UNIVERSIDADE FEDERAL DE MINAS GERAIS
Escola de Educação Física, Fisioterapia e Terapia Ocupacional
Programa de Pós-graduação em Ciências da Reabilitação

Nayara Santos Silva

PREVALÊNCIA E QUALIDADE DOS PROTOCOLOS DE REGISTROS DE ENSAIOS CLÍNICOS NA FISIOTERAPIA

Belo Horizonte
2022

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Versão final

Dissertação 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 para obtenção do título de Mestre em Ciências da Reabilitação

Orientador: Prof. Dr. Rafael Zambelli de Almeida Pinto

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UNIVERSIDADE FEDERAL DE MINAS GERAIS

PROGRAMA DE PÓS-GRADUAÇÃO EM CIÊNCIAS DA REABILITAÇÃO

ATA DA DEFESA DA DISSERTAÇÃO DA ALUNA
NAYARA SANTOS SILVA

Realizou-se, no dia 10 de fevereiro de 2022, às 14:00 horas, Ambiente Virtual, da Universidade Federal de Minas Gerais, a defesa de dissertação, intitulada *Prevalência e qualidade dos protocolos de registros de ensaios clínicos na fisioterapia*, apresentada por NAYARA SANTOS SILVA, número de registro 2019713610, graduada no curso de FISIOTERAPIA, como requisito parcial para a obtenção do grau de Mestre em CIÊNCIAS DA REABILITAÇÃO, à seguinte Comissão Examinadora: Prof(a). Rafael Zambelli de Almeida Pinto - Orientador (UFMG), Prof(a). Aline Alvim Scianni (UFMG), Prof(a). Ana Paula Coelho Figueira Freire (UNOESTE).

A Comissão considerou a dissertação:

(X) Aprovada

( ) Reprovada

Finalizados os trabalhos, lavrei a presente ata que, lida e aprovada, vai assinada por mim e pelos membros da Comissão.
Belo Horizonte, 10 de fevereiro de 2022.

Prof(a). Rafael Zambelli de Almeida Pinto (Doutor)

Prof(a). Aline Alvim Scianni (Doutora)

Prof(a). Ana Paula Coelho Figueira Freire (Doutora)

A minha família.

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“Não choraremos o que houve,
nem os que chorar queremos:
contra rocas de ignorância
rebenta a nossa aflição.
Choramos esse mistério,
esse esquema sobre-humano,
a força, o jogo, o acidente
da indizível conjunção
que ordena vidas e mundos
em pólos inexoráveis
de ruína e de exaltação
Ó silenciosas vertentes
por onde se precipitam
inexplicáveis torrentes
por eterna escuridão!”

(Cecília Meireles)

RESUMO

OBJETIVO: Investigar a prevalência e qualidade dos registros de ensaios clínicos randomizados e a prevalência de relato seletivo de desfechos em uma amostra de ensaios clínicos de intervenções em fisioterapia publicados em 2019; e compará-las com os dados equivalentes coletados em 2009. **MÉTODOS:** Uma amostra aleatória de 200 ensaios clínicos foi obtida da plataforma *Physiotherapy Evidence Database* (PEDro). Os dados relativos ao registro foram obtidos de cada um dos ensaios clínicos através de seu protocolo de registro e através de contato direto com os autores, para posteriormente serem comparados com a publicação. Foram avaliadas as prevalências de registro de ensaio clínico; de registro prospectivo (que é realizado antes do início do recrutamento de participantes); de desfechos primários não ambíguos (com descrição do período de avaliação e definição do método de avaliação do desfecho realizados no protocolo de registro); de registro adequado (realizado de forma prospectiva e com descrição não ambígua do desfecho primário); de inconsistência de desfechos (ocorre quando os desfechos descritos no registro não são os mesmos da publicação, considerando os desfechos ambíguos e não ambíguos); de reporte seletivo dos dados (nessa avaliação, são levados em conta apenas os registros com descrição não ambígua dos desfechos); se os ensaios clínicos publicados em revistas de maior impacto apresentaram maior prevalência de registros em contraste com a amostra geral; e quais fatores estavam associados ao registro dos ensaios clínicos. **RESULTADOS:** A proporção de ensaios clínicos registrados em 2019 foi de 126/200 (63%) versus 67/200 (34%) em 2009 (Risco Relativo – RR 1.88, 95% IC 1.51 a 2.35). Os ensaios clínicos publicados em jornais de alto impacto tiveram uma significativa maior prevalência de registro, 100% em 2019 (RR 1.58, 95% IC 1.42 a 1.76) do que a amostra geral do mesmo ano. Em 2019, o registro prospectivo teve uma prevalência de 35/200 (18%) em contraste com 12/200 (6%) em 2009 (RR 2.91, 95% IC 1.56 a 5.45). Desfechos primários não ambíguos estiveram presentes em 60 ensaios clínicos em 2019. O registro adequado aconteceu em 15/200 (8%) da amostra de 2019, comparado com 5/200 (3%) em 2009 (RR 3.00, 95% IC 1.11 a 8.10). Em 2019, 44 ensaios clínicos (73%), de 60 que permitiram a avaliação, evidenciaram o reporte seletivo dos dados, contra 23/49 (47%) em 2009 (RR 1.56, 95% IC 1.12 a 2.18). **CONCLUSÃO:** O registro de ensaios clínicos de intervenções de fisioterapia aumentou na última década, mas ainda não é realizado de forma adequada. Sendo assim, os benefícios do registro dos ensaios clínicos ainda não estão sendo atingidos em sua totalidade. Estes dados indicam que ainda é necessário um esforço complementar para que os ensaios clínicos de intervenções de fisioterapia sejam realizados da forma correta.

Palavras-chave: Ensaio clínico. Fisioterapia. Metodologia. Avaliação da Pesquisa em Saúde.

ABSTRACT

OBJECTIVE: To investigate the completeness of clinical trial registration and the extent of selective reporting of outcomes in randomized trials of physical therapy interventions published in 2019 and to compare them with equivalent data from 2009. **METHODS:** A random sample of 200 randomized trials was obtained from the Physiotherapy Evidence Database (PEDro) platform. Data about registration were obtained from each of the randomized trials through their registered protocol and through direct contact with the authors and were compared with the data available from the published report. We evaluated the percentages of registered trials; of prospective registration (trials registered prior to the start of enrollment); unambiguous primary outcomes (definition and time point of assessment clearly defined in the registered protocol); adequate registration (prospective registration with an unambiguous primary outcome); inconsistency of outcomes (a mismatch between the published report and registered protocol); selective reporting of outcome (only registry entries with unambiguous outcomes are taken into account); whether clinical trials published in journals of higher impact factor had a higher prevalence of registries in contrast to the general sample; and which factors were associated with clinical trial registration. RESULTS: The proportion of clinical trials registered in 2019 was 126/200 (63%) versus 67/200 (34%) in 2009 (Relative Risk – RR 1.88, 95% CI 1.51 to 2.35). Randomized trials published in high-impact factor journals had a significantly higher prevalence of registration, 100% in 2019 (RR 1.58, 95% CI 1.42 to 1.76) than the general sample from the same year. In 2019, the prospective registry had a prevalence of 35/200 (18%) in contrast to 12/200 (6%) in 2009 (RR 2.91, 95% CI 1.56 to 5.45). Unambiguous primary outcomes were present in 60 clinical trials in 2019. Adequate registration occurred in 15/200 (8%) of the 2019 sample, compared to 5/200 (3%) in 2009 (RR 3.00, 95% CI 1.11 to 8.10). In 2019, 44 clinical trials (73%), out of 60 that allowed the evaluation, evidenced the selective reporting of data, against 23/49 (47%) in 2009 (RR 1.56, 95% CI 1.12 to 2.18). **CONCLUSION:** The registration of clinical trials of physical therapy interventions has increased in the last decade, but it is still not adequately performed. Therefore, the benefits of clinical trial registration are not yet being fully achieved. These data indicate that a complementary effort is still needed for clinical trials of physical therapy interventions to be performed correctly.

Keywords: Clinical trial. Physical therapy. Methodology. Health Research Evaluation.

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LISTA DE ABREVIATURAS E SIGLAS

C&WH	*continence and women's health*
CI	*confidence interval*
CONSORT	*Consolidated Standards of Reporting Trials*
CP	*cardiopulmonary*
E&OH	*ergonomics and occupational health*
ECA	Ensaio Clínico Randomizado
Ger	*gerontology*
ICMJE	*International Committee of Medical Journal Editors*
IQR	*interquartile range*
ISPJE	*International Society of Physiotherapy Journal Editors*
MEDLINE	*Medical Literature Analysis and Retrieval System Online*
Musc	*musculoskeletal*
N/A	*no applicable subdiscipline*
Neuro	*neurology*
OMS	Organização Mundial de Saúde
Onco	*oncology*
Ortho	*orthopedics*
Paeds	*paediatrics*
PBE	Prática Baseada em Evidências
PEDro	*Physiotherapy Evidence Database*
ReBEC	Registro Brasileiro de Ensaios Clínicos
SPIRIT	*Standard Protocolo Items Recomendations for Interventional trials*
Spor	*sports*

SUMÁRIO

PREFÁCIO

A presente dissertação foi elaborada e estruturada em três seções, de acordo com as normas estabelecidas pelo Programa de Pós-Graduação em Ciências da Reabilitação da Universidade Federal de Minas Gerais (UFMG). A primeira seção contém a introdução com a problematização, justificativa do estudo realizado e os objetivos da dissertação. A segunda seção apresenta o artigo científico correspondente ao estudo realizado, formatado segundo as normas do periódico Physical Therapy & Rehabilitation Journal (Fator de impacto Journal Citation Report 2021= 3.021). Na terceira seção estão expostas as considerações finais relacionadas aos resultados encontrados nesta dissertação. Em seguida, estão indicadas as referências bibliográficas, anexos, apêndices e mini currículo da autora.

1 INTRODUÇÃO

A prática baseada em evidências (PBE) é definida como a prática guiada por pesquisa clínica relevante e de alta qualidade, que leva em consideração as preferências do paciente e a experiência clínica do profissional de saúde[1]. No contexto clínico, onde o fisioterapeuta deve selecionar a intervenção mais adequada para o seu paciente, a pesquisa clínica de alta qualidade refere-se às evidências científicas provenientes dos ensaios clínicos aleatorizados (ECAs), e de suas respectivas revisões sistemáticas de alta qualidade metodológica[1,2]. Os ECAs são estudos prospectivos, no qual os participantes com uma determinada condição de saúde são alocados, de forma aleatória, em 2 ou mais grupos, com objetivo de avaliar o efeito de uma intervenção, ou a ausência dele, nos desfechos de interesse daquele estudo[2]. O ECA, portanto, é o delineamento de estudo mais adequado para avaliar a magnitude do fenômeno de causa-efeito das intervenções sobre os desfechos[3].

Para conduzir um ECA de alta qualidade metodológica, é necessário seguir etapas específicas, como o registro de seu protocolo, a execução do estudo de forma adequada e a preparação da publicação do estudo no formato de artigo científico[3]. O *Standard Protocol Items Recomendations for Interventional trials (SPIRIT)*[4,5]*,* o *Consolidated Standards of Reporting Trials* (CONSORT)[6] e para ECAs relacionados às intervenções de fisioterapia, a escala de avaliação metodológica desenvolvida pela *Physiotherapy Evidence Database* (PEDro), conhecida como Escala PEDro (veja mais em: pedro.org.au/english/resources/pedro-scale/), são ferramentas recomendadas que irão auxiliar os pesquisadores no planejamento, na execução do estudo e em como reportar, na publicação, todas as informações necessárias de forma clara, completa, transparente e com menor risco de viés.

O registro do protocolo do ensaio clínico é o ponto de partida para a sua condução, e ocorre por meio de seu cadastro gratuito em uma plataforma eletrônica de livre acesso[7]. Estes registros devem ser realizados de forma prospectiva, ou seja, registro do protocolo do estudo antes do início do recrutamento dos participantes, em plataformas públicas, como por exemplo, no Registro Brasileiro de Ensaios Clínicos (ReBEC), no *ClinicalTrials.gov e* no *Australian New Zealand Clinical Trials Registry*. A Organização Mundial de Saúde (OMS) possui atualmente uma plataforma[8], que

permite a visualização de protocolos de ensaios clínicos, conectada a uma rede de colaboração internacional que inclui diversos países.

O registro do ensaio clínico pode auxiliar na prevenção de condução duplicadas de ECAs, facilitar o voluntariamento de participantes e a localização, por autores de evidências sumarizadas como as revisões sistemáticas e diretrizes clínicas, de estudos conduzidos, além de facilitar o acesso à literatura cinzenta a quem interessar[9]. O preenchimento do protocolo de registro, de forma prospectiva, possui também um efeito educativo para o pesquisador, visto que por meio dele é possível que o pesquisador entenda de forma mais aprofundada quais são os principais passos para a execução de um ECA e quais os pontos-chave a serem seguidos[10].

A recomendação de se registrar o protocolo de um ensaio clínico se iniciou ainda no final do século XX. Segundo Moher[11], o primeiro ensaio clínico moderno[12] foi publicado em 1948, e o primeiro registro de um protocolo de ensaio clínico ocorreu 27 anos depois, em 1975[13]. A primeira recomendação sobre a importância do registro de protocolos de ensaios clínicos foi realizada em 1993[11], objetivando dar maior transparência ao processo de pesquisa clínica. Em 2005 o *International Committee of Medical Journal Editors* (ICMJE) publicou a recomendação mandatória do registro de ensaios clínicos[14], popularizando assim tal prática na área da saúde em geral. Além do mais, em 2008 a Declaração de Helsinque[15] descreve a necessidade do registro prospectivo para estudos clínicos realizados em humanos, caracterizando a ausência de registro como uma infração ética durante a execução de um estudo. A recomendação mandatória para registro prospectivo do protocolo de ECAs na área da fisioterapia se iniciou em 2013, após a copublicação do editorial liderado pela *International Society of Physiotherapy Journal Editors* (ISPJE)[7] em vários periódicos da área, esclarecendo para a comunidade científica fisioterapêutica a importância e os benefícios do registro prospectivo dos ensaios clínicos. A OMS atualizou recentemente para a versão 1.3.1[10] as principais informações que devem constar no registro de um ensaio clínico (Quadro 1).

O registro prospectivo pode evitar o viés de seleção de desfecho, também conhecido como viés de relato[16–18], que ocorre quando os autores, após a conclusão do estudo ou com o estudo já em andamento, selecionam de maneira arbitrária quais os desfechos pretendem publicar; ou decidem quais os desfechos serão considerados primários e secundários para a publicação do artigo. O viés de relato tem impacto não somente no ambiente acadêmico, mas também na prática clínica. Visto que os

ensaios clínicos funcionam como guias para a prática clínica, resultados de ECAs enviesados podem ter impacto em como os profissionais conduzem seus atendimentos[1], como por exemplo, ao crer em resultados positivos de desfechos primários que eram, inicialmente, secundários no projeto de pesquisa, desta forma, sem força estatística para as conclusões descritas pelos autores. Outro tipo de viés que pode ser influenciado pelo registro prospectivo é o viés de publicação, que pode ocorrer quando os autores decidem não publicar os resultados do estudo devido à direção ou significância do resultado encontrado[16,19,20]. Essa tendência de escolha arbitrária sobre quais desfechos publicar também pode ocorrer baseado no fato de que editores e outros atores associados às publicações tendem a dificultar ou impedir a publicação de resultados negativos ou neutros[20]. Os efeitos negativos do viés de publicação para a prática clínica estão relacionados ao desconhecimento de possíveis efeitos desfavoráveis ou inócuos de certas intervenções pela ausência de publicação desses resultados[1].

O registro prospectivo pode trazer outros benefícios, como promover maior transparência no processo de pesquisa e auxiliar editores de revistas e revisores a auditar os estudos submetidos para publicação[9,21]. Além da importância de fazer o registro do ensaio clínico de maneira prospectiva, a qualidade do que é registrado e a consistência entre as informações registradas e informações publicadas no artigo final[19,20,22] devem também ser colocadas em pauta.

Quadro 1. Síntese da Versão 1.3.1 da Série de Dados da Organização Mundial de Saúde

Variável	Detalhes
Identificação do Registro	• Número do registro e da aprovação do comitê de ética, data do registro, dados relacionados ao fomento
Fomento e contato	• Fonte de suporte monetário e material, patrocinadores (sujeitos, grupos ou organizações), primário e secundário • Contato para esclarecimentos científicos e/ou gerais
Detalhes do estudo	• Tipo de estudo (intervencional ou observacional) • Método de alocação, mascaramento, participação • Fase do estudo (quando aplicável) • Condição de saúde estudada • Intervenções (nome, descrição)

	• Desfecho(s) primário(s) (nome, métrica e período de avaliação)
	• Desfechos secundários
	• País de recrutamento
Participantes	• Critérios de inclusão e exclusão
	• Tamanho da amostra
Histórico do estudo	• Status de recrutamento
	• Status da aprovação no Comitê de Ética
Caráter ético	• Data de aprovação
	• Nome e detalhes de contato do Comitê de Ética

Fonte: OMS

Ao seguir o protocolo de registro, os autores demonstram um bom planejamento prévio do projeto de pesquisa e, nos casos em que isso não é possível, ao atualizar o protocolo de registro para as possíveis mudanças e seguir tais atualizações, os autores evidenciam uma maior transparência do processo de execução e reporte do projeto de pesquisa. Sendo assim, a fim de evitar os vieses previamente citados, o mais adequado é que o protocolo de registro tenha os desfechos adequadamente descritos e sem alterações em dados importantes[23]. Um desfecho descrito adequadamente é aquele que apresenta a definição da sua ferramenta de avaliação e do seu período de avaliação[19,22]. Quando atualizações nesses dados principais forem estritamente necessárias, que estas sejam justificadas. Desta forma, apenas registrar um ensaio clínico não é suficiente, é importante que a publicação esteja alinhada com as informações descritas no protocolo de registro.

