Curso de curta duração).
2. **MENEZES, K. K. P.** Água, um espaço de diversão, integração e reabilitação. 2017. (Curso de curta duração).
3. **MENEZES, K. K. P.**; GONCALVES, L.; MAGALHAES, A.; PAULA, M. N. L. Crioterapia e Termoterapia - quando usar? 2016. (Mesa redonda).
4. **MENEZES, K. K. P.** Atividade física: Saúde e lazer. 2016. (Curso de curta duração).

10. PARTICIPAÇÃO EM BANCAS DE TRABALHOS DE CONCLUSÃO

MONOGRAFIAS DE CURSOS DE APERFEIÇOAMENTO/ESPECIALIZAÇÃO

1. **MENEZES, K. K. P.** Participação em banca de Ana Gabriela Pimental de Souza. Lesões músculo esqueléticas relacionadas com o salto vertical em atletas de elite de voleibol: revisão narrativa. 2016. Monografia (Aperfeiçoamento/Especialização em Programa de Pós-graduação em Fisioterapia / Especialização - Ortopedia) - Universidade Federal de Minas Gerais.

2. **MENEZES, K. K. P.** Participação em banca de Douglas Novaes Bonifácio. Efeito de programas de reabilitação baseados em movimento para redução da dor e melhora de atividade em indivíduos com diagnóstico de espondilólise e espondilolistese: revisão sistemática. 2016. Monografia (Aperfeiçoamento/Especialização em Programa de Pós-graduação em Fisioterapia / Especialização - Ortopedia) - Universidade Federal de Minas Gerais.
3. **MENEZES, K. K. P.** Participação em banca de Francisco de Assis da Silva Gomes. Eficácia da mobilização neural na melhora da dor em pacientes com síndrome do túnel do carpo: uma revisão narrativa. 2016. Monografia (Aperfeiçoamento/Especialização em Programa de Pós-graduação em Fisioterapia / Especialização - Ortopedia) - Universidade Federal de Minas Gerais.
4. **MENEZES, K. K. P.** Participação em banca de Maria Inês Soares Dias. O efeito do ultrassom terapêutico na dor de pacientes com osteoartrite de joelho: uma revisão crítica da literatura. 2016. Monografia (Aperfeiçoamento/Especialização em Programa de Pós-graduação em Fisioterapia / Especialização - Ortopedia) - Universidade Federal de Minas Gerais.
5. **MENEZES, K. K. P.** Participação em banca de Poliane Gonçalves de Mello. Tratamento conservador ou intervenção cirúrgica? Critérios clínicos para a seleção da abordagem terapêutica em lesões sintomáticas do manguito rotador. 2016. Monografia (Aperfeiçoamento/Especialização em Programa de Pós-graduação em Fisioterapia / Especialização - Ortopedia) - Universidade Federal de Minas Gerais.
6. **MENEZES, K. K. P.** Participação em banca de Roberta Lima Marcelino Freire. Avaliação clínica para a medida do alinhamento do retropé e antepé: revisão da literatura. 2016. Monografia (Aperfeiçoamento/Especialização em Programa de Pós-graduação em Fisioterapia / Especialização - Ortopedia) - Universidade Federal de Minas Gerais.
7. **MENEZES, K. K. P.** Participação em banca de Thaís Brasil Cardoso. Eficácia de programas de fortalecimento muscular do manguito rotador na dor e função de pacientes com síndrome do impacto. 2016. Monografia (Aperfeiçoamento/Especialização em Programa de Pós-graduação em Fisioterapia / Especialização - Ortopedia) - Universidade Federal de Minas Gerais.
8. **MENEZES, K. K. P.** Participação em banca de Víctor Leandro Esteves Borges. A efetividade do ultrassom terapêutico nas

tendinopatias crônicas. 2016. Monografia (Aperfeiçoamento/Especialização em Programa de Pós-graduação em Fisioterapia / Especialização - Ortopedia) - Universidade Federal de Minas Gerais.

