UNIVERSIDADE FEDERAL DOS VALES DO JEQUITINHONHA E MUCURI
Programa de Pós-Graduação Em Reabilitação e Desempenho Funcional
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EFICÁCIA DO TREINO DE FORÇA DA MUSCULATURA ROTADORA LATERAL DO QUADRIL NA RIGIDEZ PASSIVA, CINÉTICA E CINEMÁTICA DO QUADRIL.

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HYTALO DE JESUS SILVA

EFICÁCIA DO TREINO DE FORÇA DA MUSCULATURA ROTADORA LATERAL DO QUADRIL SOBRE A RIGIDEZ PASSIVA E CINEMÁTICA DO QUADRIL: UM ESTUDO CLÍNICO RANDOMIZADO

Dissertação apresentada ao MESTRADO EM REABILITAÇÃO E DESEMPENHO FUNCIONAL, nível de MESTRADO como parte dos requisitos para obtenção do título de MESTRE EM REABILITAÇÃO E DESEMPENHO FUNCIONAL

Orientador (a): Prof.ª Dr.ª Luciana De Michelis Mendonça

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RESUMO

INTRODUÇÃO - A força dos músculos rotadores laterais (RL) do quadril é frequentemente investigada por interferir em tarefas funcionais, como marcha, corrida e aterrissagem do salto. No entanto além da ação muscular, outras propriedades da articulação do quadril como sua rigidez articular passiva merecem atenção, pelo fato de contribuírem durante a realização dessas tarefas. Uma rigidez passiva adequada pode resistir ao movimento articular reduzindo a necessidade de contração muscular, e consequentemente o gasto energético para promoção da estabilidade funcional. Além disso, uma rigidez passiva adequada pode limitar a ocorrência de padrões de movimento rotação medial do membro inferior e pronação excessiva da subtalar, além diversas lesões nos membros inferiores, como, dor patelofemoral, lesão de ligamento cruzado anterior e síndrome do estresse tibial medial. **OBJETIVO** - Verificar a viabilidade de um estudo sobre o efeito do fortalecimento dos rotadores laterais na rigidez passiva, cinética e cinemática do quadril. **MÉTODOS** - Foram realizados os seguintes testes: Teste isométrico de rotadores laterais do quadril; amplitude de movimento passiva de rotação medial do quadril; Cinética e cinemática do quadril durante agachamento unipodal. Os participantes foram aleatoriamente distribuídos entre dois grupos. Grupo 1 - intervenção, grupo 2 - controle. O programa de fortalecimento muscular foi realizado 3 vezes a semana durante 8 semanas com carga de 80% de 1RM. A alocação dos participantes para cada grupo aleatorizada utilizando envelope pardo. Três artigos compõem esse estudo 1) Protocolo de Viabilidade de Estudo Clínico Aleatorizado; 2) Viabilidade de Estudo Clínico Aleatorizado; 3) Protocolo de Estudo Clínico Aleatorizado. **RESULTADOS –** Três dos cinco critérios de viabilidade previamente estabelecidos foram alcançados, não houve diferença significativas entre os grupos quanto aos desfechos de interesse para o estudo final. **CONCLUSÃO -** O Estudo Clínico Aleatorizado é viável na população sedentária.

Palavras-chave: Palavras chaves: Rigidez passiva; Rotador lateral; Cinemática do quadril

ABSTRAT

INTRODUCTION - The strength of the hip external rotator muscles (LR) is often investigated because it interferes with functional tasks such as gait, running vertical jump. However, in addition to muscle action, other hip properties joint, such as its passive joint stiffness, deserve attention because they contribute during the performance of these tasks. Passive stiffness is determined by the rate of change in resistance torque during angular displacement of a joint in the absence of muscle contraction. Adequate passive stiffness can withstand joint movement reducing the need for muscle contraction, and consequently energy expenditure to promote functional stability. In addition, adequate passive stiffness may limit the occurrence of movement patterns of lower limb internal rotation and excessive subtalar pronation, as well as several lower limb injuries such as patellofemoral pain, anterior cruciate ligament injury, and medial tibial stress syndrome. **OBJECTIVE** - To enable a more robust study to verify the effect of external rotator strengthening on passive, kinetic and kinematic hip stiffness. **METHODS** - The following tests was performed: Hip external rotator Isometric torque test; hip IR range of motion, hip and knee kinetics and kinematics. The participants were randomly distributed between two groups. Group 1 – intervention and group 2 - control. The muscle strengthening program was performed 3 times a week for 8 weeks, three sets of eight repetitions with an intensity of 80% of one-repetition maximum (1RM) with a 2-min rest allowed between sets. The allocation of participants to each randomized group using the brown envelope. Three articles make up this study 1) Randomized Clinical Trial Viability Protocol; 2) Protocol Feasibility of Randomized Clinical Trial; 3) Randomized Clinical Trial. **RESULTS** - Three of the five previously established viability criteria were met, there was no significant difference between the groups regarding the outcomes of interest for the final study. **CONCLUSION** - Randomized Clinical Trial is feasible in sedentary population.