Em 2013, Pinto e colaboradores[23] avaliaram uma amostra de 200 ECAs de fisioterapia, publicados em 2009, e observaram que 34% dessa amostra possuía registro. Quando os autores avaliaram especificamente os ensaios clínicos publicados em revistas de maior fator de impacto, a prevalência de registro observada foi de 75%, demonstrando que esse recorte específico da amostra não reflete a proporção geral de registros na fisioterapia. A baixa prevalência de registros de ensaios clínicos não é uma realidade apenas da área da fisioterapia. Por exemplo, a prevalência de registro de ECAs na área da saúde em geral varia entre 44% a 58%[24]; nos periódicos de medicina de urgência e emergência a prevalência é de 46%[25]; nos periódicos de enfermagem a prevalência é de 35%[26]; na área da ortodontia a prevalência chega a

16%[27]. Já em relação à local de condução, nos estudos conduzidos na América Latina e Caribe a prevalência de registro varia entre 19,8% e 59%[28,29]. Essas estimativas sugerem que a proporção de registros na fisioterapia é semelhante a outras áreas da saúde. Na amostra total de Pinto et al[23] apenas 2,5% dos artigos foram registrados de forma adequada (de forma prospectiva e com desfecho primário não-ambíguo, sendo desfecho não ambíguo aquele que possui descrição de sua ferramenta de avaliação e o período de avaliação), reforçando ainda mais a discussão sobre a importância da adequação dos registros. Além da baixa prevalência de adesão do registro dos ensaios clínicos entre autores, editores de periódicos[30] também podem apresentar dificuldade em perceber a importância do registro de ensaios clínicos, demonstrando assim a necessidade de conscientização não somente dos autores, mas também de outros atores envolvidos no processo de publicação.

Considerando que o último estudo realizado na área de fisioterapia incluiu uma amostra de artigos publicados em 2009 e indexados na PEDro[23], e que a recomendação mandatória do registro de ensaios clínicos pela ISPJE foi realizada em 2013[7], faz-se necessária uma avaliação atualizada da prevalência e qualidade dos registros realizados atualmente na fisioterapia. Desta forma será possível verificar-se a mudança ou não do quadro geral das publicações da área através da mensuração da influência da recomendação mandatória de se registrar ensaios clínicos na fisioterapia, e da avaliação de quais deficiências seus registros ainda apresentam. Portanto, a presente dissertação, seguindo a metodologia proposta em 2013 por Pinto e colaboradores[23], tem como objetivos investigar: (1) a proporção de ensaios clínicos randomizados na fisioterapia que são registrados, e entre eles, a proporção de registros realizados de forma adequada; (2) se a proporção de registros é maior entre os ensaios clínicos randomizados publicados em jornais com maior fator de impacto; (3) se existem características específicas que estão associadas ao registro dos ensaios clínicos; (4) a proporção de registros que foram feitos com descrição ambígua de desfechos primários; (5) se há discrepâncias entre a publicação e o registro em relação aos desfechos primários e não-primários; e (6) a proporção de ensaios clínicos randomizados registrados com evidência de reporte seletivo dos desfechos e se esse viés favorece resultados com significância estatística. Com o objetivo de avaliar se o registro de ensaios clínicos aumentou na fisioterapia após uma década, também foi comparada a proporção de ensaios clínicos de 2019 versus 2009 que foram:

registrados; registrados de forma prospectiva; registrados com descrição adequada do desfecho primário; e que demonstraram reporte seletivo dos desfechos.

2 ARTIGO

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CLINICAL TRIAL REGISTRATION HAS BECOME MORE PREVALENT IN PHYSICAL THERAPY BUT ITS QUALITY IS STILL INADEQUATE

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ABSTRACT

OBJECTIVE: To investigate the completeness of clinical trial registration and the extent of selective reporting of outcomes in randomized trials of physical therapy interventions published in 2019 and to compare these with equivalent (previously published) data from 2009. **METHODS:** A random sample of 200 trials was obtained from the Physiotherapy Evidence Database (PEDro). Evidence of registration was sought for each of these trials on clinical trial registers and by contacting authors. **RESULTS:** The proportion of randomized trials that were registered was 126/200 (63%) versus 67/200 (34%) in 2009 (Risk Relative (RR) 1.88, 95% CI 1.51 - 2.35). Trials published in high impact factor journals had a higher prevalence of registration, 100% in 2019 (RR 1.58, 95% CI 1.42 - 1.76) than in the general sample of the same year. Prospective registration had a prevalence of 35/200 (18%) in contrast with 12/200 (6%) in 2009 (RR 2.91, 95% CI 1.56 - 5.45). Unambiguous primary outcomes (ie, method and timepoints of measurement clearly defined in the trial registry entry) were registered for 60 trials. Registration was adequate (ie, prospective with unambiguous primary outcomes) for 15/200 (8%), compared with 5/200 (3%) in 2009 (RR 3.00, 95% CI 1.11 - 8.10). Selective outcome reporting occurred in 44 (73%) of the 60 trials in which it was assessable, in 2009 this proportion was 23/49 (47%) (RR 1.56, 95% CI 1.12 - 2.18). **CONCLUSION:** Registration of randomized trials in physical therapy interventions has increased in the past decade, but it is still not adequately performed. Therefore, the full benefits of trial registration are not being realized. **IMPACT:** These data indicate that more effort is still required by clinical trialists, reviewers and editors to implement and enforce adequate registration among randomized trials of physical therapy interventions.

INTRODUCTION

Randomized clinical trials are critical for clinical decision-making and are the best study design to inform clinicians about the effects of an intervention.[1,2] To ensure transparency in the conduct and reporting of clinical trials, clinical trial registration has been well advocated among health-related journals.[3,4] Registration of clinical trials was first discussed in 1993[5] but the International Committee of Medical Journals only developed a policy requiring mandatory clinical trial registration in 2005.[3] In the field of physical therapy, prospective registration of trials was first promoted in 2006,[6] and in 2013 several major physical therapy journals co-published a joint editorial led by the International Society of Physiotherapy Journal Editors (ISPJE) encouraging mandatory prospective pre-registration.[4]

Clinical trial registration is the practice of documenting the protocol of a planned clinical trial in a publicly available clinical trial register.[5] The registration of a trial must be prospective, meaning that registration should be completed prior to, or at the beginning of, patient enrollment.[3] Prospective clinical trial registration is an important defense against two common types of reporting bias: publication bias and selective outcome reporting bias.[7] Reporting bias refers broadly to differences in the dissemination of the trial's results depending on the nature and direction of results.[8,9] Publication bias is a form of reporting bias defined as the failure to publish a report of a study based on the direction or strength of the study findings[10,11] whereas selective outcome reporting bias occurs when a subset of the originally planned outcome variables is selectively chosen for publication based on their results.[12]

A previous study[13] conducted to determine the extent of clinical trial registration among MEDLINE-indexed member journals of the ISPJE found that registration increased from 4% in 2008 to 48% in 2012. Pinto et al.[14] assessed the prevalence and completeness of registration among a random sample of 200 physical therapy trials indexed on Physiotherapy Evidence Database (PEDro) in 2009 and found that 34% (67/200) were registered but only 2.5% (5/200) were prospectively registered with an unambiguous primary outcome (ie, including both a definition and timepoints of assessment). In addition, the prevalence of trial registration was higher among those journals with the highest impact factors.[14] However, both studies[13,14] were conducted prior to the publication of the joint editorial recommending prospective registration by several ISPJE members.[4]

Therefore, the objective of this study is to reexamine the completeness of registration and the extent of selective reporting in a sample of physical therapy trials indexed on PEDro, ten years after the original publication.[14] More specifically, we sought to determine: (1) the proportion of published randomized trials in physical therapy that are registered and, among these, the proportion that has adequate registration; (2) whether the proportion of registered trials is higher among randomized trials published in journals with higher impact factors; (3) whether there are specific trial characteristics associated with clinical trial registration; (4) the proportion of trial registry entries that registered unambiguous primary outcomes; (5) whether there are discrepancies between published reports and registry entries regarding primary and nonprimary outcomes; and (6) the proportion of registered randomized trials with selective outcome reporting bias and whether this bias favors statistically significant results. In order to investigate if registration of trials has improved in the field of physical therapy

in the past decade, using the data from the previously published manuscript in 2009,[14] we compared the proportion of trials in 2019 versus in 2009 that were registered, were prospectively registered, were registered with an unambiguous primary outcome, and showed selective outcome reporting.[14]

METHODS

Study selection

Published reports were eligible if they described a randomized trial published in 2019 and were indexed on the Physiotherapy Evidence Database (PEDro). Randomized clinical trials described as a pilot, parallel, crossover, or secondary analysis of the original randomized trial were all considered eligible. We excluded trial reports in languages other than English, Portuguese, or Spanish, and those trial reports published ahead of print in 2019. We downloaded data for all trials indexed in PEDro published in 2019, and randomly selected 200 trial reports using the random number function in Microsoft Excel software (Microsoft Excel®, 2010, Microsoft Corporation, Redmond, Washington). Trials that did not meet the inclusion criteria, initially or found to be inappropriate during screening, were excluded and replaced by the subsequent trial on the list.

Citation details and the available information on the PEDro database, such as the PEDro score of methodological quality and PEDro codes for subdiscipline, were also downloaded. As these data have been verified by the PEDro team, by at least two independent assessors, we felt confident using these data. For subdiscipline codes,

there are 11 possible categories in the PEDro database (further details for each category are available at http://www.pedro.org.au/english/downloads/codes/). Each trial report can be assigned more than one subdiscipline. In these cases, one investigator was responsible for deciding the most appropriate subdiscipline.

Full-text copies of each trial report were retrieved. One investigator extracted the following data from each trial report: sample size (defined as the number of participants initially randomized), the country where the trial was conducted, whether the trial was funded, and whether the trial was single-centered or multi-centered. For each trial report, we also downloaded the 2019 impact factor of its publishing journal.[15] Based on the ISPJE journal members' list (available at https://ispje.org/), we classified each trial report as published or not in a specific physical therapy journal.

We searched for the registration number or other details included in the trial reports. If we did not find any registration details in the trial report, we requested this information from the corresponding author by email. If the corresponding author did not reply, a reminder e-mail was sent after two weeks. If no response was received, corresponding authors were deemed uncontactable and we searched the national register of the country of origin of each author and the three main registries that contain protocols from various countries: ClinicalTrials.gov, the International Standard Randomized Controlled Trial Number Register (ISRCTN), and the Australian New Zealand Clinical Trials Register (ANZCTR). This search was aided by the World Health Organization (WHO) registry search portal. If found through additional searches the investigator compared the citation details of the published report within each registry entry, including the publication title; any funding sources; and the first, second and last

authors, to ensure the registry entry was linked to the published report. If no evidence of registration was found using the above strategy, the trial was considered unregistered. Published reports describing the secondary analysis of the original randomized trial were excluded from the remaining analyses because we expect differences in the outcomes reported in the trial report and registry entry.

Adequacy of registration

Two independent investigators reviewed the trial registry entry, its history of amendments, and the published trial report. We extracted the following information: registration date, the enrollment period, the primary outcome(s), other outcomes, and definition of each outcome including its timepoint of assessment, and statistical analysis if available. When available, key data were extracted from the last registry entry amendment prior to the date of the first enrolled participant. An "outcome" was defined as the variable monitored during the trial to document the effectiveness or harm of an intervention compared to the comparison intervention(s). An outcome was considered primary in the registry entry or published trial report if it was explicitly described as “main”, “primary” or “key” or - in the absence of those three descriptors - if it was used to calculate sample size in the published report. All other outcomes were considered nonprimary. In the absence of a clear primary outcome, all outcomes were considered nonprimary. Disagreements between investigators were resolved through discussion; if consensus was not reached, a third investigator was consulted.

The registered trials were classified as having prospective, concurrent, or retrospective registration by comparing the registration date (i.e., the date on which the trial record

was first available on the register) and the start and end dates of enrollment. Prospective registration was defined as a trial registration performed prior to the start of enrollment. Concurrent registration was defined as trial registration that occurred while participants were being recruited or during data collection. Retrospective registration was defined as registration that occurred when data collection was complete. Clinical trials were also classified as having an adequate registration when there was prospective registration with unambiguous primary outcome(s).[14,16] Primary outcomes were classified as unambiguous if the definition and the timepoint of the analysis were clearly stated in the registry entry.[17] For example, "disability" would be ambiguous on both criteria, whereas "disability measured using the Roland Morris disability questionnaire after 12 weeks" would be unambiguous.

To determine whether trials published in higher impact journals had a higher proportion of registration, we ordered the trials according to the 2019 impact factor of their publishing journals.[15] Following this, the highest 10% of impact factors in this list were selected, and the proportion of trials that were registered was calculated. This proportion was compared with the proportion of the remaining trials.

Inconsistency of outcomes

The criteria established by Chan et al.[18] and modified by Mathieu et al.[16] were used to classify the discrepancies between the published trial report and registry entry. These criteria were: (1) the registered primary outcome was reported as nonprimary in the published trial report, (2) the registered primary outcome was omitted in the published trial report, (3) a new primary outcome was introduced in the published trial report (for

example a nonprimary outcome became a primary outcome in the publication, or an outcome that was not registered became a primary outcome in the published trial report), (4) the primary outcome described in the published trial report was considered a nonprimary outcome in the registry entry, and (5) there are differences in the timepoint of assessment for the primary outcome between the registry entry and the published trial report. Nonprimary outcomes were considered inconsistent when the nonprimary outcomes listed in the registry entry did not match with those listed in the published trial. Two independent investigators also determined whether trials had inconsistent primary outcomes by comparing the most recent registry entry including the amendments performed before the enrollment start with the published report. Disagreements between investigators were resolved through discussion. A third investigator was consulted if consensus was not reached.

Selective reporting of outcomes

We assessed the presence of selective reporting of outcomes in the subset of trials that had unambiguous primary outcomes. Selective reporting of outcomes was present when at least one of the five discrepancies described above was present. When selective reporting of outcomes was identified, two investigators determined if this could be as a result of selecting outcomes based on attaining statistical significance of the primary outcome.

Data synthesis and analyses

To summarize the characteristics of all included trials we used frequency and percentage and median and interquartile range (IQR) due to data distribution. Statistical Package for Social Science (IBM Corp. Released 2011. IBM SPSS Statistics® for Windows, Version 20.0. Armonk, NY: IBM Corp) and Microsoft Excel software (Microsoft Excel®, 2010, Microsoft Corporation, Redmond, Washington) were used for statistical analyses. We planned to use unpaired T-test or Mann-Whitney U test to compare the PEDro scores and sample sizes between registered and unregistered trials. Results were reported as differences in medians with 95% confidence intervals (CI). To calculate 95% CI for median between-group differences, we used the Hodges-Lehman estimator. The associations between trial characteristics (continent, funding, number of sites, and impact factor of the publishing journal) and registration were assessed using relative risk (RR) with 95% CI. To compare 2009 study data[14] with data collected in 2019 we used RR with 95% CI. We also recorded the registers used and the number and percentage of registered trials in each register.

Role of funding source

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RESULTS

The search was conducted on August 3rd, 2020. On this date, there were 2180 randomized trials indexed in PEDro and published in 2019. Of these 2180, 2055 were published in English (n = 2043), Portuguese (n = 5), or Spanish (n = 7). Among these, we randomly selected 200 trial reports (appendix). Figure 1 shows that the random sample of 200 reports selected was similar to the 2055 eligible trial reports published in 2019, in terms of subdiscipline and PEDro score.

Regarding clinical trial registration, our findings showed that 126 (63%) trial reports were registered (Figure 2). Of these, 99 (79%) stated their registry number in the published trial report. The registry number for the remaining trials were found by contacting authors (n = 15, 12%) or hand-searching trial registries (n = 12, 10%).

Table 1 shows the characteristics of all randomized trials, stratified by registered and unregistered trials. The median (IQR) sample size was 60 (37 - 104) for the registered randomized trials and 43 (24 - 61) for the unregistered randomized trials (median difference 16, 95% CI 7 - 26). The median (IQR) PEDro score was 6 (5 - 7) for registered trials, and 5 (4 - 6) for unregistered trials (median difference 1, 95% CI 1 - 2). Figure 3 shows the relative risk of registration in trials: a) from different continents, b) with versus without funding, and c) with single versus multiple sites.

Among the 126 registered randomized trials, 65% (n = 82) were registered with ClinicalTrials.gov. The other registers used were the Australian New Zealand Clinical Trials Registry (n = 10, 8%), the International Standard Randomized Controlled Trial

(n = 7, 6%), the Brazilian Clinical Trials Registry (n = 6, 5%), the Iranian Registry of Clinical Trials (n = 5, 4%), the Chinese Clinical Trial Registry (n = 5, 4%), the Clinical Research Information Service (n = 4, 3%), the Thai Clinical Trials Registry (n = 3, 2%) the German Clinical Trials Register (n = 1, 1%), the Netherlands Trial Register (n = 1, 1%), the Pan-African Clinical Trials Registry (n = 1, 1%), and the University Hospital Medical Information Network Clinical Trials Registry (n = 1, 1%).

The publishing journal had an impact factor for 146 of the trials and had no impact factor for 54 trials. The trials published in a journal with an impact factor had a median (IQR) impact factor of 2.5 (1.8 - 3.2). Among the top 10% of these ranking reports, the median (IQR) impact factor was 5.4 (4.4 - 12.0). While all trials in the top-ranked journals were registered, the prevalence of registration among the remaining trials was 63% (RR 1.58, 95% CI 1.42 - 1.76).

Of the 126 published reports of registered trials, 19 were reports of secondary analysis of the trial (Figure 2). Without these nineteen trials, 107 trials were included in the analyses of the adequacy of registration, inconsistency of outcomes, and selective outcome reporting (Table 2).

Adequacy of registration

Among the 200 randomized trials assessed, 35 (18%) had been registered prospectively (Table 2). Of these thirty-five prospectively registered trials, 15 (43%) reported their primary outcome unambiguously (ie, including both a definition and timepoints of assessment). The proportions of trial registry entries that defined the

primary outcome, their method of analysis, and the timepoints of assessment are shown in Table 2. Fifteen randomized trials could be considered adequately registered (ie, prospectively registered, with an unambiguous primary outcome) and represented 7.5% of the total sample of 200 published trial reports.

Inconsistency of outcomes

The registry entry was compared with the published report to analyze the consistency in reporting of outcomes. Among the primary outcome discrepancies, at least one discrepancy was found in 82 registered trials (77%). Table 2 presents the number and percentage of trials in each category of discrepancy. Of the total 107 registered trials, 95 (89%) trials had some difference with regards to the nonprimary outcome(s) between the trial registry entry and published report, and 100 (93%) presented evidence of inconsistency in any outcome when registry and published report were compared (Table 2).