9. **MENEZES, K. K. P.** Participação em banca de Fábio da Silva Paes Leme. Epidemiologia das lesões nas artes marciais: revisão da literatura. 2016. Monografia (Aperfeiçoamento/Especialização em Programa de Pós-graduação em Fisioterapia / Especialização - Ortopedia) - Universidade Federal de Minas Gerais.
10. **MENEZES, K. K. P.** Participação em banca de Flávia Marques Oliveira Moraes. Alterações de parâmetros biomecânicos da marcha em indivíduos idosos -uma revisão. 2016. Monografia (Aperfeiçoamento/Especialização em Programa de Pós-graduação em Fisioterapia / Especialização - Ortopedia) - Universidade Federal de Minas Gerais.
11. **MENEZES, K. K. P.** Participação em banca de Henrique Couto da Gama Magalhães. Efeitos do uso do *kinesio taping* na marcha de indivíduos pós acidente vascular encefálico: uma revisão sistemática com metanálise. 2016. Monografia (Aperfeiçoamento/Especialização em Programa de Pós-graduação em Fisioterapia / Especialização - Ortopedia) - Universidade Federal de Minas Gerais.
12. **MENEZES, K. K. P.** Participação em banca de Lívia Carolina Guimarães da Silva. Os benefícios do método Pilates em indivíduos hemiparéticos: uma revisão sistemática da literatura. 2016. Monografia (Aperfeiçoamento/Especialização em Programa de Pós-graduação em Fisioterapia / Especialização - Ortopedia) - Universidade Federal de Minas Gerais.
13. **MENEZES, K. K. P.** Participação em banca de Ludmilla Grazielle Medeiros Silva. Efeitos do exercício neuromuscular na força muscular e desempenho funcional. 2016. Monografia (Aperfeiçoamento/Especialização em Programa de Pós-graduação em Fisioterapia / Especialização - Ortopedia) - Universidade Federal de Minas Gerais.
14. **MENEZES, K. K. P.** Participação em banca de Marcos Renato Ribeiro da Hora. Relação entre a pronação excessiva da articulação subTalar e a ocorrência. 2016. Monografia (Aperfeiçoamento/Especialização em Programa de Pós-graduação em Fisioterapia / Especialização - Ortopedia) - Universidade Federal de Minas Gerais.

15. **MENEZES, K. K. P.** Participação em banca de Maria Carolina Viana Ferreira. Associação da pronação excessiva e alinhamento patelar em mulheres. 2016. Monografia (Aperfeiçoamento/Especialização em Programa de Pós-graduação em Fisioterapia / Especialização - Ortopedia) - Universidade Federal de Minas Gerais.
16. **MENEZES, K. K. P.** Participação em banca de Mary Helen da Silva Ferreira. Eficácia de exercício de estabilização escapular em indivíduos com síndrome do impacto subacromial: uma revisão bibliográfica. 2016. Monografia (Aperfeiçoamento/Especialização em Programa de Pós-graduação em Fisioterapia / Especialização - Ortopedia) - Universidade Federal de Minas Gerais.
17. **MENEZES, K. K. P.** Participação em banca de Paula Helena Saraiva Santos. Análise dos efeitos do *Kinesiotaping* em diversas populações. 2016. Monografia (Aperfeiçoamento/Especialização em Programa de Pós-graduação em Fisioterapia / Especialização - Esporte) - Universidade Federal de Minas Gerais.
18. **MENEZES, K. K. P.** Participação em banca de Pollyanna Flávia Cordeiro. Efeitos do treinamento de correr descalço em indivíduos saudáveis: uma revisão sistemática. 2016. Monografia (Aperfeiçoamento/Especialização em Programa de Pós-graduação em Fisioterapia / Especialização - Ortopedia) - Universidade Federal de Minas Gerais.
19. **MENEZES, K. K. P.** Participação em banca de Carina Mara Barbosa Vieira. O uso de laser na cicatrização de úlceras neurotróficas em indivíduos acometidos pela Hanseníase e Diabetes Mellitus. 2015. Monografia (Aperfeiçoamento/Especialização em Fisioterapia) - Universidade Federal de Minas Gerais.
20. **MENEZES, K. K. P.** Participação em banca de Poliana Kelly da Silveira. A eficácia do método Pilates na melhora da força muscular e flexibilidade em indivíduos saudáveis: revisão da literatura. 2015. Monografia (Aperfeiçoamento/Especialização em Fisioterapia) - Universidade Federal de Minas Gerais.
21. **MENEZES, K. K. P.** Participação em banca de Rafael Virgínio de Souza. Eficácia do treinamento excêntrico no reparo tecidual de indivíduos com Tendinopatia de Aquiles: uma revisão bibliográfica. 2015. Monografia (Aperfeiçoamento/Especialização em Fisioterapia) - Universidade Federal de Minas Gerais.