Keywords: Passive stiffness; External rotator; Hip kinematics

SUMÁRIO

CAPÍTULO 1 – REFERENCIAL TEÓRICO

A força dos músculos RL do quadril é frequentemente investigada por interferir em tarefas funcionais, como marcha, corrida e aterrissagem do salto (SOUZA *et al*., 2014)(SOUZA *et al*., 2010) (BITTENCOURT *et al*., 2012). No entanto além da ação muscular, outras propriedades da articulação do quadril, como sua rigidez articular passiva merecem atenção. Rigidez passiva é determinada pela taxa de mudança do torque de resistência durante o deslocamento angular de uma articulação, na ausência de contração muscular (HERBERT, 1988) (MAGNUSSON, 1998). As propriedades mecânicas dos tecidos conectivos conferem resistência ao deslocamento articular, exercendo ação complementar a ativação muscular durante tarefas funcionais (GAJDOSIK, 2001). A rigidez articular é dependente da área de secção transversa e da composição dos tecidos que estão ao redor da articulação (RYAN *et al*., 2009). Alguns autores investigaram a correlação entre rigidez passiva e força muscular (RYAN *et al*., 2009) (CHLEBOUN *et al.,* 1997). Ryan e colaboradores (2009) encontraram um coeficiente de correlação de 0,83 entre a área de secção transversa dos flexores plantares e a rigidez passiva durante o movimento de dorsiflexão do tornozelo. Por sua vez Chleboun e colaboradores (1997) demonstraram coeficientes de correlação entre 0,79 e 0,92 para as mesmas medidas nos flexores do cotovelo.

Uma rigidez passiva adequada pode resistir ao movimento articular reduzindo a necessidade de contração muscular (SILVA *et al*., 2009), e consequentemente o gasto energético (DUMKE *et al*., 2010) (ARAMPATZIS *et al*., 2006) para promoção da estabilidade funcional. Desta forma, a baixa rigidez dos músculos rotadores laterais do quadril pode resultar em rotação medial excessiva do quadril durante a realização de atividades em cadeia cinética fechada (FONSECA *et al*., 2007), podendo contribuir, por exemplo, para a ocorrência de pronação excessiva da articulação subtalar (SOUZA *et al*., 2010), alteração da postura pélvica nos planos sagital e frontal e do alinhamento da coluna vertebral (PINTO *et al*., 2008). Além disso, diversas lesões nos membros inferiores podem estar associadas a essa disfunção do movimento, como por exemplo, dor patelofemoral

(POWERS, 2003) (THIJS et al., 2011), lesão de ligamento cruzado anterior (HEWETT et al., 2005) e síndrome do estresse tibial medial (SOUZA et al., 2011).

Bittencourt e colaboradores (2012) identificaram que durante o agachamento unipodal, o excessivo ângulo de projeção frontal do joelho foi resultado da interação entre baixo torque isométrico de abdutores do quadril e excessiva amplitude de movimento passiva de rotação medial (AMPRM) do quadril. Durante a fase de aterrissagem do salto vertical, o ângulo de projeção do joelho no plano frontal foi devido à interação entre o alinhamento perna/antepé, baixo torque isométrico de abdutores de quadril, e AMPRM do quadril. Segundo Souza e colaboradores (2014) a AMPRM do quadril prediz parcialmente a cinemática do retropé durante caminhada e postura ortostática, estando diretamente relacionada a pronação da articulação subtalar. Esses resultados apontam para uma grande influência da AMPRM sobre atividades do cotidiano, e a necessidade de sua adequação para possibilitar uma melhor postura estática e melhoria no padrão de movimento durantes tarefas funcionais.