Selective reporting of outcomes

Among the 107 registered trials, the primary outcome was not clearly defined in 47 (44%) published trial reports (Table 2). The remaining 60 registered published trial reports, which defined the primary outcome, were used in the analysis of selective outcome reporting bias in relation to the primary outcome. Of the 60 trials assessed, 44 (73%) showed evidence of selective reporting. Among these 44 trial reports, 3 (5%) introduced a new outcome in the published trial report that was not mentioned in the registry entry or had a registered primary outcome that was not reported at all in the

published trial report. We were unable to assess the statistical significance impact among these 3 trials. In contrast, 9 trial reports (22%) out of the remaining 41 registered trials showed evidence of selective outcome reporting that favored statistical significance: six trials (15%) had a primary registered outcome that was published as a secondary outcome and it did not show a statistically significant result; two trials (5%) had their registered secondary outcome published as a primary outcome when it showed a statistically significant difference in favor of the intervention group, and one trial (2%) used both strategies**.**

Comparison with 2009 study data[14]

Table 3 shows the registration data in 2009[14] and 2019. Trials published in 2019 were 1.88 times (95% CI 1.51 - 2.35) more likely to be registered than trials published in 2009. Regarding prospective and adequate registration, trials published in 2019 were 2.92 times (95% CI 1.56 - 5.45) more likely to be prospectively registered and 3.00 times (95% CI 1.11 - 8.10) more likely to be adequately registered than in 2009. Trials published in 2019 were 1.56 times (95% CI 1.12 - 2.18) more likely to show evidence of selective outcome reporting than in 2009.

DISCUSSION

Our findings showed that the percentage of trials in our 2019 sample that were registered was 63% (126/200), which is 1.88 times higher than in 2009, with a confidence interval that showed an improvement of at least 51% relative to 2009 (95% CI 1.51 - 2.35).[14] This improvement can be considered important progress in clinical

trial registration in physical therapy over a 10-year period. In addition, prospective registration has also increased. Trials published in 2019 were almost 3 times more likely to be prospectively registered than in 2009 (RR 2.92, 95% CI 1.56 - 5.45).[14] The lower limit of the CI suggests that there was an increase of at least 56% in the prevalence of prospective registration in 2019 compared to 2009, meaning that awareness of the importance of trial registration prior to the start of enrollment has been raised among trialists. Mandatory recommendation to prospectively register randomized trials among physical therapy journals started in 2013.[4] Although 86% of trials included in our sample were registered after 2013 (Table 2), nearly 40% of our sample were not registered. This finding suggests that despite the increase in trial registration and prospective registration, there is still room for improvement.

Trials published in 2019 were nearly 3 times more likely to be adequately registered (i.e., prospectively registered with an unambiguous primary outcome), than in 2009 (RR 95% CI 1.11 - 8.10). The wide CI indicates greater uncertainty regarding adequate registration. Although the upper limit suggests that trials in 2019 were 8 times more likely to be adequately registered than in 2009, the lower limit indicates that the true increase over the last decade in adequate registration may be only 11% which may be considered a trivial increase.

Inconsistencies were also found among primary and nonprimary outcomes. Nearly 8 in 10, and 9 in 10 registered trials reported inconsistencies in primary and nonprimary outcome(s), respectively, between the trial registry entry and published report. Our results show evidence that trial registration is increasing and so is prospective registration but the quality of registration, particularly concerning completeness of

information for primary and nonprimary outcomes, is still suboptimal. We would argue action is required to ensure trialists have accurately registered all the necessary information about the primary and nonprimary outcomes before commencing a trial. Registered information should include the instruments/scales used to measure the outcomes as well as the time point of assessment (e.g., disability measured using the Roland Morris disability questionnaire after 12 weeks).

An important premise of clinical trial registration is that, once the outcomes are registered, trialists should strictly report in the published report the primary and nonprimary outcomes according to how they were registered in the protocol. In the present study, we also assessed selective outcome reporting among trials that described their primary outcome unambiguously. Our results showed that 73% of these trials (44/60) showed evidence of selective outcome reporting in 2019. This proportion is higher than trials published in 2009 (23/49)[14] (RR = 1.5, 95% CI 1.1 - 2.2). Although the CI shows uncertainty about the magnitude of the increase, selective reporting of outcomes is clearly still an issue despite the increase in registration. This finding suggests that authors are failing to follow their own registered protocols. Interestingly, the presence of selective outcome reporting seems unrelated to the statistical significance of the primary outcome, since it has decreased from 50% (9/18) in 2009[14] to 22% (9/41) in 2019. It suggests that these discrepancies might be occurring unintentionally because trialists have not realized the importance of following the registered protocol. This suggests that trialists require education on the reasons for complete registration and the threats to trial validity / potential biases if outcomes are switched.

Journals with higher impact factors were more likely to publish trials that are registered, in comparison with the general sample (RR 1.58, 95% CI 1.42 - 1.76). The narrow CI shows a consistently higher prevalence of registration among trials published in higher impact factor journals than in general journals. Using the data from Pinto et al,[14] the prevalence of registration in trials published in high impact factors also increased from 75% in 2009[14] to 100% in 2019. This finding is presumably influenced by the fact that 100% of these high-impact journals demand registration and 70% of them require prospective registration. Similarly, previous studies reported registration rates above 82% for trials published in high-impact medical journals.[19,20]

Furthermore, our results demonstrated that trials with larger samples and with higher PEDro scores are more likely to be registered. These findings together with the finding of 100% of registration in trials published in high-impact journals, suggest that recommendations about registration may only be reaching those authors who are aware of contemporary methods to conduct high-quality trials.[21] Also, a greater prevalence of trial registration was observed in randomized trials conducted in Oceania than in Europe, North America, and South and Central America, and Africa, in that order, showing that trial registration in physical therapy varies widely across continents, as reported by Pinto et al[14] in 2009. A more effective strategy is needed to raise awareness of prospective trial registration and quality of registration among physical therapy trialists across the globe.

We also evaluated whether methods of statistical analysis for the primary outcome were described in the registry entry. We found that in 12/107 (11%) registry entries stated how the statistical analysis would be conducted. In 2009, 8/62 (13%) registry

entries reported how the statistical analysis would be conducted.[14] The WHO trial registration data set does not include methods of statistical analysis as part of the minimum amount of trial information that must be registered.[22] Pre-specifying a statistical analysis plan in registry entries seems to be an uncommon practice in physical therapy trials. Even in trials published in high impact factor general medicine journals,[20] only 7% of the trials included an *a priori* version of the statistical analysis plan. Publication of statistical analysis plan, or simply describing the statistical analysis in the registry entry, would contribute to improve reporting transparency and research integrity by preventing selective outcome reporting.[23]

Efforts to raise awareness about trial registration among researchers and journal editors are still required. Authors should receive training on how to register their trials prospectively with unambiguous outcomes and justify any change made to the original protocol. Clinical trial registry platforms could design their forms to prevent an ambiguous description of important registry data or provide feedback to trialists during registration to ensure, for instance, that the necessary information about primary and nonprimary outcomes is adequately registered. Ethics review committees might require, as a final step, evidence of prospective registration with an adequate description of outcomes to approve a research project. Aiming to encourage authors to follow the methods listed in the registry entry and decrease outcome discrepancy, journal editors and reviewers should compare submitted manuscripts with registry entries and raise any discrepancies with authors between the registry entry and the submitted trial, to better understand the study's research context and updates. Although changes related to outcomes may occur after trial registration, journal editors and reviewers may advise authors to follow the CONSORT statement (i.e., item 6b –

Any changes to trial outcomes after the trial commenced, with reasons) and identify any deviation of the protocol in the published report. Ultimately, trials that are prospectively and adequately registered should be preferred by all stakeholders, including readers and journals.

The ISPJE should continue to reinforce the benefits of prospective trial registration[4] and promote forums to discuss clinical trial registration among its members because not all journal members are adhering to the prospective registration policy.[23] Given that our findings revealed issues related to the quality of registration, an updated recommendation targeting the importance of providing a clear definition of primary and nonprimary outcomes including the timepoint of assessment when registering the trial may help to improve the quality of registration.

We believe that the 63% prevalence of trial registration in our study is an accurate estimate of prevalence among published randomized trials in physical therapy because we have a large and random sample of trials indexed on PEDro, a database that indexes randomized trials of physical therapy interventions regardless of whether they are registered, the journal in which they are published, the electronic database they are indexed or their methodological quality.[24] Furthermore, the subdiscipline and PEDro score in the sample was representative of the total trials, which allows transferability of our overall estimates to all trials published in 2019 and indexed on PEDro. The sample is also representative as it is not skewed towards particular publishing journals (for example, journals with high impact factors only). Four percent of trials published and indexed on PEDro in 2019 were non-English. Although we planned to analyze any randomly sampled trials that were published in Spanish and

Portuguese, the randomization process did not retrieve reports written in these two languages.

Our results suggest that prospective trial registration has increased over the last decade, however, the quality of registration is still suboptimal. The mandatory recommendation by the ISPJE in 2013 together with prospective registration policy adopted by some ISPJE journal members has made some progress in the field of physical therapy. Nevertheless, the quality of registration, particularly concerning completeness of information for primary and non-primary outcomes and selective outcome reporting, should be reinforced. Authors should be aware that registration per se is not sufficient. Trials should be registered prospectively (i.e., before data collection begins) and changes after registration should ideally not occur and not involve the outcomes of the trial but if needed should be well justified in the published report. We would argue that policy about clinical trial registration should come from journal editors, funding agencies, and societies such as ISPJE.

Authorship and contributorship

Ms Silva, Dr Elkins, Dr Pinto, Dr Franco, Dr Stubbs and Dr Lemes provided concept/idea/reserch design. Ms Silva, Dr Pinto, Dr Stubbs and Dr Elkins provided data analysis and interpretation of data. Dr Elkins, Dr Franco, Dr Stubbs, Dr Pinto, Dr Lemes, and Ms Silva provided data collection. Dr Franco, Ms Silva, Dr Elkins, Dr Pinto, Dr Lemes and Dr Stubbs provided writing. Dr Stubbs, Dr Lemes, Dr Pinto, Dr Franco, Ms Silva and Dr Elkins provided consultation (including review of manuscript before submission). Dr Elkins, Ms Silva, Dr Franco, Dr Pinto, Dr Stubbs and Dr Lemes agreed

to be accountable for all aspects of the work in ensuring that questions related to the accuracy or integrity of any part of the work are appropriately investigated and resolved.

Conflict of interest

Conflict of Interest: none declared.

REFERENCES

1. Herbert RD, Jamtvedt G, Mead J et al. *Practical Evidence-Based Physiotherapy*. Vol 2. Elsevier Butterworth Heinemann; 2010.
2. Hariton E, Locascio JJ, Hospital MG. Randomised controlled trials—the gold standard for effectiveness research. *BJOG*. 2018;125(13):1-4. doi:10.1111/1471-0528.15199.Randomised
3. De Angelis C, Drazen JM, Frizelle FA, et al. Is this clinical trial fully registered? A statement from the International Committee of Medical Journal Editors. *N Engl J Med*. 2005;352:2436-2438.
4. Costa LOP, Lin CWC, Grossi DB, et al. Clinical trial registration in physiotherapy journals: Recommendations from the International Society of Physiotherapy Journal Editors. *Eur J Physiother*. 2013;15(2):42-45. doi:10.3109/21679169.2013.802476
5. Moher D. Clinical-trial registration: a cal its implementation in Canada. *Can Med Assoc J*. 1993;149(11):1657-1658.
6. Askie L, Ghersi D, Simes J. Prospective registration of clinical trials. *Aust J Physiother*. 2006;52(4):237-239. doi:10.1016/S0004-9514(06)70002-2
7. Jones CW, Keil LG, Holland WC, Caughey MC, Platts-mills TF. Comparison of registered and published outcomes in randomized controlled trials : a systematic review. *BMC Med*. Published online 2015. doi:10.1186/s12916-015-0520-3
8. Dwan K, Gamble C, Williamson PR, Kirkham JJ, Bias R. Systematic Review of the Empirical Evidence of Study Publication Bias and Outcome Reporting Bias — An Updated Review. *PLoS One*. 2013;8(7):1-37. doi:10.1371/journal.pone.0066844
9. Dwan K, Altman DG, Arnaiz JA, et al. Systematic Review of the Empirical Evidence of Study Publication Bias and Outcome Reporting Bias. *PLoS One*. 2008;3(8):1-31. doi:10.1371/journal.pone.0003081
10. Devito NJ, Goldacre B. Catalogue of bias: Publication bias. *BMJ Evidence-Based Med*. 2019;24(2):53-54. doi:10.1136/bmjebm-2018-111107

11. Hopewell S, Loudon K, Clarke MJ, Oxman AD, Dickersin K. Publication bias in clinical trials due to statistical significance or direction of trial results. *Cochrane Database Syst Rev*. 2009;(1). doi:10.1002/14651858.MR000006.pub3

12. Hutton JL, Williamson PR. Bias in Meta-Analysis Due to Outcome Variable Selection within Studies. *Journal, Source Stat R Ser Soc Stat C Appl*. 2000;49(3):359-370.

13. Babu AS, Veluswamy SK, Rao PT, Maiya AG. Clinical Trial Registration in Physical Therapy Journals: A Cross-Sectional Study. *Phys Ther*. 2014;94(1):83-90. doi:10.2522/ptj.20120531

14. Pinto RZ, Elkins MR, Moseley AM, et al. Many Randomized Trials of Physical Therapy Interventions Are Not Adequately Registered: A Survey of 200 Published Trials. *Phys Ther*. 2013;93(3):299-309. doi:10.2522/ptj.20120206

15. Clarivate. Journal Citation Reports 2019. Accessed August 20, 2020. https://clarivate.com/webofsciencegroup/wp-content/uploads/sites/2/dlm_uploads/2019/08/JCR_Full_Journal_list140619.pdf

16. Mathieu S, Moher D, Altman DG. Comparison of Registered and Published Primary Outcomes in Randomized Controlled Trials. *JAMA - J Am Med Assoc*. 2009;302(9):977-984.

17. Zarin DA, Tse T, Williams RJ, Califf RM, Ide NC. The ClinicalTrials.gov results database - Update and key issues. *N Engl J Med*. 2011;364(9):852-860. doi:10.1056/NEJMsa1012065

18. Chan AW, Hróbjartsson A, Haahr MT, Gøtzsche PC, Altman DG. Empirical evidence for selective reporting of outcomes in randomized trials: Comparison of protocols to published articles. *J Am Med Assoc*. 2004;291(20):2457-2465. doi:10.1001/jama.291.20.2457

19. Walker KF, Stevenson G, Thornton JG. Discrepancies between registration and publication of randomised controlled trials: an observational study. *JRSM Open*. 2014;5(5):1-4. doi:10.1177/2042533313517688

20. Spence OM, Hong K, Uba RO, Doshi P. Availability of study protocols for randomized trials published in high-impact medical journals: A cross-sectional analysis. *Clin Trials*. 2020;17(1):99-105. doi:10.1177/1740774519868310

21. Al-durra M, Nolan RP, Seto E, Cafazzo JA. Prospective registration and reporting of trial number in randomised clinical trials : global cross sectional study of the adoption of ICMJE and Declaration of Helsinki recommendations. *BMJ*. 2020;369:1-12. doi:10.1136/bmj.m982

22. World Health Organization. WHO Trial Registration Data Set (Version 1.3.1). Accessed October 28, 2021. https://www.who.int/clinical-trials-registry-platform/network/who-data-set

23. Riley SP, Swanson BT, Shaffer SM, Sawyer SF, Cleland JA. The Unknown Prevalence of Postrandomization Bias in 15 Physical Therapy Journals: A Methods Review. *J Orthop Sport Phys Ther*. 2021;51(11):542-550. doi:10.2519/jospt.2021.10491

24. Moseley AM, Elkins MR, Herbert RD, Maher CG, Sherrington C. Cochrane reviews used more rigorous methods than non-Cochrane reviews : survey of systematic reviews in physiotherapy. *J Clin Epidemiol*. 2009;62(10):1021-1030. doi:10.1016/j.jclinepi.2008.09.018

TABLES

Table 1. Characteristics of all randomized trials (n = 200), unregistered randomized trials (n = 74), and registered randomized trials (n = 126).

Characteristic	All Trials, n (%)	Unregistered Trials, n (%)	Registered Trials, n (%)
Continent			
Asia	56 (28)	34 (46)	22 (18)
Africa	8 (4)	5 (7)	3 (2)
Europe	56 (28)	13 (17)	43 (34)
North America	49 (25)	14 (19)	35 (28)
Oceania	10 (5)	1 (1)	9 (7)
South and Central America	21 (10)	7 (10)	14 (11)
No. of participants recruited			
≤25	34 (17)	21 (28)	13 (10)
26 - 50	71 (36)	27 (37)	44 (35)
51 - 100	53 (26)	17 (23)	36 (29)
101 - 499	37 (18)	9 (12)	28 (22)
≥500	5 (3)	0 (0)	5 (4)
Subdiscipline[a]			
Cardiothoracics	25 (13)	7 (10)	18 (14)
Continence and women's health	14 (7)	5 (7)	9 (7)
Ergonomics and occupational health	2 (1)	1 (1)	1 (1)
Gerontology	28 (14)	12 (16)	16 (13)
Musculoskeletal	35 (18)	11 (15)	24 (19)
Neurology	27 (14)	8 (11)	19 (15)
Oncology	10 (5)	3 (4)	7 (6)
Orthopedics	5 (2)	0 (0)	5 (4)
Pediatrics	21 (10)	9 (12)	12 (9)
Sports	10 (5)	9 (12)	1 (1)
No applicable subdiscipline	23 (11)	9 (12)	14 (11)
Publishing journal			
Physical therapy-specific journals[b]	15 (8)	6 (8)	9 (7)
Journal's impact factor			
≤1	7 (4)	5 (7)	2 (2)
>1 to ≤2	39 (19)	19 (26)	20 (16)
>2 to ≤5	91 (46)	20 (27)	71 (56)
>5 to ≤10	3 (1)	0 (0)	3 (2)
>10	6 (3)	0 (0)	6 (5)
No impact factor	54 (27)	30 (40)	24 (19)

[a]Subdiscipline categories were all based on Physiotherapy Evidence Database (PEDro) indexing codes. [b]International Society of Physiotherapy Journal Editors (ISPJE) member journals were considered physical therapy-specific journals.