22. **MENEZES, K. K. P.** Participação em banca de Aline Gracielly da Silva Lemos. Fatores de risco para primeiro episódio de dor lombar. 2015. Monografia (Aperfeiçoamento/Especialização em Fisioterapia) - Universidade Federal de Minas Gerais.
23. **MENEZES, K. K. P.** Participação em banca de Camila Taisis Limirio. Contribuição do mecanismo de co-contração muscular na estabilidade da coluna lombar: revisão da literatura. 2015. Monografia (Aperfeiçoamento/Especialização em Fisioterapia) - Universidade Federal de Minas Gerais.

TRABALHOS DE CONCLUSÃO DE CURSO DE GRADUAÇÃO

1. **MENEZES, K. K. P.;** COSTA, H. S.; GUERRA, M. R. S. Participação em banca de Vitania Cota. Perfil do estresse dos enfermeiros atuantes em UTI a partir de publicações do ano de 2005 a 2015. 2017. Trabalho de Conclusão de Curso (Graduação em Enfermagem) - Fundação Comunitária de Ensino Superior de Itabira.
2. **MENEZES, K. K. P.;** COSTA, H. S.; VIEIRA, T. A. Participação em banca de Sandro Samuel Silva. Ambiente de trabalho em uma subestação elétrica de usina de beneficiamento de minério de ferro na cidade de Itabira/MG: análise ergonômica e sugestões de melhorias. 2017. Trabalho de Conclusão de Curso (Graduação em Engenharia de Produção) – Fundação Comunitária de Ensino Superior de Itabira.
3. **MENEZES, K. K. P.;** BASILIO, M. L. Participação em banca de Samara Costa e Carla Lage. Análise das propriedades de medida do “Here’s How I Write”: uma autoavaliação da escrita de crianças. 2015. Trabalho de Conclusão de Curso (Graduação em Terapia Ocupacional) - Universidade Federal de Minas Gerais.

EVENTOS

1. **MENEZES, K. K. P.** 3ª Feira Brasileira de Colégios de Aplicação e Escolas Técnicas (FEBRAT). 2015. Universidade Federal de Minas Gerais.
2. **MENEZES, K. K. P.** II Jornada Acadêmica de Fisioterapia - UFMG. 2015. Universidade Federal de Minas Gerais.

3. **MENEZES, K. K. P.** 2ª Feira Brasileira de Colégios de Aplicação e Escolas Técnicas (FEBRAT). 2014. Universidade Federal de Minas Gerais.

11. PARTICIPAÇÃO EM EVENTOS

1. III Seminário de Empreendedorismo, Inovação e Tecnologias – Criatividade e Inovação. 2017.
2. Seminário de Cultura, Meio Ambiente e Sociedade - ÁGUA, ARTE E VIDA. 2017.
3. Congresso Brasileiro de Fisioterapia Neurofuncional. 2016.
4. Congresso Brasileiro de Neurologia. 2016.
5. I Seminário de Empreendedorismo, Inovação e Tecnologias - Transformando ideias em negócios. 2016.
6. Mostra de profissões - UFMG. FISIOTERAPIA. 2016.
7. Mostra de profissões - FUNCESI. FISIOTERAPIA. 2016.
8. VIII Jornada de Integração Acadêmica do Curso de Fisioterapia da FUNCESI. 2016.
9. X Congresso Brasileiro de Doenças Cerebrovasculares. 2015.
10. Congresso Brasileiro de Fisioterapia Neurofuncional. 2014.
11. 7º Congresso Internacional de Fisioterapia. 2014.
12. XIV Fórum Brasileiro de Neuropsiquiatria Geriátrica. 2014.