No intuito de aumentar a rigidez articular passiva, Araújo e colaboradores (2017) realizaram um estudo longitudinal que compreendia no fortalecimento da musculatura do quadril e tronco. O fortalecimento foi realizado três vezes por semana durante oito semanas com intensidade entre 70% a 80% de uma repetição máxima. Como resultado esses autores observaram mudança no ponto de repouso da articulação do quadril. O ponto de repouso de uma articulação pode ser definida como à posição angular em que os torques de agonista e antagonista são de igual magnitude (CARVALHAIS et al., 2011). Nesse sentido, os resultados demonstraram que o fortalecimento muscular foi suficiente para mudar a posição articular em direção à rotação lateral do quadril. De forma similar, Ocarino e colaboradores (2008) observaram mudança significativa no ponto de repouso da articulação do cotovelo após oito semanas de fortalecimento muscular de flexores de cotovelo em posição encurtada quando comparado com o controle. Essas informações sugerem que o fortalecimento dos músculos RL do quadril pode ser utilizado como ferramenta clínica para modificar os níveis de rigidez articular.

Apesar das informações indicadas anteriormente, a eficácia do fortalecimento dos rotadores laterais do quadril na rigidez passiva articular ainda é incerta devido ao pequeno número de ensaios clínicos randomizado (OCARINO *et al*.,2008). Além disso, falhas metodológicas podem ser apontadas nos estudos anteriormente desenvolvidos, como por exemplo, o número de exercícios de fortalecimento insuficientes para causar alterações na estrutura muscular, avaliador não cego, pequeno tamanho da amostra e baixo poder estatístico Por esse fato são necessários ensaios clínicos randomizados de alta qualidade para esclarecer os efeitos do fortalecimento muscular na rigidez passiva e na cinemática.

No intuito de construir um estudo com qualidade metodológica adequada para responder essa pergunta, é fundamental que se desenvolva um estudo com aleatorizado, com tamanho amostral adequado e que seja composto de um protocolo de fortalecimento com propriedade para causar mudança na estrutura musculo tendínea. Uma revisão de literatura previamente realizada descreveu protocolos de fortalecimento para ganho nos diferentes domínios musculares. Foi observado que para aumento da hipertrofia muscular o protocolo mais adequado é composto por três séries de oito repetições com uma intensidade de 80% de uma repetição máxima e dois minutos de repouso entre as séries (KRAEMER et al., 2002). Este protocolo é capaz de fornecer estímulo suficiente para produzir hipertrofia muscular. Caso o participante consiga realizar uma repetição acima do número estabelecido em todas as séries em duas sessões de treinamento consecutivas, a carga de ser aumentada em 10% da força muscular máxima (KRAEMER *et al*., 2002) para garanter a progressão da carga.

O presente estudo se justifica devido à necessidade de viabilizar um estudo mais robusto para verificar o efeito do fortalecimento dos RL na rigidez, cinética e cinemática do quadril.

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CAPÍTOLO 2. Efficacy of strength training of the hip external rotator muscles on hip passive stiffness and kinematics: protocol of a feasibility randomized controlled trial

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Abstract

Background. Stress and strain relationship are acknowledged to be important determinants for muscle stiffness. An adequate stiffness control joint excessive movement promoting functional stability. Decreased stiffness of the hip external rotator (ER) muscles could result in excessive hip internal rotation (IR) during closed kinematic chain tasks. Some lower-limb injuries are associated with excessive hip IR. However, whether muscle hypertrophy increases passive stiffness and enhances proper movement pattern remains unclear.

Objective. This study will assess the feasibility of a randomized controlled trial (RCT) investigating the effects of hip external rotator (ER) muscle strengthening on hip passive stiffness and transverse plane hip kinematics during the single-leg squat.

Design. Feasibility Protocol for a Randomized Clinical Trial

Setting. University's physical therapy clinical center.

Participants. Eighty healthy sedentary adults will participate in the study.

Methods. Participants will be randomly allocated to an 8-week hip ER muscle strengthening program or will undergo no intervention. The primary outcomes are related to feasibility, including: (1) assessor blinding; (2) eligibility and recruitment rates; (3) acceptability of screening procedures and random allocation; (4) possible between-group contamination; (5) intervention adherence; (6) treatment satisfaction; and (7) difficulty in understanding the provided intervention.

Ethics/dissemination. The protocol was approved by University's Ethics research committee (protocol number 88004918.2.0000.5108). The results of the study will be presented at national and international conferences and published in a peer reviewed journal.

Keywords

stiffness; muscle; Hip; kinematics

Introduction

The stress and strain curve is acknowledged to be important determinants for muscle stiffness, and an adequate passive stiffness may control joint excessive movement[8] promoting functional stability[18]. In this context, joint motions of the lower limb during closed chain are interdependent and an inappropriate passive stiffness may cause excessive movements from specific joints overloading local and non-local tissues [11 19]. For instance, an excessive hip internal rotation may move the knee joint center medially in relation to the fixed foot considering lower limbs fixed to the ground[20]. This undesirable movement pattern of the knee joint[1611] may cause many different musculoskeletal conditions[13 16] such as, patellofemoral pain[13 14], anterior cruciate ligament injury[15] and medial tibial stress syndrome[16]. Therefore, we should investigate interventions which could contributes to avoid this type of undesirable movement patterns.