Table 2. Characteristics of the registered randomized trials in the study cohort that reported the primary analysis (n = 107).

Characteristic	Trials n (%)
Registration	
Prospective	35 (33)
Concurrent	40 (37)
Retrospective	32 (30)
Year of registration	
2008	2 (2)
2009	0 (0)
2010	2 (2)
2011	4 (4)
2012	7 (6)
2013	7 (6)
2014	11 (10)
2015	16 (15)
2016	22 (21)
2017	20 (19)
2018	13 (12)
2019	3 (3)
Primary outcome characteristics specified in the trial registry entry	
Definition	65 (61)
Analysis method	8 (7)
Timepoints of assessment	93 (87)
Registry entry with unambiguous primary outcome	60 (56)
Prospective trial registry entry with unambiguous primary outcome	15 (14)
Published trial that did not explicitly define the primary outcomes	47 (44)
Inconsistency in the primary outcome between registry entry and published trial report	
A registered primary outcome was nonprimary in the published trial report	38 (36)
A registered primary outcome was omitted in the published trial report	21 (20)
A new primary outcome was introduced in the published trial report	32 (30)
A published primary outcome was nonprimary in the protocol	9 (8)
Registry entry and published report differ in assessment time for a primary outcome	43 (40)
At least one of the criteria above	82 (77)
Inconsistency in nonprimary outcomes between registry entry and published trial report	95 (89)
Inconsistency in any outcome between registry entry and published trial report	100 (93)

Table 3. Comparison of registration data between 2009[14] and 2019.

	2009	**2019**
Trial registration	67 / 200	126 / 200
Prospective registration	12 / 200	35 / 200

FIGURE LEGENDS

Figure 1. Graphs A and B show the representativeness of the sample of 200 published reports used in this study based upon the subdiscipline of physical therapy and the Physiotherapy Evidence Database (PEDro) score. The orange bars represent the sample of 200 randomly sampled trials, and the blue bars represent the 2055 trials indexed in PEDro with the publication year of 2019 and published in English, Portuguese, or Spanish. (A) Percentage of trials coded in each PEDro subdiscipline. (B) Percentage of trials rated with each possible total PEDro score.

Figure 2. Flowchart of randomized trial report selection and assessment of registration status. PEDro= Physiotherapy Evidence Database

Figure 3. Factors potentially associated with trial registration (Relative risk and 95% confidence interval [95%CI]). Dashed lines indicate the reference group used in the relative risk analysis. Results with a relative risk greater than 1 indicate a greater likelihood of registration compared with the reference category.

FIGURES

Figure 1.

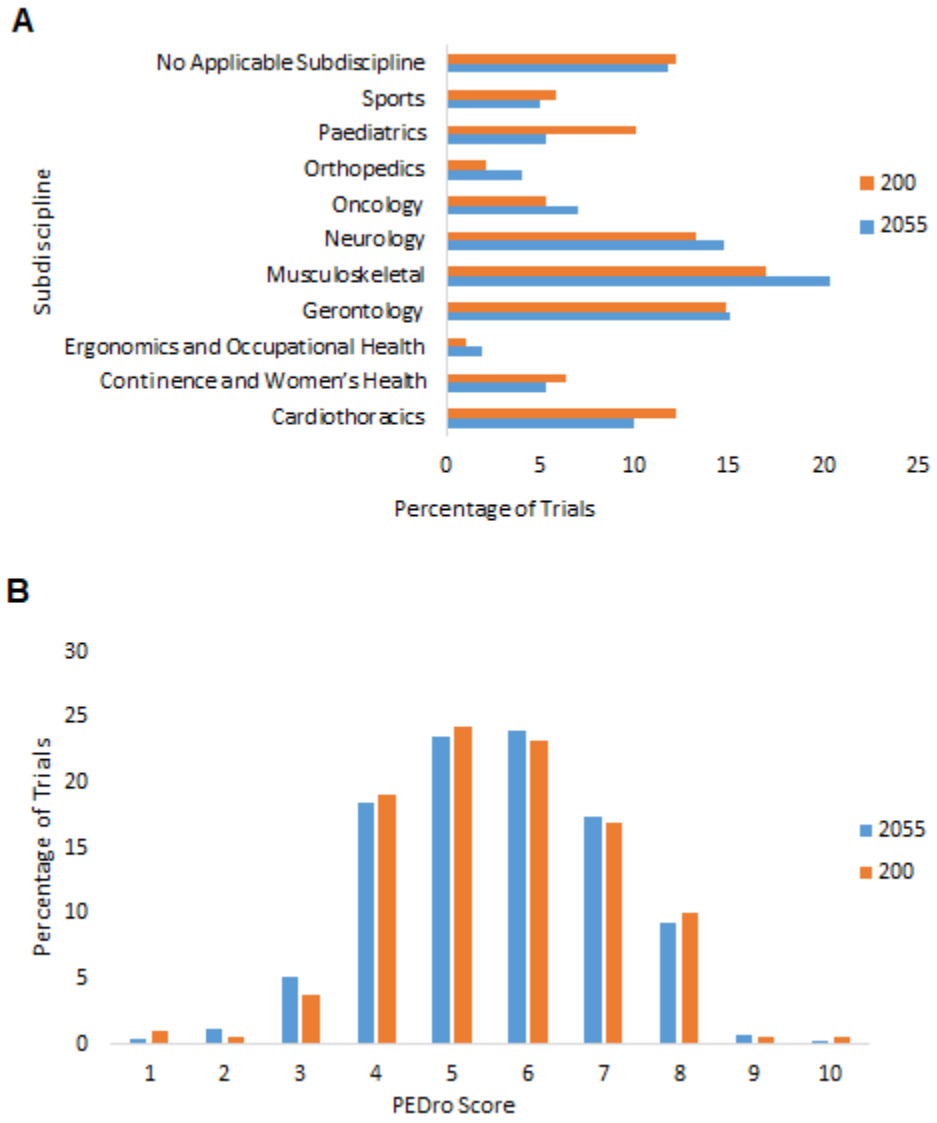


Figure 2.

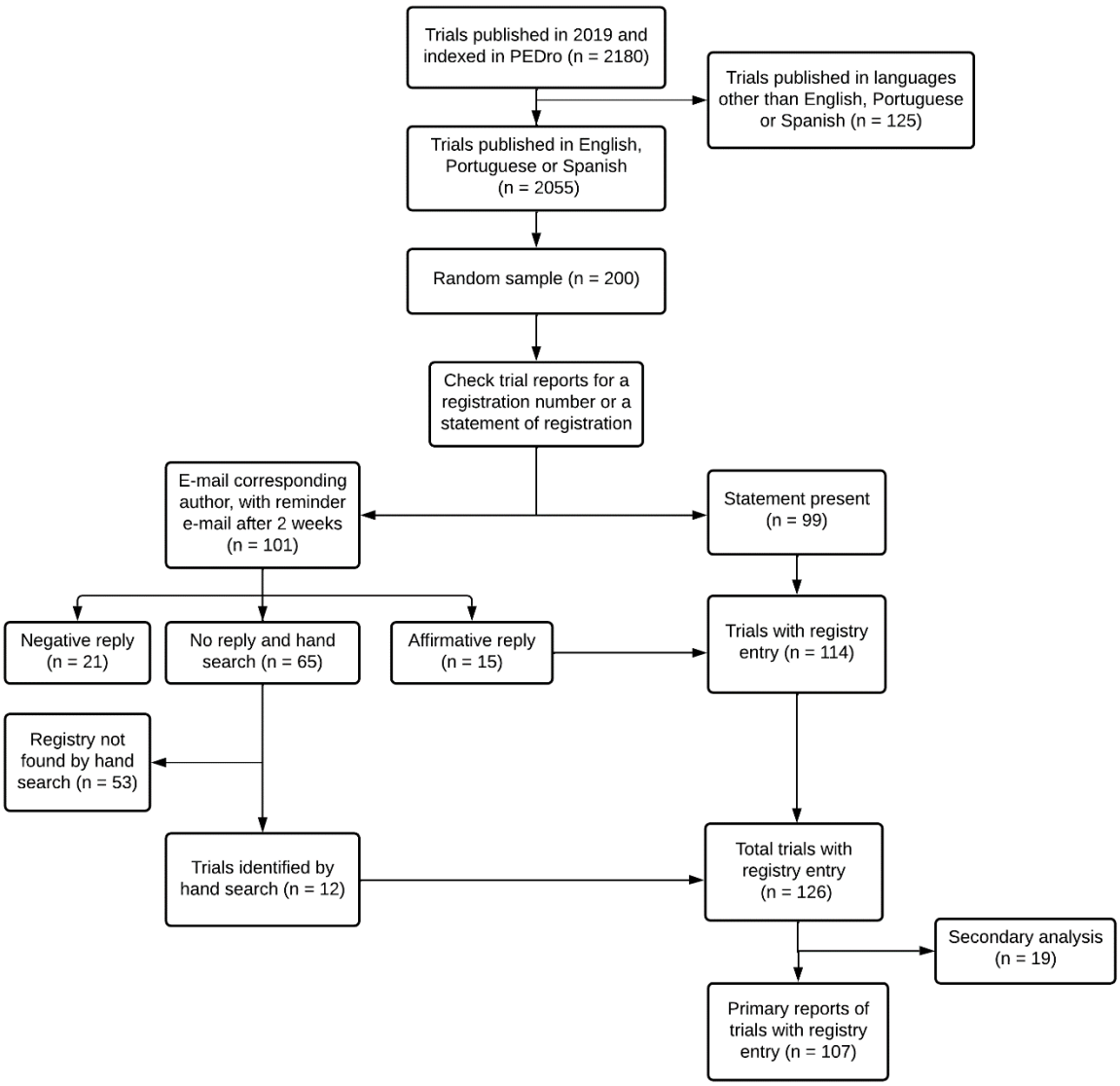
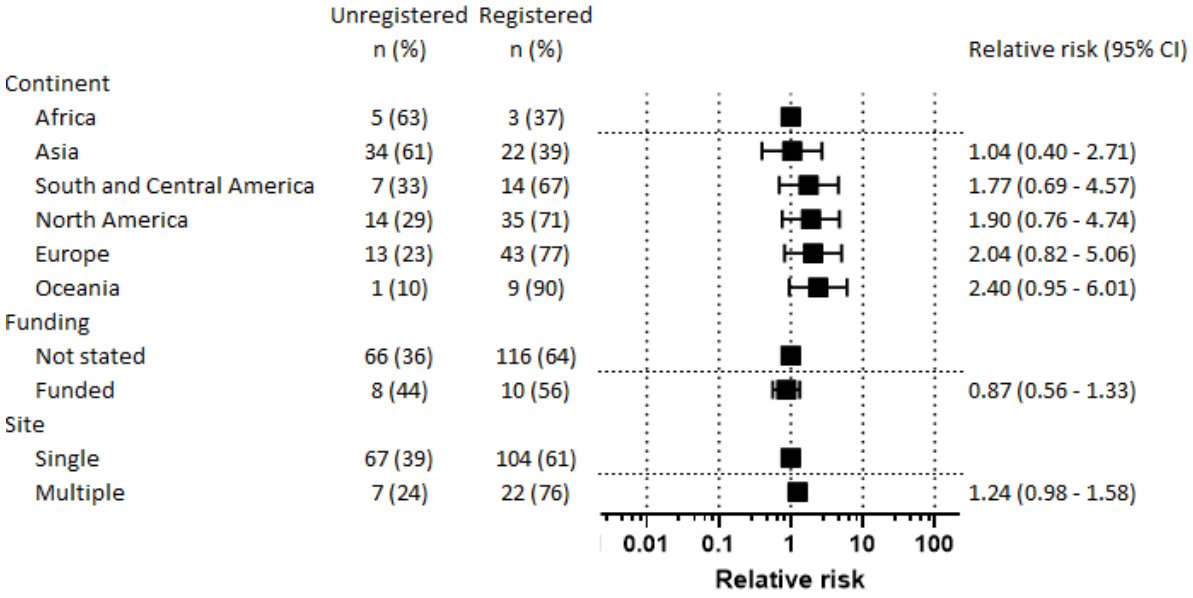

Trials published in 2019 and indexed in PEDro (n = 2180)
Trials published in languages other than English, Portuguese or Spanish (n = 125)
Trials published in English, Portuguese or Spanish (n = 2055)
Random sample (n = 200)
Check trial reports for a registration number or a statement of registration
E-mail corresponding author, with reminder e-mail after 2 weeks (n = 101)
Statement present (n = 99)
Negative reply (n = 21)
No reply and hand search (n = 65)
Affirmative reply (n = 15)
Trials with registry entry (n = 114)
Registry not found by hand search (n = 53)
Trials identified by hand search (n = 12)
Total trials with registry entry (n = 126)
Secondary analysis (n = 19)
Primary reports of trials with registry entry (n = 107)

Figure 3.



APPENDIX

List of 200 randomized trials include in the study

	Authors (Registered Randomized Trials)	Article Title	Journal and Details of Publication
1	Nunes PRP, Martins FM, Souza AP, Carneiro MAS, Nomelini RS, Michelin MA, Murta EFC, de Oliveira EP, Orsatti FL	Comparative effects of high-intensity interval training with combined training on physical function markers in obese postmenopausal women: a randomized controlled trial	*Menopause 2019 Nov;26(11):1242-1249*
2	Phattharasupharerk S, Purepong N, Eksakulkla S, Siriphorn A	Effects of Qigong practice in office workers with chronic non-specific low back pain: a randomized control trial	*Journal of Bodywork and Movement Therapies 2019 Apr;23(2):375-381*
3	Shellington EM, Gill DP, Shigematsu R, Petrella RJ	Innovative exercise as an intervention for older adults with knee osteoarthritis: a pilot feasibility study	*Canadian Journal on Aging 2019 Mar;38(1):111-121*
4	Ogwumike OO, Badaru UM, Adeniyi AF	Effect of task-oriented training on balance and motor function of ambulant children with cerebral palsy	*Rehabilitacion [Rehabilitation] 2019 Oct-Dec;53(4):276-283*
5	Buckingham-Schutt LM, Ellingson LD, Vazou S, Campbell CG	The behavioral wellness in pregnancy study: a randomized controlled trial of a multi-component intervention to promote appropriate weight gain	*The American Journal of Clinical Nutrition 2019 Apr;109(4):1071-1079*
6	Hamari L, Jarvela LS, Lahteenmaki PM, Arola M, Axelin A, Vahlberg T, Salantera S	The effect of an active video game intervention on physical activity, motor performance, and fatigue in children with cancer: a randomized controlled trial	*BMC Research Notes 2019 Nov 29;12(784):Epub*

7	Okubo Y, Sturnieks DL, Brodie MA, Duran L, Lord SR	Effect of reactive balance training involving repeated slips and trips on balance recovery among older adults: a blinded randomized controlled trial	*The Journals of Gerontology. Series A, Biological Sciences and Medical Sciences 2019 Sep;74(9):1489-1496*
8	Wollersheim T, Grunow JJ, Carbon NM, Haas K, Malleike J, Ramme SF, Schneider J, Spies CD, Mardian S, Mai K, Spuler S, Fielitz J, Weber-Carstens S	Muscle wasting and function after muscle activation and early protocol-based physiotherapy: an explorative trial	*Journal of Cachexia, Sarcopenia and Muscle 2019 Aug;10(4):734-747*
9	Arrieta H, Astrugue C, Regueme S, Durrieu J, Maillard A, Rieger A, Terrebonne E, Laurent C, Maget B, Servent V, Lavau-Denes S, Dauba J, Fonck M, Thiebaut R, Bourdel-Marchasson I	Effects of a physical activity programme to prevent physical performance decline in onco-geriatric patients: a randomized multicentre trial	*Journal of Cachexia, Sarcopenia and Muscle 2019 Apr;10(2):287-297*
10	el-Shamy FF, Ribeiro AP, Abo Gazia AA	Effectiveness of proprioceptive training on dynamic postural balance during pregnancy: a randomized controlled trial	*Physiotherapy Practice and Research 2019 Feb;40(1):77-85*
11	Ziaeifar M, Arab AM, Mosallanezhad Z, Nourbakhsh MR	Dry needling versus trigger point compression of the upper trapezius: a randomized clinical trial with two-week and three-month follow-up	*The Journal of Manual & Manipulative Therapy 2019;27(3):152-161*
12	Lohman EB, Pacheco GR, Gharibvand L, Daher N, Devore K, Bains G, AlAmeri M, Berk LS	The immediate effects of cervical spine manipulation on pain and biochemical markers in females with acute non-specific mechanical neck pain: a randomized clinical trial	*The Journal of Manual & Manipulative Therapy 2019;27(4):186-196*
13	Clark DO, Keith N, Weiner M, Xu H	Outcomes of an RCT of videoconference versus in-person or in-clinic nutrition and exercise in midlife adults with obesity	*Obesity Science & Practice 2019 Apr;5(2):111-119*
14	Wahba ES, Hamada HA, el Khatib AE	Effect of silicone gel versus Contractubex or corticosteroid phonophoresis for post-burn hypertrophic scars: a single-blind randomized controlled trial	*Physiotherapy Quarterly 2019;27(1):1-5*
15	Areeudomwong P, Buttagat V	Comparison of core stabilisation exercise and proprioceptive neuromuscular facilitation training on pain-related and neuromuscular response outcomes for chronic low back pain: a randomised controlled trial	*The Malaysian Journal of Medical Science 2019 Nov;26(6):77-89*
16	Nishimura M, Sasai H, Nakata Y, Maeda S	Effects of vibrotactile feedback on sedentary behaviors in adults: a pilot randomized controlled trial	*International Journal of Environmental Research & Public Health 2019 Dec;16(23):4612*
17	Alison JA, McKeough ZJ, Leung RWM, Holland AE, Hill K, Morris NR, Jenkins S, Spencer LM, Hill CJ, Lee AL, Seale H, Cecins N, McDonald CF	Oxygen compared to air during exercise training in COPD with exercise-induced desaturation	*The European Respiratory Journal 2019 May;53(5):1802429*