12. ORGANIZAÇÃO DE EVENTOS

1. MENEZES, K. K. P. Mostra de Profissões da FUNCESI. 2016.

13. ORIENTAÇÕES

MONOGRAFIAS DE CONCLUSÃO DE CURSO DE APERFEIÇOAMENTO/ESPECIALIZAÇÃO - EM ANDAMENTO

1. Daniel Ribeiro Oliveira. Tratamento conservador versus cirúrgico para dor lombar: uma revisão sistemática. Início: 2017. Monografia (Aperfeiçoamento/Especialização em Programa de Pós-graduação em Fisioterapia / Especialização - Ortopedia) - Universidade Federal de Minas Gerais. (Orientador).
2. Luíza Nogueira de Freitas. Efeitos do método Pilates em pacientes com hérnia de disco lombar: uma revisão sistemática. Início: 2017. Monografia (Aperfeiçoamento/Especialização em Programa de Pós-graduação em Fisioterapia / Especialização - Ortopedia) - Universidade Federal de Minas Gerais. (Orientador).
3. Virgínia Barbosa. Efeito do método Pilates no esporte de alto rendimento: uma revisão. Início: 2017. Monografia (Aperfeiçoamento/Especialização em Programa de Pós-graduação em Fisioterapia / Especialização - Ortopedia) - Universidade Federal de Minas Gerais. (Orientador).
4. Letícia Costa Queiroz. Efeitos do treino de realidade virtual na participação social de hemiparéticos. Início: 2016. Monografia (Aperfeiçoamento/Especialização em Programa de Pós-Graduação em Fisioterapia - Especialização / Neurologia) - Universidade Federal de Minas Gerais. (Orientador).
5. Pricila de Lima. Efeitos do treino de equilíbrio na velocidade de marcha e participação social de hemiparéticos. Início: 2016. Monografia (Aperfeiçoamento/Especialização em Programa de Pós-Graduação em Fisioterapia - Especialização / Neurologia) - Universidade Federal de Minas Gerais. (Orientador).

TRABALHO DE CONCLUSÃO DE CURSO DE GRADUAÇÃO - EM ANDAMENTO

1. Maria Tereza Mota Alvarenga e Tályta Lamarquiana. Correlação entre a força muscular respiratória e medidas de endurance, dispneia e capacidade funcional em indivíduos hemiparéticos. Início: 2016. Trabalho de Conclusão de Curso (Graduação em Fisioterapia) - Universidade Federal de Minas Gerais. (Orientador).
2. Bruna Guimarães Madureira e Maria Geralda Pereira. Efeitos de um programa multidisciplinar na reabilitação de pacientes com Alzheimer: uma revisão sistemática. Início: 2016. Trabalho de

Conclusão de Curso (Graduação em Fisioterapia) - Fundação Comunitária de Ensino Superior de Itabira. (Orientador).

MONOGRAFIAS DE CONCLUSÃO DE CURSO DE APERFEIÇOAMENTO/ESPECIALIZAÇÃO – CONCLUÍDAS

1. Henrique Couto. Efeitos do método Pilates em pacientes pós acidente vascular cerebral. 2015. Monografia. (Aperfeiçoamento/Especialização em Fisioterapia) - Universidade Federal de Minas Gerais. Orientador: Kênia Kiefer Parreiras de Menezes.
2. Pollyanna Flávia Cordeiro. Efeitos do treinamento de correr descalço ou com tênis minimalistas em corredores. 2015. Monografia. (Aperfeiçoamento/ Especialização em Fisioterapia) - Universidade Federal de Minas Gerais. Orientador: Kênia Kiefer Parreiras de Menezes.
3. Lívia Carolina Guimarães da Silva. Efeitos do taping em pacientes pós acidente vascular cerebral. 2015. Monografia. (Aperfeiçoamento/ Especialização em Fisioterapia) - Universidade Federal de Minas Gerais. Orientador: Kênia Kiefer Parreiras de Menezes.