18	Liposcki DB, Ferreirada Silva Nagata I, Silvano GA, Zanella K, Schneider RH	Influence of a Pilates exercise program on the quality of life of sedentary elderly people: a randomized clinical trial	*Journal of Bodywork and Movement Therapies 2019 Apr;23(2):390-393*
19	Marusiak J, Fisher BE, Jaskolska A, Slotwinski K, Budrewicz S, Koszewicz M, Kisiel-Sajewicz K, Kaminski B, Jaskolski A	Eight weeks of aerobic interval training improves psychomotor function in patients with Parkinson's disease -- randomized controlled trial	*International Journal of Environmental Research & Public Health 2019 Mar;16(5):880*
20	Karssemeijer EGA, Aaronson JA, Bossers WJR, Donders R, Olde Rikkert MGM, Kessels RPC	The quest for synergy between physical exercise and cognitive stimulation via exergaming in people with dementia: a randomized controlled trial	*Alzheimer's Research & Therapy 2019 Jan 5;11(3):Epub*
21	Kobel S, Wartha O, Lammle C, Dreyhaupt J, Steinacker JM	Intervention effects of a kindergarten-based health promotion programme on obesity related behavioural outcomes and BMI percentiles	*Preventive Medicine Reports 2019 Sep;15:100931*
22	Gutierrez-Espinoza H, Araya-Quintanilla F, Gutierrez-Monclus R, Rios-Riquelme M, Alvarez-Bueno C, Martinez-Vizcaino V, Cavero-Redondo I	Does pectoralis minor stretching provide additional benefit over an exercise program in participants with subacromial pain syndrome? A randomized controlled trial [with consumer summary]	*Musculoskeletal Science & Practice 2019 Aug;44:102052*
23	Bale P, Easton V, Bacon H, Jerman E, Watts L, Barton G, Clark A, Armon K, MacGregor AJ	The effectiveness of a multidisciplinary intervention strategy for the treatment of symptomatic joint hypermobility in childhood: a randomised, single centre parallel group trial (the Bendy study)	*Pediatric Rheumatology Online Journal 2019 Jan 8;17(2):Epub*
24	Kirpalani H, Ratcliffe SJ, Keszler M, Davis PG, Foglia EE, te Pas A, Fernando M, Chaudhary A, Localio R, van Kaam AH, Onland W, Owen LS, Schmolzer GM, Katheria A, Hummler H, Lista G, Abbasi S, Klotz D, Simma B, Nadkarni V	Effect of sustained inflations versus intermittent positive pressure ventilation on bronchopulmonary dysplasia or death among extremely preterm infants: the SAIL randomized clinical trial [with consumer summary]	*JAMA 2019 Mar 26;321(12):1165-1175*
25	Freeman J, Hendrie W, Jarrett L, Hawton A, Barton A, Dennett R, Jones B, Zajicek J, Creanor S	Assessment of a home-based standing frame programme in people with progressive multiple sclerosis (SUMS): a pragmatic, multi-centre, randomised, controlled trial and cost-effectiveness analysis [with consumer summary]	*Lancet Neurology 2019 Aug;18(8):736-747*
26	Haroy J, Clarsen B, Wiger EG, Oyen MG, Serner A, Thorborg K, Holmich P, Andersen TE, Bahr R	The Adductor Strengthening Programme prevents groin problems among male football players: a cluster-randomised controlled trial [with consumer summary]	*British Journal of Sports Medicine 2019 Feb;53(3):150-157*
27	Ligibel J, Dillon DA, Giobbie-Hurder A, McTiernan A, Frank ES, Cornwell M, Pun M, Campbell N, Dowling RJO,	Impact of a pre-operative exercise intervention on breast cancer proliferation and gene expression: results from the Pre-Operative Health and Body (PreHAB) study	*Clinical Cancer Research 2019 Sep;25(17):5398-5406*

	Chang MC, Tolaney SM, Chagpar AB, Yung R, Freedman RA, Dominici LS, Golshan M, Rhei E, Taneja K, Huang Y, Brown M, Winer EP, Jeselsohn R, Irwin ML		
28	Jayaraman A, O'Brien MK, Madhavan S, Mummidisetty CK, Roth HR, Hohl K, Tapp A, Brennan K, Kocherginsky M, Williams KJ, Takahashi H, Rymer WZ	Stride management assist exoskeleton versus functional gait training in stroke: a randomized trial	*Neurology 2019 Jan 15;92(3):e263-e273*
29	de Sousa DG, Harvey LA, Dorsch S, Varettas B, Jamieson S, Murphy A, Giaccari S	Two weeks of intensive sit-to-stand training in addition to usual care improves sit-to-stand ability in people who are unable to stand up independently after stroke: a randomised trial [with consumer summary]	*Journal of Physiotherapy 2019 Jul;65(3):152-158*
30	Chandler MJ, Locke DE, Crook JE, Fields JA, Ball CT, Phatak VS, Dean PM, Morris M, Smith GE	Comparative effectiveness of behavioral interventions on quality of life for older adults with mild cognitive impairment: a randomized clinical trial [with consumer summary]	*JAMA Network Open 2019 May 3;2(5):e193016*
31	Ozalp O, Inal-Ince D, Cakmak A, Calik-Kutukcu E, Saglam M, Savci S, Vardar-Yagli N, Arikan H, Karakaya J, Coplu L	High-intensity inspiratory muscle training in bronchiectasis: a randomized controlled trial [with consumer summary]	*Respirology 2019 Mar;24(3):246-253*
32	Rasmussen HM, Pedersen NW, Overgaard S, Hansen LK, Dunkhase-Heinl U, Petkov Y, Engell V, Holsgaard-Larsen A	Gait analysis for individually tailored interdisciplinary interventions in children with cerebral palsy: a randomized controlled trial [with consumer summary]	*Developmental Medicine and Child Neurology 2019 Oct;61(10):1189-1195*
33	Dufour S, Fedorkow D, Kun J, Deng SX, Fang Q	Exploring the impact of a mobile health solution for postpartum pelvic floor muscle training: pilot randomized controlled feasibility study	*JMIR MHealth and UHealth 2019 Jul;7(7):e12587*
34	Heron N, Kee F, Mant J, Cupples ME, Donnelly M	Rehabilitation of patients after transient ischaemic attack or minor stroke: pilot feasibility randomised trial of a home-based prevention programme [with consumer summary]	*British Journal of General Practice 2019 Oct;69(687):E706-E714*
35	Pujol J, Ramos-Lopez D, Blanco-Hinojo L, Pujol G, Ortiz H, Martinez-Vilavella G, Blanch J, Monfort J, Deus J	Testing the effects of gentle vibrotactile stimulation on symptom relief in fibromyalgia	*Arthritis Research & Therapy 2019 Jun 14;21(148):Epub*
36	Ampomah K, Amano S, Wages NP, Volz L, Clift R, Ludin AFM, Nakazawa M, Law TD, Manini TM, Thomas JS, Russ DW, Clark BC	Blood flow-restricted exercise does not induce a cross-transfer of effect: a randomized controlled trial	*Medicine and Science in Sports and Exercise 2019 Sep;51(9):1817-1827*

37	Jaakkola JJK, Aalto SAM, Hernberg S, Kiihamaki SP, Jaakkola MS	Regular exercise improves asthma control in adults: a randomized controlled trial	*Scientific Reports 2019 Aug 19;9(12088):Epub*
38	Stuart M, Dromerick AW, Macko R, Benvenuti F, Beamer B, Sorkin J, Chard S, Weinrich M	Adaptive physical activity for stroke: an early-stage randomized controlled trial in the United States	*Neurorehabilitation and Neural Repair 2019 Aug;33(8):668-680*
39	Nasstasia Y, Baker AL, Lewin TJ, Halpin SA, Hides L, Kelly BJ, Callister R	Differential treatment effects of an integrated motivational interviewing and exercise intervention on depressive symptom profiles and associated factors: a randomised controlled cross-over trial among youth with major depression [with consumer summary]	*Journal of Affective Disorders 2019 Dec;259:413-423*
40	Young IA, Pozzi F, Dunning J, Linkonis R, Michener LA	Immediate and short-term effects of thoracic spine manipulation in patients with cervical radiculopathy: a randomized controlled trial [with consumer summary]	*The Journal of Orthopaedic and Sports Physical Therapy 2019 May;49(5):299-309*
41	Boudreau N, Gaudreault N, Roy JS, Bedard S, Balg F	The addition of glenohumeral adductors coactivation to a rotator cuff exercises program for rotator cuff tendinopathy: a single-blind randomized controlled trial [with consumer summary]	*The Journal of Orthopaedic and Sports Physical Therapy 2019 Mar;49(3):126-135*
42	Piau A, Krams T, Voisin T, Lepage B, Nourhashemi F	Use of a robotic walking aid in rehabilitation to reduce fear of falling is feasible and acceptable from the end user's perspective: a randomised comparative study [with consumer summary]	*Maturitas 2019 Feb;120:40-46*
43	Wu S, Jo E-A, Ji H, Kim K-H, Park J-J, Kim B-H, Cho K-I	Exergaming improves executive functions in patients with metabolic syndrome: randomized controlled trial	*JMIR Serious Games 2019 Jul 31;7(3):e13575*
44	Novakovic M, Krevel B, Rajkovic U, Vizintin Cuderman T, Jansa Trontelj K, Fras Z, Jug B	Moderate-pain versus pain-free exercise, walking capacity, and cardiovascular health in patients with peripheral artery disease [with consumer summary]	*Journal of Vascular Surgery 2019 Jul;70(1):148-156*
45	Langoni CDS, Resende TL, Barcellos AB, Cecchele B, Knob MS, Silva TDN, da Rosa JN, Diogo TS, Filho I, Schwanke CHA	Effect of exercise on cognition, conditioning, muscle endurance, and balance in older adults with mild cognitive impairment: a randomized controlled trial	*Journal of Geriatric Physical Therapy 2019 Apr-Jun;42(2):E15-E22*
46	Alegria M, Frontera W, Cruz-Gonzalez M, Markle SL, Trinh-Shevrin C, Wang Y, Herrera L, Ishikawa RZ, Velazquez E, Fuentes L, Guo Y, Pan J, Cheung M, Wong J, Genatios U, Jimenez A, Ramos Z, Perez G, Wong JY, Chieng CK, Bartels SJ, Duan N, Shrout PE	Effectiveness of a disability preventive intervention for minority and immigrant elders: the Positive Minds -- Strong Bodies randomized clinical trial [with consumer summary]	*American Journal of Geriatric Psychiatry 2019 Dec;27(12):1299-1313*

47	Karp JF, Zhang J, Wahed AS, Anderson S, Dew MA, Fitzgerald GK, Weiner DK, Albert S, Gildengers A, Butters M, Reynolds CF 3rd	Improving patient reported outcomes and preventing depression and anxiety in older adults with knee osteoarthritis: results of a Sequenced Multiple Assignment Randomized Trial (SMART) study [with consumer summary]	*American Journal of Geriatric Psychiatry 2019 Oct;27(10):1035-1045*
48	Vasic D, Novakovic M, Bozic Mijovski M, Barbic Zagar B, Jug B	Short-term water- and land-based exercise training comparably improve exercise capacity and vascular function in patients after a recent coronary event: a pilot randomized controlled trial	*Frontiers in Physiology 2019 Jul 16;10(903):Epub*
49	Nejati P, Safarcherati A, Karimi F	Effectiveness of exercise therapy and manipulation on sacroiliac joint dysfunction: a randomized controlled trial	*Pain Physician 2019 Jan;22(1):53-61*
50	dos Santos TD, Pereira SN, Portela LOC, Cardoso DM, Lago PD, dos Santos Guarda N, Moresco RN, Pereira MB, de Albuquerque IM	Moderate-to-high intensity inspiratory muscle training improves the effects of combined training on exercise capacity in patients after coronary artery bypass graft surgery: a randomized clinical trial [with consumer summary]	*International Journal of Cardiology 2019 Mar 15;279:40-46*
51	Lotzke H, Brisby H, Gutke A, Hagg O, Jakobsson M, Smeets R, Lundberg M	A person-centered prehabilitation program based on cognitive-behavioral physical therapy for patients scheduled for lumbar fusion surgery -- a randomized controlled trial	*Physical Therapy 2019 Aug;99(8):1069-1088*
52	Harbourne RT, Berger SE	Embodied cognition in practice: exploring effects of a motor-based problem-solving intervention	*Physical Therapy 2019 Jun;99(6):786-796*
53	Foroughi F, Sobhani S, Yoosefinejad AK, Motealleh A	Added value of isolated core postural control training on knee pain and function in women with patellofemoral pain syndrome: a randomized controlled trial	*Archives of Physical Medicine and Rehabilitation 2019 Feb;100(2):220-229*
54	Uebelacker LA, Van Noppen D, Tremont G, Bailey G, Abrantes A, Stein M	A pilot study assessing acceptability and feasibility of Hatha yoga for chronic pain in people receiving opioid agonist therapy for opioid use disorder [with consumer summary]	*Journal of Substance Abuse Treatment 2019 Oct;105:19-27*
55	Bonzano L, Pedulla L, Tacchino A, Brichetto G, Battaglia MA, Mancardi GL, Bove M	Upper limb motor training based on task-oriented exercises induces functional brain reorganization in patients with multiple sclerosis [with consumer summary]	*Neuroscience 2019 Jul;410:150-159*
56	Ghayomzadeh M, Seyed Alinaghi SA, Shamsi MM, Rezaei S, Earnest CP, Akbarnejad S, Taj L, Mohraz M, Navalta JW, Ghasemi P, Voltarelli FA	Effect of 8 weeks of hospital-based resistance training program on TCD4+ cell count and anthropometric characteristic of HIV patients in Tehran, Iran: a randomized controlled trial [with consumer summary]	*Journal of Strength & Conditioning Research 2019 Apr;33(4):1146-1155*
57	Cattaneo D, Gervasoni E, Pupillo E, Bianchi E, Aprile I, Imbimbo I, Russo R, Cruciani A, Turolla A,	Educational and exercise intervention to prevent falls and improve participation in subjects with neurological conditions: the	*Frontiers in Neurology 2019 Sep 13;10(865):Epub*

	Jonsdottir J, Agostini M, Beghi E, NEUROFALL Group	NEUROFALL randomized controlled trial	
58	Lim C	Multi-sensorimotor training improves proprioception and balance in subacute stroke patients: a randomized controlled pilot trial	*Frontiers in Neurology 2019 Mar 1;10(157):Epub*
59	Chalmers JD, Crichton ML, Brady G, Finch S, Lonergan M, Fardon TC	Pulmonary rehabilitation after exacerbation of bronchiectasis: a pilot randomized controlled trial	*BMC Pulmonary Medicine 2019 May 6;19(85):Epub*
60	Flack KD, Ufholz KE, Johnson L, Roemmich JN	Inducing incentive sensitization of exercise reinforcement among adults who do not regularly exercise -- a randomized controlled trial	*PLoS ONE 2019 May;14(5):e0216355*
61	Turner J, Yates P, Kenny L, Gordon LG, Burmeister B, Hughes BGM, McCarthy AL, Perry C, Chan RJ, Paviour A, Skerman H, Batstone M, Mackenzie L	The ENHANCES study: a randomised controlled trial of a nurse-led survivorship intervention for patients treated for head and neck cancer	*Supportive Care in Cancer 2019 Dec;27(12):4627-4637*
62	Abolfazli M, Lajevardi L, Mirzaei L, Abdorazaghi HA, Azad A, Taghizadeh G	The effect of early intervention of mirror visual feedback on pain, disability and motor function following hand reconstructive surgery: a randomized clinical trial [with consumer summary]	*Clinical Rehabilitation 2019 Mar;33(3):494-503*
63	Hollerbach BS, Jahnke SA, Poston WSC, Harms CA, Heinrich KM	Examining a novel firefighter exercise training program on simulated fire ground test performance, cardiorespiratory endurance, and strength: a pilot investigation	*Journal of Occupational Medicine and Toxicology 2019 Apr 23;14(12):Epub*
64	Connelly M, Schanberg LE, Ardoin S, Blakley M, Carrasco R, Chira P, Hayward K, Ibarra M, Kimura Y, Kingsbury DJ, Klein-Gitelman MS, Lawson E, Stinson J	Multisite randomized clinical trial evaluating an online self-management program for adolescents with juvenile idiopathic arthritis	*Journal of Pediatric Psychology 2019 Apr;44(3):363-374*
65	Santa-Clara H, Abreu A, Melo X, Santos V, Cunha P, Oliveira M, Pinto R, Carmo MM, Fernhall B	High-intensity interval training in cardiac resynchronization therapy: a randomized control trial	*European Journal of Applied Physiology 2019 Aug;119(8):1757-1767*
66	Sole ML, Talbert S, Yan X, Penoyer D, Mehta D, Bennett M, Emery KP, Middleton A, Deaton L, Abomoelak B, Deb C	Impact of deep oropharyngeal suctioning on microaspiration, ventilator events, and clinical outcomes: a randomized clinical trial	*Journal of Advanced Nursing 2019 Nov;75(11):3045-3057*
67	Liu Z, Li Q, Maddison R, Ni Mhurchu C, Jiang Y, Wei D-M, Cheng L, Cheng Y, Wang D, Wang H-J	A school-based comprehensive intervention for childhood obesity in China: a cluster randomized controlled trial	*Childhood Obesity 2019 Feb-Mar;15(2):105-115*
68	Robinson SA, Bisson AN, Hughes ML, Ebert J, Lachman ME	Time for change: using implementation intentions to promote physical activity in a randomised pilot trial	*Psychology & Health 2019 Feb;34(2):232-254*
69	Hodgkinson A, Abbott J, Hurley MA, Lowe N, Qualter P	An educational intervention to prevent overweight in pre-school years: a cluster randomised trial with a focus on disadvantaged families	*BMC Public Health 2019 Nov 1;19(1430):Epub*

70	Obling KH, Overgaard K, Juul L, Maindal HT	Effects of a motivational, individual and locally anchored exercise intervention (MILE) on cardiorespiratory fitness: a community-based randomised controlled trial	*BMC Public Health 2019 Feb 28;19(239):Epub*
71	Berube M, Gelinas C, Feeley N, Martorella G, Cote J, Laflamme GY, Rouleau DM, Choiniere M	Feasibility of a hybrid web-based and in-person self-management intervention aimed at preventing acute to chronic pain transition after major lower extremity trauma (iPACT-E-Trauma): a pilot randomized controlled trial	*Pain Medicine 2019 Oct;20(10):2018-2032*
72	Brown DM, Mahlberg N, Pohl D, Timmons BW, Bray SR, Streiner DL, Ferro MA, Hamer S, Rosenbaum PL, Ronen GM	Can behavioral strategies increase physical activity and influence depressive symptoms and quality of life among children with epilepsy? Results of a randomized controlled trial [with consumer summary]	*Epilepsy & Behavior 2019 May;94:158-166*
73	McCarthy CJ, Potter L, Oldham JA	Comparing targeted thrust manipulation with general thrust manipulation in patients with low back pain. A general approach is as effective as a specific one. A randomised controlled trial [with consumer summary]	*BMJ Open Sport & Exercise Medicine 2019 Oct 5;5(1):e000514*
74	Clifford C, Paul L, Syme G, Millar NL	Isometric versus isotonic exercise for greater trochanteric pain syndrome: a randomised controlled pilot study [with consumer summary]	*BMJ Open Sport & Exercise Medicine 2019 Sep 21;5(1):e000558*
75	Molassiotis A, Suen LKP, Cheng HL, Mok TSK, Lee SCY, Wang CH, Lee P, Leung H, Chan V, Lau TKH, Yeo W	A randomized assessor-blinded wait-list-controlled trial to assess the effectiveness of acupuncture in the management of chemotherapy-induced peripheral neuropathy	*Integrative Cancer Therapies 2019 Jan-Dec;18:1534735419836501*
76	Peacock KS, Stoerkel E, Libretto S, Zhang W, Inman A, Schlicher M, Cowsar JD Jr, Eddie D, Walter J	A randomized trial comparing the Tennant Biomodulator to transcutaneous electrical nerve stimulation and traditional Chinese acupuncture for the treatment of chronic pain in military service members	*Military Medical Research 2019 Dec 2;6(37):Epub*
77	Wang Y, Bhatt T, Liu X, Wang S, Lee A, Wang E, Pai Y-C	Can treadmill-slip perturbation training reduce immediate risk of over-ground-slip induced fall among community-dwelling older adults?	*Journal of Biomechanics 2019 Feb;84:58-66*
78	de Oliveira MCE, de Oliveira de Lima VC, Pegado R, Silva-Filho EM, Fayh APT, Micussi MT	Comparison of pelvic floor muscle training isolated and associated with weight loss: a randomized controlled trial	*Archives of Gynecology and Obstetrics 2019 Nov;300(5):1343-1351*
79	Dalewski B, Kaminska A, Szydlowski M, Kozak M, Sobolewska E	Comparison of early effectiveness of three different intervention methods in patients with chronic orofacial pain: a randomized, controlled clinical trial	*Pain Research & Management 2019 Mar 11;(7954291):Epub*
80	Kim E-D, Won YH, Park S-H, Seo J-H, Kim D-S, Ko M-H, Kim G-W	Efficacy and safety of a stimulator using low-intensity pulsed ultrasound combined with transcutaneous electrical nerve	*Pain Research & Management 2019 Jun 16;(7964897):Epub*

		stimulation in patients with painful knee osteoarthritis	
81	Wang H, Cao Y, Jin X, Yan M, Wang J, Li R, Ji L	Effect of an acupuncture technique of penetrating through Zhibian (BL54) to Shuidao (ST28) with long needle for pain relief in patients with primary dysmenorrhea: a randomized controlled trial	*Pain Research & Management 2019 Dec 17;(7978180):Epub*
82	Grey EB, Thompson D, Gillison FB	Effects of a web-based, evolutionary mismatch-framed intervention targeting physical activity and diet: a randomised controlled trial	*International Journal of Behavioral Medicine 2019 Dec;26(6):645-657*
83	Sisconeto de Freitas S, Cabral AL, de Melo Costa Pinto R, Magalhaes Resende AP, Pereira Baldon VS	Effects of perineal preparation techniques on tissue extensibility and muscle strength: a pilot study	*International Urogynecology Journal 2019 Jun;30(6):951-957*
84	Philippot A, Meerschaut A, Danneaux L, Smal G, Bleyenheuft Y, de Volder AG	Impact of physical exercise on symptoms of depression and anxiety in pre-adolescents: a pilot randomized trial	*Frontiers in Psychology 2019 Aug 8;10(1820):Epub*
85	de Souza Simoni LH, Dos Santos DO, de Souza HCD, Baddini-Martinez JA, Santos MK, Gastaldi AC	Acute effects of oscillatory PEP and thoracic compression on secretion removal and impedance of the respiratory system in non-cystic fibrosis bronchiectasis	*Respiratory Care 2019 Jul;64(7):818-827*
86	Wu J, Vratsistas-Curto A, Shiner CT, Faux SG, Harris I, Poulos CJ	Can in-reach multidisciplinary rehabilitation in the acute ward improve outcomes for critical care survivors? A pilot randomized controlled trial [with consumer summary]	*Journal of Rehabilitation Medicine 2019 Sep;51(8):598-606*
87	Resende APM, Bernardes BT, Stupp L, Oliveira E, Castro RA, Girao MJBC, Sartori MGF	Pelvic floor muscle training is better than hypopressive exercises in pelvic organ prolapse treatment: an assessor-blinded randomized controlled trial	*Neurourology and Urodynamics 2019 Jan;38(1):171-179*
88	Koolen MKE, Kruyt MC, Oner FC, Schaden W, Weinans H, van der Jagt OP	Effect of unfocused extracorporeal shockwave therapy on bone mineral content of twelve distal forearms of postmenopausal women: a clinical pilot study	*Archives of Osteoporosis 2019 Dec;14(1):113*
89	Kernot J, Lewis L, Olds T, Maher C	Effectiveness of a Facebook-delivered physical activity intervention for postpartum women: a randomized controlled trial	*Journal of Physical Activity & Health 2019 Feb;16(2):125-133*
90	Miyamoto ST, Valim V, Carletti L, Ng WF, Perez AJ, Lendrem DW, Trennel M, Giovelli RA, Dias LH, Serrano EV, Subtil AM, Abreu VC, Natour J	Supervised walking improves cardiorespiratory fitness, exercise tolerance, and fatigue in women with primary Sjogren's syndrome: a randomized-controlled trial	*Rheumatology International 2019 Feb;39(2):227-238*
91	Barnason S, Zimmerman L, Schulz P, Pullen C, Schuelke S	Weight management telehealth intervention for overweight and obese rural cardiac rehabilitation participants: a randomised trial [with consumer summary]	*Journal of Clinical Nursing 2019 May;28(9-10):1808-1818*
92	Ehrensberger M, Simpson D, Broderick P, Blake C,	Unilateral strength training and mirror therapy in chronic stroke patients: a pilot randomised trial	*American Journal of Physical Medicine &*

	Horgan F, Hickey P, O'Reilly J, Monaghan K		*Rehabilitation 2019 Aug;98(8):657-665*
93	Gao C, Zheng Y, Fan C, Yang Y, He C, Wong M	Could the clinical effectiveness be improved under the integration of orthotic intervention and scoliosis-specific exercise in managing adolescent idiopathic scoliosis? A randomized controlled trial study	*American Journal of Physical Medicine & Rehabilitation 2019 Aug;98(8):642-648*
94	Romero-Moraleda B, Gonzalez-Garcia J, Cuellar-Rayo A, Balsalobre-Fernandez C, Munoz-Garcia D, Morencos E	Effects of vibration and non-vibration foam rolling on recovery after exercise with induced muscle damage [with consumer summary]	*Journal of Sports Science and Medicine 2019 Mar;18(1):172-180*
95	Huang S, Yu X, Lu Y, Qiao J, Wang H, Jiang L-M, Wu X, Niu W	Body weight support-Tai Chi footwork for balance of stroke survivors with fear of falling: a pilot randomized controlled trial [with consumer summary]	*Complementary Therapies in Clinical Practice 2019 Nov;37:140-147*
96	Jimenez-Garcia JD, Hita-Contreras F, de la Torre-Cruz M, Fabrega-Cuadros R, Aibar-Almazan A, Cruz-Diaz D, Martinez-Amat A	Risk of falls in healthy older adults: benefits of high-intensity interval training using lower body suspension exercises	*Journal of Aging and Physical Activity 2019 Jun;27(3):325-333*
97	Milios JE, Ackland TR, Green DJ	Pelvic floor muscle training in radical prostatectomy: a randomized controlled trial of the impacts on pelvic floor muscle function and urinary incontinence	*BMC Urology 2019 Nov 15;19(116):Epub*
98	Ptaszkowska L, Ptaszkowski K, Halski T, Taradaj J, Dymarek R, Paprocka-Borowicz M	Immediate effects of the respiratory stimulation on ventilation parameters in ischemic stroke survivors: a randomized interventional study (CONSORT)	*Medicine 2019 Sep;98(38):e17128*
99	Petrozzi MJ, Leaver A, Ferreira PH, Rubinstein SM, Jones MK, Mackey MG	Addition of MoodGYM to physical treatments for chronic low back pain: a randomized controlled trial	*Chiropractic & Manual Therapies 2019 Oct 25;27(54):Epub*
100	Gomes de Resende-Neto AG, do Nascimento MA, de Sa CA, Ribeiro AS, de Santana JM, da Silva-Grigoletto ME	Comparison between functional and traditional resistance training on joint mobility, determinants of walking and muscle strength in older women	*The Journal of Sports Medicine and Physical Fitness 2019 Oct;59(10):1659-68*
101	Parisien-La Salle S, Abel Rivest E, Boucher VG, Lalande-Gauthier M, Morisset J, Manganas H, Poirier C, Comtois AS, Dube BP	Effects of pursed lip breathing on exercise capacity and dyspnea in patients with interstitial lung disease: a randomized, crossover study	*Journal of Cardiopulmonary Rehabilitation and Prevention 2019 Mar;39(2):112-117*
102	Zanini M, Nery RM, de Lima JB, Buhler RP, da Silveira AD, Stein R	Effects of different rehabilitation protocols in inpatient cardiac rehabilitation after coronary artery bypass graft surgery: a randomized clinical trial	*Journal of Cardiopulmonary Rehabilitation and Prevention 2019 Nov;39(6):E19-E25*
103	Guillet AD, Cirino NH, Hart KD, Leclair CM	Mindfulness-based group cognitive behavior therapy for provoked localized vulvodynia: a randomized controlled trial	*Journal of Lower Genital Tract Disease 2019 Apr;23(2):170-175*
104	Fosdahl MA, Jahnsen R, Kvalheim K, Holm I	Stretching and progressive resistance exercise in children with	*Pediatric Physical Therapy 2019 Jul;31(3):264-271*

		cerebral palsy: a randomized controlled trial	
105	Wang H-Q, Hou M, Bao CL, Min L, Li H	Effects of acupuncture treatment on lower limb spasticity in patients following hemorrhagic stroke: a pilot study	*European Neurology 2019 Jun;81(1-2):5-12*
106	Cho J, Lee E, Lee S	Effectiveness of mid-thoracic spine mobilization versus therapeutic exercise in patients with subacute stroke: a randomized clinical trial	*Technology and Health Care 2019;27(2):149-158*
107	Ahn J-Y, Kim H, Park C-B	Effects of whole-body vibration on upper extremity function and grip strength in patients with subacute stroke: a randomised single-blind controlled trial	*Occupational Therapy International 2019;(5820952):Epub*
	Authors (Secondary Analyses of Original Studies)	**Article Title**	***Journal and Details of Publication***
108	Arntzen EC, Straume B, Odeh F, Feys P, Normann B	Group-based, individualized, comprehensive core stability and balance intervention provides immediate and long-term improvements in walking in individuals with multiple sclerosis: a randomized controlled trial [with consumer summary]	*Physiotherapy Research International 2019 Sep;36(9):2364-2373*
109	McNamara DA, Aiad N, Howden E, Hieda M, Link MS, Palmer D, Samels M, Everding B, Ng J, Adams-Huet B, Opondo MA, Sarma S, Levine BD	Left atrial electromechanical remodeling following 2 years of high-intensity exercise training in sedentary middle-aged adults [with consumer summary]	*Circulation 2019 Mar 19;139(12):1507-1516*
110	Blond MB, Rosenkilde M, Gram AS, Tindborg M, Christensen AN, Quist JS, Stallknecht BM	How does 6 months of active bike commuting or leisure-time exercise affect insulin sensitivity, cardiorespiratory fitness and intra-abdominal fat? A randomised controlled trial in individuals with overweight and obesity [with consumer summary]	*British Journal of Sports Medicine 2019 Sep;53(18):1183-1192*
111	Chaves GSS, Lima de Melo Ghisi G, Britto RR, Grace SL	Maintenance of gains, morbidity, and mortality at 1 year following cardiac rehabilitation in a middle-income country: a wait-list control crossover trial [with consumer summary]	*Journal of the American Heart Association 2019 Feb 19;8(4):e011228*
112	Liao Y-Y, Hsuan Chen I, Lin Y-J, Chen Y, Hsu W-C	Effects of virtual reality-based physical and cognitive training on executive function and dual-task gait performance in older adults with mild cognitive impairment: a randomized control trial	*Frontiers in Aging Neuroscience 2019 Jul 16;11(162):Epub*
113	Loh KP, Kleckner IR, Lin PJ, Mohile SG, Canin BE, Flannery MA, Fung C, Dunne RF, Bautista J, Culakova E, Kleckner AS, Peppone LJ, Janelsins M, McHugh C, Conlin A, Cho JK, Kasbari S, Esparaz	Effects of a home-based exercise program on anxiety and mood disturbances in older adults with cancer receiving chemotherapy	*Journal of the American Geriatrics Society 2019 May;67(5):1005-1011*

	BT, Kuebler JP, Mustian KM		
114	Fernandez-de-las-Penas C, Ortega-Santiago R, Diaz HF, Salom-Moreno J, Cleland JA, Pareja JA, Arias-Buria JL	Cost-effectiveness evaluation of manual physical therapy versus surgery for carpal tunnel syndrome: evidence from a randomized clinical trial [with consumer summary]	*The Journal of Orthopaedic and Sports Physical Therapy 2019 Feb;49(2):55-63*
115	Rech A, Ehlers Botton C, Lopez P, Quincozes-Santos A, Umpierre D, Silveira Pinto R	Effects of short-term resistance training on endothelial function and inflammation markers in elderly patients with type 2 diabetes: a randomized controlled trial [with consumer summary]	*Experimental Gerontology 2019 Apr;118:19-25*
116	Weiner LS, Takemoto M, Godbole S, Nelson SH, Natarajan L, Sears DD, Hartman SJ	Breast cancer survivors reduce accelerometer-measured sedentary time in an exercise intervention [with consumer summary]	*Journal of Cancer Survivorship 2019 Jun;13(3):468-476*
117	Reddy R, Wittenberg A, Castle JR, el Youssef J, Winters-Stone K, Gillingham M, Jacobs PG	Effect of aerobic and resistance exercise on glycemic control in adults with type 1 diabetes [with consumer summary]	*Canadian Journal of Diabetes 2019 Aug;43(6):406-414*
118	Lichtenberg T, von Stengel S, Sieber C, Kemmler W	The favorable effects of a high-intensity resistance training on sarcopenia in older community-dwelling men with osteosarcopenia: the randomized controlled FrOST study	*Clinical Interventions in Aging 2019 Dec;14:2173-2186*
119	Robinson SA, Shimada SL, Quigley KS, Moy ML	A web-based physical activity intervention benefits persons with low self-efficacy in COPD: results from a randomized controlled trial	*Journal of Behavioral Medicine 2019 Dec;42(6):1082-1090*
120	Klamroth S, Gasner H, Winkler J, Eskofier B, Klucken J, Pfeifer K, Steib S	Interindividual balance adaptations in response to perturbation treadmill training in persons with Parkinson disease	*Journal of Neurologic Physical Therapy 2019 Oct;43(4):224-232*
121	Hochsmann C, Dorling JL, Apolzan JW, Johannsen NM, Hsia DS, Church TS, Martin CK	Effect of different doses of supervised aerobic exercise on heart rate recovery in inactive adults who are overweight or obese: results from E-MECHANIC	*European Journal of Applied Physiology 2019 Sep;119(9):2095-2103*
122	Ihle-Hansen H, Langhammer B, Lydersen S, Gunnes M, Indredavik B, Askim T	A physical activity intervention to prevent cognitive decline after stroke: secondary results from the Life After Stroke study, an 18-month randomized controlled trial [with consumer summary]	*Journal of Rehabilitation Medicine 2019 Oct;51(9):646-651*
123	Jablochkova A, Backryd E, Kosek E, Mannerkorpi K, Ernberg M, Gerdle B, Ghafouri B	Unaltered low nerve growth factor and high brain-derived neurotrophic factor levels in plasma from patients with fibromyalgia after a 15-week progressive resistance exercise [with consumer summary]	*Journal of Rehabilitation Medicine 2019 Nov;51(10):779-787*
124	Kucharski D, Lange E, Ross AB, Svedlund S, Feldthusen C, Onnheim K, Mannerkorpi K, Gjertsson I	Moderate-to-high intensity exercise with person-centered guidance influences fatigue in older adults with rheumatoid arthritis	*Rheumatology International 2019 Sep;39(9):1585-1594*
125	Wong-Yu ISK, Mak MKY	Multisystem balance training reduces injurious fall risk in Parkinson disease: a randomized trial	*American Journal of Physical Medicine & Rehabilitation 2019 Mar;98(3):239-244*