TRABALHO DE CONCLUSÃO DE CURSO DE GRADUAÇÃO - CONCLUÍDAS

1. Jeferson Willian Oliveira Costa. Avaliação postural dos mecânicos de manutenção preventiva na manutenção dos tratores de esteira: Uma contribuição ergonômica. 2017. Trabalho de Conclusão de Curso. (Graduação em Engenharia de Produção) - Universidade Federal de Minas Gerais. Orientador: Kênia Kiefer Parreiras de Menezes.
2. Patrick Roberto Avelino. Propriedades psicométricas de testes de coordenação motora dos membros superiores em pacientes hemiplégicos: uma revisão da literatura. 2013. Trabalho de Conclusão de Curso. (Graduação em Fisioterapia) - Universidade Federal de Minas Gerais. Orientador: Kênia Kiefer Parreiras de Menezes.

14. OUTRAS INFORMAÇÕES RELEVANTES

- Aprovada no Processo Seletivo para preenchimento de vaga de Professor Substituto, na Universidade Federal de Minas Gerais, Escola de Educação Física, Fisioterapia e Terapia Ocupacional, área de conhecimento: Fisioterapia em Saúde Pública e Ensino Clínico, Edital n 154, de 20/02/2015, publicado no DOU de 23/02/2015.
- Aprovada no Processo Seletivo para preenchimento de vaga de Professora Adjunta na Fundação Comunitária de Ensino Superior de Itabira - FUNCESI.

15. TRABALHOS SUBMETIDOS

DOUTORADO

- MENEZES KKP, NASCIMENTO LR, AVELINO PR, ALVARENGA MTM, TEIXEIRA-SALMELA LF. Efficacy of interventions at improving respiratory function after stroke: A systematic review. Submetido à revista *Respiratory Care*.
- MENEZES KKP, NASCIMENTO LR, AVELINO PR, POLESE JC, TEIXEIRA-SALMELA LF. A review on respiratory muscle training devices. Submetido à revista *The Clinical Respiratory Journal*.
- MENEZES KKP, NASCIMENTO LR, ALVARENGA MTM, AVELINO PR, TEIXEIRA-SALMELA LF. Prevalence of dyspnea after a stroke: A telephone-based survey. Submetido à Revista *Topics in Stroke Rehabilitation*.

MESTRADO

- MENEZES KKP, NASCIMENTO LR, ALVARENGA MTM, AVELINO PR, TEIXEIRA-SALMELA LF. Prevalence of dyspnea after a stroke: A telephone-based survey. Submetido à Revista *Topics in Stroke Rehabilitation*.

DEMAIS TRABALHOS

- MENEZES KKP, AVELINO PR, FARIA-FORTINI I, BASÍLIO ML, NASCIMENTO LR, TEIXEIRA-SALMELA LF. Reproducibility of the ABILOCO-Brazil questionnaire in individuals with stroke. Submetido à Revista *Disability and Rehabilitation*.
- MENEZES KKP, AVELINO PR, FARIA-FORTINI I, BASÍLIO ML, NASCIMENTO LR, TEIXEIRA-SALMELA LF. Predictors of locomotion ability after stroke. Submetido à Revista *Neurorehabilitation*.
- NASCIMENTO LR, MENEZES KKP, SCIANNI AA, TEIXEIRA-SALMELA LF. Deficits in motor coordination of the paretic lower limb limit the ability to increase walking speed in individuals with chronic stroke. Submetido à Revista *Disability and Rehabilitation*.
- SILVA LCG, MENEZES KKP, AVELINO PR. Os benefícios do método Pilates em indivíduos hemiparéticos: uma revisão sistemática. Submetido à Revista *Acta Fisiátrica*.
- CORDEIRO PF, MENEZES KKP, AVELINO PR. Efeitos do treinamento de correr descalço em indivíduos saudáveis: uma revisão sistemática. Submetido à Revista *Fisioterapia Brasil*.