126	Bauer CM, Kankaanpaa MJ, Meichtry A, Rissanen SM, Suni JH	Efficacy of six months neuromuscular exercise on lumbar movement variability -- a randomized controlled trial	*Journal of Electromyography and Kinesiology 2019 Jun;48:84-93*
127	Ericksen HM, Lefevre C, Luc-Harkey BA, Thomas AC, Gribble PA, Pietrosimone B	Females decrease vertical ground reaction forces following 4-week jump-landing feedback intervention without negative affect on vertical jump performance	*Journal of Sport Rehabilitation 2019 Aug;28(8):866-870*
	Authors (Unregistered Randomized Trials)	**Article Title**	***Journal and Details of Publication***
128	Deodato M, Guolo F, Monticco A, Fornari M, Manganotti P, Granato A	Osteopathic manipulative therapy in patients with chronic tension-type headache: a pilot study	*The Journal of the American Osteopathic Association 2019 Oct;119(10):682-687*
129	Patten CA, Vickers KS, Lewis BA, Finnie SB, Wheeldon TJ, Decker PA, Stevens S, Hathaway JC, Reese MM, Seime RJ	Feasibility trial of an unsupervised, facility-based exercise programme for depressed outpatients	*Psychology, Health & Medicine 2019 Mar;24(3):320-332*
130	Madrona Marcos F, Panisello Royo JM, Tarraga Marcos ML, Rosich N, Carbayo Herencia JA, Alins J, Castell E, Tarraga Lopez PJ	Effect of a motivational physical activity program on lipid parameters in patients with obesity and overweight	*Clinica e Investigacion en Arteriosclerosis 2019 Nov-Dec;31(6):245-250*
131	Takeda K, Yoshikata H, Imura M	Do squat exercises with weight shift during pregnancy improve postural control?	*International Journal of Women's Health and Reproduction Sciences 2019 Jan;7(1):10-16*
132	Zhang M, Fan C, Zhu P, Qin H, Wang Y	Clinical efficacy evaluation of body acupuncture and scalp acupuncture combined with extracorporeal shock wave for scapulohumeral periarthritis	*World Journal of Acupuncture-Moxibustion 2019 Jun;29(2):108-112*
133	Moravveji A, Sayyah M, Shamsnia E, Vakili Z	Comparing the prolonged effect of interval versus continuous aerobic exercise on blood inflammatory marker of Visfatin level and body mass index of sedentary overweigh/fat female college students	*AIMS Public Health 2019 Dec;6(4):568-576*
134	da Silva Rocha Paz T, Guimaraes F, Santos de Britto VL, Correa CL	Treadmill training and kinesiotherapy versus conventional physiotherapy in Parkinson's disease: a pragmatic study	*Fisioterapia em Movimento [Physical Therapy in Movement] 2019;32(1):e003201*
135	Jacobson BH, Sellers J, Monaghan T, Schnaiter-Brasche J, Loy K, Estrada C, Moghaddam M	Comparison of a static, independent balance protocol and the National Institute on Aging balance protocol on stability and risk of falling in the elderly	*Activities, Adaptation & Aging 2019 Jan-Mar;43(1):37-50*
136	Kimoto M, Yonetsu R, Okada K, Horioka W, Kondou T, Sasaki M, Sakamoto H	Effect of home-based training focused on increasing maximum step length in walking function of children with cerebral palsy	*Physical Therapy Reviews 2019;24(6):358-365*
137	Ofori EK, Frimpong E, Ademiluyi A, Olawale OA	Ergometer cycling improves the ambulatory function and cardiovascular fitness of stroke	*Journal of Physical Therapy Science 2019 Mar;31(3):211-216*

		patients -- a randomized controlled trial	
138	Sakata J, Nakamura E, Suzuki T, Suzukawa M, Akeda M, Yamazaki T, Ellenbecker TS, Hirose N	Throwing injuries in youth baseball players: can a prevention program help? A randomized controlled trial	*The American Journal of Sports Medicine 2019 Sep;47(11):2709-2716*
139	Karapolat H, Cinar ME, Tanigor G, Nalbantgil S, Kayikcioglu M, Mogulkoc N, Kultursay H	Effects of cardiopulmonary rehabilitation on pulmonary arterial hypertension: a prospective, randomized study	*Turkiye Fiziksel Tip ve Rehabilitasyon Dergisi [Turkish Journal of Physical Medicine and Rehabilitation] 2019;65(3):278-286*
140	Jackson LR, Purvis J, Brown T	The effects of postural and anatomical alignment on speed, power, and athletic performance in male collegiate athletes: a randomized controlled trial	*International Journal of Sports Physical Therapy 2019 Jul;14(4):623-636*
141	Perez Ramirez NE, Cares PN, Penailillo PSM	Effectiveness of Watsu therapy in patients with juvenile idiopathic arthritis. A parallel, randomized, controlled and single-blind clinical trial	*Revista Chilena de Pediatria 2019 Jun;90(3):282-292*
142	Ribeiro dos Santos B, Leite Gomes J, Coutinho Luciano Pompermayer R, Pampolim Abreu GK	Os beneficios da eletroestimulacao transcutanea via nervo tibial posterior e parassacral no tratamento de bexiga hiperativa (The benefits of transcutaneous electrostimulation via the posterior tibial and parasacral nerves in the treatment of overactive bladder) [Portuguese]	*Fisioterapia Brasil [Physical Therapy Brazil] 2019;20(2):239-248*
143	Gokmen YG, Akkoyunlu ME, Kilic L, Algun C	The effect of Tai Chi and Qigong training on patients with obstructive sleep apnea: a randomized controlled study	*Journal of Alternative & Complementary Medicine 2019 Mar;25(3):317-325*
144	Grbovic V, Stefanovic S, Djukic S, Nurkovic J, Petrovic NZ, Ilic KP, Divjak A, Jurisic-Skevin A	The effects of the physical procedures in patients with diabetic neuropathy	*Vojnosanitetski Pregled [Military Medical and Pharmaceutical Review] 2019 Aug;76(8):787-794*
145	Kashoo FZ, Ahmad M	Effect of sensory integration on attention span among children with infantile hemiplegia	*International Journal of Health Sciences 2019 May-Jun;13(3):29-33*
146	Mohamed AA, Shendy WS, Semary M, Mourad HS, Battecha KH, Soliman ES, el Sayed SH, Mohamed GI	Combined use of cervical headache SNAG and cervical SNAG half rotation techniques in the treatment of cervicogenic headache	*Journal of Physical Therapy Science 2019 Apr;31(4):376-381*
147	Cardozo DC, de Salles BF, Mannarino P, Vasconcelos APS, Miranda H, Willardson JM, Simao R	The effect of exercise order in circuit training on muscular strength and functional fitness in older women	*International Journal of Exercise Science 2019;12(4):657-665*
148	Akbas E, Erdem EU	Effectiveness of group aerobic training on menstrual cycle symptoms in primary dysmenorrhea	*Bakirkoy Tip Dergisi [Medical Journal of Bakirkoy] 2019 Sep;15(3):209-216*
149	Okmen BM, Aslan MD, Nakipoglu Yuzer GF, Ozgirgin N	Effect of virtual reality therapy on functional development in children with cerebral palsy: a single-blind, prospective, randomized-controlled study	*Turkiye Fiziksel Tip ve Rehabilitasyon Dergisi [Turkish Journal of Physical Medicine and*

			Rehabilitation] 2019;65(4):371-378
150	Feldbrugge CM, Pathoomvanh MM, Powden CJ, Hoch MC	Joint mobilization and static stretching for individuals with chronic ankle instability -- a pilot study	*Journal of Bodywork and Movement Therapies 2019 Jan;23(1):194-201*
151	Mohite SA, Shinde SB	Effect of early intervention with spinal isometric exercises in acute lumbar intervertabral disc prolapse	*Indian Journal of Physiotherapy and Occupational Therapy 2019 Apr-Jun;13(2):170-175*
152	Emamvirdi M, Letafatkar A, Khaleghi Tazji M	The effect of valgus control instruction exercises on pain, strength, and functionality in active females with patellofemoral pain syndrome	*Sports Health 2019 May-Jun;11(3):223-237*
153	Singh M, Pawar M	Mirror therapy for improving motor functions in patients with leprosy with grade 2 disabilities	*Neurology Clinical Practice 2019 Apr;9(2):118-123*
154	Yamanishi T, Suzuki T, Sato R, Kaga K, Kaga M, Fuse M	Effects of magnetic stimulation on urodynamic stress incontinence refractory to pelvic floor muscle training in a randomized sham-controlled study	*Lower Urinary Tract Symptoms 2019 Jan;11(1):61-65*
155	Sawant VS, Kanase SB	Effect of conventional therapy and positioning with isometric shoulder exercises on functional shoulder subluxation in post stroke survivors	*Indian Journal of Public Health Research & Development 2019 Aug;10(8):536-540*
156	Maring J, Wentzell E	Constraint induced movement therapy: impact of setting on outcomes	*Journal of Allied Health 2019 Sep;48(3):e73-e77*
157	Georga G, Chrousos G, Artemiadis A, Panagiotis PP, Bakakos P, Darviri C	The effect of stress management incorporating progressive muscle relaxation and biofeedback-assisted relaxation breathing on patients with asthma: a randomised controlled trial	*Advances in Integrative Medicine 2019 May;6(2):73-77*
158	Romain AJ, Fankam C, Karelis AD, Letendre E, Mikolajczak G, Stip E, Abdel-Baki A	Effects of high intensity interval training among overweight individuals with psychotic disorders: a randomized controlled trial	*Schizophrenia Research 2019 Aug;210:278-286*
159	Joung HJ, Lee Y	Effect of creative dance on fitness, functional balance, and mobility control in the elderly	*Gerontology 2019 Aug;65(5):537-546*
160	Tercero-Perez K, Cortes H, Torres-Ramos Y, Rodriguez-Labrada R, Cerecedo-Zapata CM, Hernandez-Hernandez O, Perez-Gonzalez N, Gonzalez-Pina R, Leyva-Garcia N, Cisneros B, Velazquez-Perez L, Magana JJ	Effects of physical rehabilitation in patients with spinocerebellar ataxia type 7	*The Cerebellum 2019 Jun;18(3):397-405*
161	Hammami M, Gaamouri N, Aloui G, Shephard RJ, Chelly MS	Effects of combined plyometric and short sprint with change-of-direction training on athletic performance of male U15 handball players [with consumer summary]	*Journal of Strength & Conditioning Research 2019 Mar;33(3):662-675*

162	Zheng F, Liu S, Liu Y, Deng L	Effects of an outpatient diabetes self-management education on patients with type 2 diabetes in China: a randomized controlled trial	*Journal of Diabetes Research 2019 Jan 17;(1073131):Epub*
163	Nascimento MAD, Gerage AM, Silva D, Ribeiro AS, Machado DGDS, Pina FLC, Tomeleri CM, Venturini D, Barbosa DS, Mayhew JL, Cyrino ES	Effect of resistance training with different frequencies and subsequent detraining on muscle mass and appendicular lean soft tissue, IGF-1, and testosterone in older women [with consumer summary]	*European Journal of Sport Science 2019;19(2):199-207*
164	He GX, Li N, Ren L, Shen HH, Liao N, Wen JJ, Xu YM, Wang J, Li QY	Benefits of different intensities of pulmonary rehabilitation for patients with moderate-to-severe COPD according to the GOLD stage: a prospective, multicenter, single-blinded, randomized, controlled trial	*International Journal of Chronic Obstructive Pulmonary Disease 2019 Oct;14:2291-2304*
165	Marechal R, Fontvieille A, Parent-Roberge H, Fulop T, Riesco E, Pavic M, Dionne IJ	Effect of a mixed-exercise program on physical capacity and sedentary behavior in older adults during cancer treatments	*Aging Clinical and Experimental Research 2019 Nov;31(11):1583-1589*
166	Langdown BL, Wells JET, Graham S, Bridge MW	Acute effects of different warm-up protocols on highly skilled golfers' drive performance	*Journal of Sports Sciences 2019;37(6):656-664*
167	Ardakani MK, Wikstrom EA, Minoonejad H, Rajabi R, Sharifnezhad A	Hop stabilization training and landing biomechanics in athletes with chronic ankle instability: a randomized controlled trial	*Journal of Athletic Training 2019 Dec;54(12):1296-1303*
168	Boocock M, Naude Y, Taylor S, Kilby J, Mawston G	Influencing lumbar posture through real-time biofeedback and its effects on the kinematics and kinetics of a repetitive lifting task [with consumer summary]	*Gait & Posture 2019 Jul;73:93-100*
169	Bruce H, Lai L, Bherer L, Lussier M, St-Onge N, Li KZH	The effect of simultaneously and sequentially delivered cognitive and aerobic training on mobility among older adults with hearing loss [with consumer summary]	*Gait & Posture 2019 Jan;67:262-268*
170	Venosa M, Romanini E, Padua R, Cerciello S	Comparison of high-intensity laser therapy and combination of ultrasound treatment and transcutaneous nerve stimulation in patients with cervical spondylosis: a randomized controlled trial	*Lasers in Medical Science 2019 Jul;34(5):947-953*
171	Dornelles MP, Fritsch CG, Sonda FC, Johnson DS, Leal-Junior ECP, Vaz MA, Baroni BM	Photobiomodulation therapy as a tool to prevent hamstring strain injuries by reducing soccer-induced fatigue on hamstring muscles	*Lasers in Medical Science 2019 Aug;34(6):1177-1184*
172	Riva D, Fani M, Benedetti MG, Scarsini A, Rocca F, Mamo C	Effects of high-frequency proprioceptive training on single stance stability in older adults: implications for fall prevention	*BioMed Research International 2019;(2382747):Epub*
173	Elnaggar RK, Elbanna MF	Evaluation of independent versus integrated effects of reciprocal electrical stimulation and Botulinum Toxin-A on dynamic limits of postural stability and ankle kinematics in spastic diplegia: a single-blinded randomized trial	*European Journal of Physical and Rehabilitation Medicine 2019 Apr;55(2):241-249*

174	Xiang M-Q, Liao J-W, Huang J-H, Deng H-L, Wang D, Xu Z, Hu M	Effect of a combined exercise and dietary intervention on self-control in obese adolescents	*Frontiers in Psychology 2019 Jun 28;10(1385):Epub*
175	Samhan AF, Abdelhalim NM	Impacts of low-energy extracorporeal shockwave therapy on pain, pruritus, and health-related quality of life in patients with burn: a randomized placebo-controlled study [with consumer summary]	*Burns 2019 Aug;45(5):1094-1101*
176	Mogharnasi M, Taheri Chadorneshin H, Papoli-Baravati SA, Teymuri A	Effects of upper-body resistance exercise training on serum nesfatin-1 level, insulin resistance, and body composition in obese paraplegic men	*Disability & Health Journal 2019 Jan;12(1):29-34*
177	Yamada M, Kimura Y, Ishiyama D, Nishio N, Otobe Y, Tanaka T, Ohji S, Koyama S, Sato A, Suzuki M, Ogawa H, Ichikawa T, Ito D, Arai H	Synergistic effect of bodyweight resistance exercise and protein supplementation on skeletal muscle in sarcopenic or dynapenic older adults	*Geriatrics & Gerontology International 2019 May;19(5):429-437*
178	Dominik N, Lipinska P, Roczniok R, Spieszny M, Stastny P	Off-ice agility provide motor transfer to on-ice skating performance and agility in adolescent ice hockey players	*Journal of Sports Science and Medicine 2019 Nov;18(4):680-694*
179	de Zwarte D, Kearney J, Corish CA, Glennon C, Maher L, Johnston Molloy C	Randomised study demonstrates sustained benefits of a pre-school intervention designed to improve nutrition and physical activity practices	*Journal of Public Health 2019 Dec;41(4):798-806*
180	da Silva-Grigoletto ME, Mesquita MMA, Aragao-Santos JC, Santos MS, Resende-Neto AG, de Santana JM, Behm DG	Functional training induces greater variety and magnitude of training improvements than traditional resistance training in elderly women [with consumer summary]	*Journal of Sports Science and Medicine 2019 Nov;18(4):789-797*
181	Lee K, Park D, Lee G	Progressive respiratory muscle training for improving trunk stability in chronic stroke survivors: a pilot randomized controlled trial	*Journal of Stroke & Cerebrovascular Diseases 2019 May;28(5):1200-1211*
182	de Paolis G, Naccarato A, Cibelli F, d'Alete A, Mastroianni C, Surdo L, Casale G, Magnani C	The effectiveness of progressive muscle relaxation and interactive guided imagery as a pain-reducing intervention in advanced cancer patients: a multicentre randomised controlled non-pharmacological trial	*Complementary Therapies in Clinical Practice 2019 Feb;34:280-287*
183	Korchi K, Noe F, Bru N, Paillard T	Optimization of the effects of physical activity on plantar sensation and postural control with barefoot exercises in institutionalized older adults: a pilot study	*Journal of Aging and Physical Activity 2019 Aug;27(4):452-465*
184	Boukabous I, Marcotte-Chenard A, Amamou T, Boulay P, Brochu M, Tessier D, Dionne I, Riesco E	Low-volume high-intensity interval training (HIIT) versus moderate-intensity continuous training on body composition, cardiometabolic profile and physical capacity in older women	*Journal of Aging and Physical Activity 2019 Dec;27(6):879-889*
185	Nissim M, Hutzler Y, Goldstein A	A walk on water: comparing the influence of Ai Chi and Tai Chi on fall risk and verbal working memory in ageing people with intellectual	*Journal of Intellectual Disability Research 2019 Jun;63(6):603-613*

		disabilities -- a randomised controlled trial	
186	Nishikawa Y, Watanabe K, Kawade S, Takahashi T, Kimura H, Maruyama H, Hyngstrom A	The effect of a portable electrical muscle stimulation device at home on muscle strength and activation patterns in locomotive syndrome patients: a randomized control trial	*Journal of Electromyography and Kinesiology 2019 Apr;45:46-52*
187	Leach HJ, Covington KR, Voss C, LeBreton KA, Harden SM, Schuster SR	Effect of group dynamics-based exercise versus personal training in breast cancer survivors	*Oncology Nursing Forum 2019 Mar;46(2):185-197*
188	Lee JS, Boafo A, Greenham S, Longmuir PE	The effect of high-intensity interval training on inhibitory control in adolescents hospitalized for a mental illness [with consumer summary]	*Mental Health and Physical Activity 2019 Oct;17(100298):Epub*
189	Sadeghi M, Ghasemi G, Karimi M	Effect of 12-week rebound therapy exercise on static stability of patients with spinal cord injury	*Journal of Sport Rehabilitation 2019 Jul;28(5):464-467*
190	Ferreira J, Bebiano A, Raro D, Martins J, Silva AG	Comparative effects of tensioning and sliding neural mobilization on static postural control and lower limb hop testing in football players	*Journal of Sport Rehabilitation 2019 Aug;28(8):840-846*
191	Zhang YF, Yang LD	Exercise training as an adjunctive therapy to montelukast in children with mild asthma: a randomized controlled trial	*Medicine 2019 Jan;98(2):e14046*
192	Szilagyi B, Kukla A, Makai A, Acs P, Jaromi M	Sports therapy and recreation exercise program in type 2 diabetes: randomized controlled trial, 3-month follow-up [with consumer summary]	*The Journal of Sports Medicine and Physical Fitness 2019 Apr;59(4):676-685*
193	la Valley G, Storer A, Szalai H, Farah M, Pack QR	A motivational telephone intervention to reduce early dropouts in cardiac rehabilitation: a feasibility pilot study	*Journal of Cardiopulmonary Rehabilitation and Prevention 2019 Sep;39(5):318-324*
194	Emami Kashfi T, Sohrabi M, Saberi Kakhki A, Mashhadi A, Jabbari Nooghabi M	Effects of a motor intervention program on motor skills and executive functions in children with learning disabilities	*Perceptual and Motor Skills 2019 Jun;126(3):477-498*
195	Nie L, Cheng J, Wen Y, Li J	The effectiveness of acupuncture combined with Tuina therapy in patients with migraine	*Complementary Medicine Research 2019;26(3):182-194*
196	Takinaci ZD, Karagulle M, Issever H, Karagulle MZ	Clinical efficacy of spa therapy (balneotherapy) for chronic low back pain: a randomized single-blind trial	*European Journal of Integrative Medicine 2019 Aug;29:100928*
197	Levi D, Springer S, Parmet Y, Ovadia D, Ben-Sira D	Acute muscle stretching and the ability to maintain posture in females with adolescent idiopathic scoliosis	*Journal of Back and Musculoskeletal Rehabilitation 2019;32(4):655-662*
198	Pasin T, Ataoglu S, Pasin O, Ankarali H	Comparison of the effectiveness of platelet-rich plasma, corticosteroid, and physical therapy in subacromial impingement syndrome	*Archives of Rheumatology 2019 Sep;34(3):308-316*
199	Mogharnasi M, TajiTabas A, Tashakorizadeh M, Nayebifar SH	The effects of resistance and endurance training on levels of nesfatin-1, HSP70, insulin resistance and body composition in women with type 2 diabetes mellitus	*Science & Sports 2019 Feb;34(1):e15-e23*

200	Ogbutor GU, Nwangwa EK, Uyagu DD	Isometric handgrip exercise training attenuates blood pressure in prehypertensive subjects at 30% maximum voluntary contraction	*Nigerian Journal of Clinical Practice 2019 Dec;22(12):1765-1771*

3 CONSIDERAÇÕES FINAIS

O objetivo do estudo foi investigar a prevalência e qualidade de registros de ensaios clínicos de intervenções fisioterápicas e a proporção de relato seletivo de desfechos; e comparar com os dados coletados em 2009 publicados em um estudo anterior[23]. O interesse em desenvolver um estudo comparativo com dados prévios veio da necessidade de se acompanhar a evolução do impacto das recomendações relacionadas ao registro de ensaios clínicos especificamente na área da fisioterapia.

O registro de ensaios clínicos de intervenções de fisioterapia aumentou neste período de 10 anos, mas ainda apresenta um déficit de registros em quase 40% da amostra total. A proporção de ensaios clínicos registrados de forma prospectiva também foi maior em 2019, quando contrastado com 2009. Entretanto, a qualidade dos registros ainda não atingiu o ideal, visto que menos de 10% da amostra apresentou um registro adequado. A variação de prevalência de registro entre continentes e a maior prevalência de registros em publicações realizadas em jornais com alto fator de impacto também trazem à tona o fato de que mesmo que muitos periódicos científicos tenham uma política mandatória de publicar apenas ensaio clínicos registrados prospectivamente, esta recomendação ainda não está atingindo igualmente todos os pesquisadores que conduzem ensaios clínicos na área da fisioterapia.

O aumento dos registros não foi acompanhado pelo aumento proporcional da qualidade da informação registrada. Nossos dados demonstram que quando considerados, conjuntamente, os registros com desfechos ambíguos e não ambíguos, houve um aumento da prevalência de inconsistência de desfechos de 55% em 2009 para 77% em 2019. Seguindo a mesma tendência, o relato seletivo de desfechos, que é um dado avaliado considerando-se apenas os registros com descrição não ambígua do desfecho primário, apresentou um aumento de 47% na amostra de 2009 para 73% em 2019. Esses dados demonstram que a prevalência de registros aumentou, mas a qualidade com que eles são realizados necessita de avanços. Ademais, nos registros em que foi possível ser avaliado, 22% apresentaram evidência de relato seletivo de desfechos favorecido pela significância estatística. Essa prevalência foi menor do que os 50% observados em 2009.

O fato do aumento no reporte seletivo de desfecho não ter acompanhado o relato seletivo de desfechos favorecido pela significância estatística sugere que outros fatores parecem estar influenciando na falta de consistência entre desfechos descritos no registro e os divulgados na publicação. Um possível motivo parece ser o não conhecimento dos autores em relação ao motivo de se registrar o ensaio clínico e de seguir os dados fornecidos no registro. Há relato de autores que veem no registro uma mera formalidade, fato esse que se distorce da real importância do registro prospectivo do ensaio clínico[31,32]. Sob esse viés, parece ser relevante que, dentro das universidades, as disciplinas sobre condução de ensaios clínicos reforcem o objetivo do registro e sua importância, para que os futuros pesquisadores tenham a real dimensão sobre o valor do registro prospectivo.

Nosso local de coleta de dados foi a base de dados PEDro. Levando em consideração que o Brasil é um dos países que mais acessam essa base de dados e pensando em uma estratégia local, também parece ser interessante reforçar para nossos pesquisadores e consumidores de produção científica no geral, o impacto do registro prospectivo dos ensaios clínicos na qualidade dos reportes acessados. Dessa forma, os próprios leitores poderiam auxiliar na melhora da qualidade da pesquisa produzida ao não dar engajamento às publicações com inconsistências importantes entre registro e reporte.

Em suma, houve um aumento de quase duas vezes na prevalência de registros de 2009 para 2019, seguido por uma prevalência três vezes maior de registro prospectivo no mesmo período. Contudo, a prevalência de ausência de registro em 40% da amostra avaliada e a qualidade incipiente dos registros realizados demonstram que ainda são necessárias estratégias para que os benefícios do registro sejam atingidos em sua totalidade.

REFERÊNCIAS

1. Herbert RD, Jamtvedt G, Mead J et al. *Practical Evidence-Based Physiotherapy*. Vol 2. Elsevier Butterworth Heinemann; 2010.

2. Hariton E, Locascio JJ, Hospital MG. Randomised controlled trials—the gold standard for effectiveness research. *BJOG*. 2018;125(13):1-4. doi:10.1111/1471-0528.15199.Randomised

3. Cashin AG, McAuley JH. Clinimetrics: Physiotherapy Evidence Database (PEDro) Scale. *J Physiother*. 2020;66(1):59. doi:10.1016/j.jphys.2019.08.005

4. Chan A, Tetzlaff J, Altman D. SPIRIT 2013 Statement: Defining Standard Protocol Items for Clinical Trials. *Ann Intern Med*. 2013;158:200-207. https://www.cdc.gov/violenceprevention/aces/fastfact.html#:~:text=Adverse childhood experiences%2C or ACEs,attempt or die by suicide

5. Yordanov Y, Dechartres A, Atal I, et al. Avoidable waste of research related to outcome planning and reporting in clinical trials. *BMC Med*. 2018;16(1):1-11. doi:10.1186/s12916-018-1083-x

6. Schulz KF, Altman DG, Moher D, Group C. CONSORT 2010 Statemen : updated guidelines for reporting parallel group randomised trials. 2010;340(march). doi:10.1136/bmj.c332

7. Costa LOP, Lin CWC, Grossi DB, et al. Clinical trial registration in physiotherapy journals: Recommendations from the International Society of Physiotherapy Journal Editors. *Eur J Physiother*. 2013;15(2):42-45. doi:10.3109/21679169.2013.802476

8. World Health Organization. Clinical Trials Registry Plataform. Accessed October 28, 2021. https://www.who.int/clinical-trials-registry-platform

9. World Health Organization. Why is trial registration Important? Accessed October 28, 2021. https://www.who.int/clinical-trials-registry-platform/network/trial-registration

10. World Health Organization. WHO Trial Registration Data Set (Version 1.3.1). Accessed October 28, 2021. https://www.who.int/clinical-trials-registry-platform/network/who-data-set

11. Moher D. Clinical-trial registration: a cal its implementation in Canada. *Can Med Assoc J*. 1993;149(11):1657-1658.

12. Weitzman D, de Wend Cayley FE, Wingfield AL. Streptomycin in the treatment of pulmonary tuberculosis. *Br J Tuberc Dis Chest*. 1950;44(4):98-104. doi:10.1016/S0366-0869(50)80004-7

13. Verstraete M. Registry of prospective clinical trials. *Thromb Diath Haemorrh*. 1975;30(33):655-663. https://pubmed.ncbi.nlm.nih.gov/125464/

14. De Angelis C, Drazen JM, Frizelle FA, et al. Is this clinical trial fully registered? A statement from the International Committee of Medical Journal Editors. *N Engl J Med*. 2005;352:2436-2438.

15. The World Medical Association Inc. Declaration of Helsinki. *DoH*. Published online 2008:1-5. https://www.wma.net/wp-content/uploads/2016/11/DoH-Oct2008.pdf%0Ahttps://www.wma.net/policies-post/wma-declaration-of-helsinki-ethical-principles-for-medical-research-involving-human-subjects/

16. Dechartres A, Ravaud P, Atal I, Riveros C, Boutron I. Association between trial registration and treatment effect estimates: A meta-epidemiological study. *BMC Med*. 2016;14(1):1-9. doi:10.1186/s12916-016-0639-x

17. Babu AS, Veluswamy SK, Rao PT, Maiya AG. Clinical Trial Registration in Physical Therapy Journals: A Cross-Sectional Study. *Phys Ther*. 2014;94(1):83-90. doi:10.2522/ptj.20120531

18. Askie L, Ghersi D, Simes J. Prospective registration of clinical trials. *Aust J Physiother*. 2006;52(4):237-239. doi:10.1016/S0004-9514(06)70002-2

19. Chan AW, Hróbjartsson A, Haahr MT, Gøtzsche PC, Altman DG. Empirical evidence for selective reporting of outcomes in randomized trials: Comparison of protocols to published articles. *J Am Med Assoc*. 2004;291(20):2457-2465. doi:10.1001/jama.291.20.2457

20. Hopewell S, Loudon K, Clarke MJ, Oxman AD, Dickersin K. Publication bias in clinical trials due to statistical significance or direction of trial results. *Cochrane Database Syst Rev*. 2009;(1). doi:10.1002/14651858.MR000006.pub3

21. U.S. National Library of Medicine. Why Should I Register and Submit Results? Accessed October 28, 2021. https://clinicaltrials.gov/ct2/manage-recs/background

22. Mathieu S, Moher D, Altman DG. Comparison of Registered and Published Primary Outcomes in Randomized Controlled Trials. *JAMA - J Am Med Assoc*. 2009;302(9):977-984.

23. Pinto RZ, Elkins MR, Moseley AM, et al. Many randomized trials of physical therapy interventions are not adequately registered: A survey of 200 published trials. *Phys Ther*. 2013;93(3):299-309. doi:10.2522/ptj.20120206

24. Trinquart L, Dunn AG, Bourgeois FT. Registration of published randomized trials : a systematic review and meta-analysis. Published online 2018:1-13.

25. Jones CW, Platts-mills TF. Quality of Registration for Clinical Trials Published in Emergency Medicine Journals. *YMEM*. 2011;60(4):458-464.e1. doi:10.1016/j.annemergmed.2012.02.005

26. Gray R, Gray G, Ellie S. A review of prospective registration of trials published in nursing science journals in 2017. 2019;(April):1-9. doi:10.1111/jan.14131

27. Koufatzidou M, Koletsi D, Fleming PS, Polychronopoulou A, Pandis N. Outcome reporting discrepancies between trial entries and published final reports of orthodontic randomized controlled trials. 2019;(July 2018):225-230. doi:10.1093/ejo/cjy046

28. García-vello P, Smith E, Elias V, Florez-pinzon C, Reveiz L. Adherence to clinical trial registration in countries of Latin America and the Caribbean , 2015. Published online 2018:1-9.

29. Reveiz L, Villanueva E, Iko C, Simera I. Compliance with clinical trial registration and reporting guidelines by Latin American and Caribbean journals Adherencia a las iniciativas de registro de ensayos clínicos y guías de reporte por revistas de América Latina y Caribe Adesão às iniciativas de. 2013;29(6):1095-1100.

30. Wager E, Williams P. “Hardly worth the effort”? Medical journals’ policies and their editors’ and publishers’ views on trial registration and publication bias: Quantitative and qualitative study. *BMJ*. 2013;347(7926). doi:10.1136/bmj.f5248

31. Riley SP, Swanson BT, Shaffer SM, Sawyer SF, Cleland JA. The Unknown Prevalence of Postrandomization Bias in 15 Physical Therapy Journals: A Methods Review. *J Orthop Sport Phys Ther*. 2021;51(11):542-550. doi:10.2519/jospt.2021.10491

32. Loder E, Loder S, Cook S. Characteristics and publication fate of unregistered and retrospectively registered clinical trials submitted to The BMJ over 4 years. Published online 2018:1-7. doi:10.1136/bmjopen-2017-020037

APÊNDICES

APÊNDICE A – QUESTIONÁRIO PARA COLETA DE DADOS

RCT Extraction

Correct Worksheet

fisioterapia.nayara@gmail.com (não compartilhado) Alternar conta

*Obrigatório

1. Reviewer *

- ◯ Mark Elkins
- ◯ Anne Moseley
- ◯ Peter Stubbs
- ◯ Márcia Franco
- ◯ Rafael Z Pinto
- ◯ Nayara Santos
- ◯ Ítalo Ribeiro

2. Date *

Data

dd/ mm/ aaaa

3. First author and year *

Sua resposta

4. Clinical trial register *

- ISRCTN (controlled-trials.com)
- Netherlands trial register (trialregister.nl)
- ANZCTR
- NCT (clinicaltrials.gov)
- Stroke trials Registry (strokecenter.org)
- Another

5. Trial registration information *

- Prospective
- Retrospective
- During
- Not registered

5.1 Comments about trial registration information

Sua resposta

6. If prospectively registered, has the protocol changed after recruitment started? *

- Yes
- No
- Unclear
- Not applicable

6.1 Comments about protocol changes

Sua resposta

7. Publication: Sample size *

Sua resposta

8. Publication: Primary Outcome *

Sua resposta

9. Publication: Secondary Outcomes *

Sua resposta

10. Publication: Time point/s of assessment *

Sua resposta

11. Protocol: Sample size *

Sua resposta

12. Protocol: Primary Outcome *

Sua resposta

13. Protocol: Secondary Outcomes *

Sua resposta

14. Protocol: Time point/s of assessment *

Sua resposta

15. Did the registered protocol specify the primary outcome's? *

- [ ] Definition
- [ ] Analysis method
- [ ] Time point
- [ ] None

15.1 Comments about item 15

Sua resposta

16. About primary outcome

- [ ] The registered primary outcome was reported as a secondary outcome in the published article
- [ ] The registered primary outcome was omitted in the published report
- [ ] A new primary outcome was introduced in the published article (e.g., a registered secondary outcome that becomes primary in the article or an outcome that does not appear at all in the registry but is introduced as primary in the article)
- [ ] The published primary outcome was described as a secondary outcome in the protocol
- [ ] The timing of assessment of the registered and published primary outcomes differed

16.1 Comments about item 16

Sua resposta

17. Did any of the above favour statistically significant results? *

- Yes
- No
- Unclear
- Not applicable

17.1 Comments about item 17

Sua resposta

18. Primary outcomes (were considered unambiguous if the trial registry entry for prospective registered trial specified both the definition and time points for analysis. For example, “lung function” would be considered ambiguous on both criteria, whereas “change in forced vital capacity at 3 months” would be considered unambiguous) *

- Unambiguous
- Ambiguous
- Not applicable (not prospectively registered)

18.1 Comments about item 18

Sua resposta

19. Nonprimary/secondary outcomes (inconsistent when the nonprimary outcomes listed in the registry entry did not match those listed in the published report) *

- ◯ Consistent
- ◯ Inconsistent

19.1 Comments about item 19

Sua resposta

20. Did the protocol include information on the statistical analysis for the trial? *

- ◯ Yes
- ◯ No
- ◯ Unclear

21. If yes, did the analyses in the protocol differ from the analyses in the publication? *

- ◯ Yes
- ◯ No
- ◯ Unclear
- ◯ Not applicable

22. If the protocol differed from the publication, what aspect of the analysis differed: *

- ◯ Subgroup analysis
- ◯ Adjusted analysis
- ◯ Other
- ◯ Not applicable

22.1 Comments about item 22

Sua resposta

Any comments on changes to the protocol or publication?

Sua resposta

Enviar Limpar formulário

MINI-CURRÍCULO

ATIVIDADES DESENVOLVIDAS ATÉ O PERÍODO DO MESTRADO (2022)

Dados Pessoais:

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2018-2019: Secretaria Municipal de Saúde de Araújos. Araújos-MG. Vínculo: Estatutário. Enquadramento Funcional: Fisioterapeuta, Carga Horária: 20.

2017: Espaço Revitta. Vínculo: Profissional autônoma. Enquadramento Funcional: Fisioterapeuta, Carga Horária: 30.

2016: Clínica Ficar Bem. Vínculo: Profissional autônoma. Enquadramento Funcional: Fisioterapeuta, Carga Horária: 30.

PRODUÇÃO BIBLIOGRÁFICA:

Projetos de Pesquisa:

The effectiveness of a neuromuscular training, that require minimal or no equipment, on youth athletes Performance, during Olympic team sport participation: A Systematic Review and Meta-Analysis. Integrantes: Nayara Santos Silva, Marina

Rocha Muller, Rafael Zambelli Pinto, Ítalo Ribeiro Lemes, Michelle Sena de Castro Silva. (Em estágio de publicação)

PINHEIRO, M. B. ; SILVA, S. L. A. ; ZAMBELLI, M. R. F. ; REIS, A. S. ; SILVA, N. S. Safe Exercise at Home Booklet, 2021. Tradução.

Orientações de trabalho:

Título: Efeito do pilates no ângulo de Cobb de indivíduos com escoliose. Aluna: Larissa Cristina Guimarães. Especialização em Fisioterapia da UFMG 2023.

Título: Terapia Manual nas Patologias Traumato-Ortopédicas do Ombro. Aluna: Joyce de Jesus Marques. Especialização em Fisioterapia da UFMG 2023.

Título: Efeito do exercício mais educação em neurociência da dor na dor e funcionalidade em indivíduos com dor lombar persistente. Aluna: Samantha Lucilia Cruz. Especialização em Fisioterapia da UFMG 2023.

Participações em cursos e congressos no período do mestrado

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