Studies have investigated effectiveness of different interventions to control joint passive stiffness, including hip external rotator muscles strengthening.[8 21 22]Joint passive stiffness is associated with the cross-sectional area and structure of surrounded tissues of the joint[23]. Therefore, strengthening may be effective on its passive stiffness and resting position[24 25 26] because it leads to an increase in the number of sarcomeres in parallel and in the number and size contractile proteins and not contractile as the titin responsible for the sarcomere support. [27 28 29] Supporting this hypothesis, previous studies found high association between passive stiffness and muscle strength in the elbow and ankle joints[23 30]. Nevertheless, the effectiveness of strengthening of the hip external rotator on joint passive stiffness and resting position is still unclear due to small number of high-quality randomized controlled trials. [21 22] Besides the small number of studies they still present important methodological failures such as, number of exercises that may have been insufficient to cause changes in muscle structure, unblinded assessor, small sample size and statistical power low. High-quality randomized controlled trials are warranted to clarify the effects of muscle strengthening on passive stiffness and kinematics.

As there was no trial of strengthening of the hip external rotator on joint passive stiffness and resting position, we propose a feasibility study to investigate potential issues such as interest of the population (i.e., healthy people) to participate in the trial because they do not have a previous diagnosed musculoskeletal condition. Conclusions of the study will be useful for planning a full trial if the results indicate that it is needed. The primary aim of the study is to assess the feasibility of a full randomized controlled trial (RCT) investigating the effects of hip external rotator (ER) muscle strengthening on hip passive stiffness and transverse plane hip kinematics during the single-leg squat. In the current study, assessment of feasibility will be related to: (1) assessor blinding; (2) eligibility and recruitment rates; (3) acceptability of screening procedures and random allocation; (4) possible between-group contamination; (5) intervention adherence; (6) treatment satisfaction; and (7) difficulty in understanding the provided intervention.

METHODS AND ANALYSIS

Study design and setting

The current feasibility study of the RCT will follow the recommendations for interventional trials (SPIRIT)[31] and the consolidated standards of reporting trials statement to feasibility trials. [32] The assessor-blinded, two-arm, feasibility RCT will be conducted in the University's outpatient physical therapy center in Diamantina, Brazil. Protocol of the current study is registered in Clinical trials (RBR-6wvd9) and project was approved by the University's ethics committee (protocol number 88004918.2.0000.5108).

Overview of the study

A convenient sample of healthy people from the community will be recruited throughout advertisement in radio and social media. Healthy people aged 18 years old or older, sedentary, will be invited to participate. After consenting, eligible participants will be randomly assigned to one of the two study groups. Participants in the experimental group (EG) will receive an 8-week hip ER muscle strengthening program, three sets of eight repetitions with an intensity of 80% of 1RM, with a 2-min rest allowed between sets. [33]

This protocol was chosen because it is described as adequate to obtain muscle hypertrophy. [33] The control group (CG) will be instructed to continue performing their activities of daily living, and not to initiate physical activities during the study. All participants will be assessed at the baseline, at post-intervention (i.e., eight weeks after the baseline) to investigate the short-term effects and at the 20-week follow-up (i.e., twenty weeks after the baseline) to investigate potential retention of effects. Detailed description of enrolment, study groups and assessment are presented in table 1.

Participants

Healthy sedentary individuals will be selected by an eligibility screening. We will include individuals of both sexes, 18 years-old or older, healthy and sedentary who have not been submitted to surgical procedures or rehabilitation on the hip or have not suffered any musculoskeletal injury on the lower limbs or trunk in the last six months. We will consider as sedentary, individuals who do less than 30 minutes of moderate aerobic physical activity during 5 days a week, or 20 minutes of vigorous aerobic activity during 3 days a week, or less than 2 days a week of resistance training[34]. Individuals will be excluded from the study if they are unable to perform the passive hip IR range of motion (ROM) test or have pain during any procedure.

Sample size

For a feasibility study, it is inappropriate to calculate sample size based on desired statistical power to detect a treatment effect[35] because the primary aim of the study is to assess whether a full trial should be conducted. Feasibility outcomes are descriptive in nature; therefore, inferential statistics regarding treatment effects will not be computed. To achieve the primary aims of the study, the research team estimated a sample of 20 participants.

Participant screening and recruitment

Interested people from the community will contact the research team and researchers will assess them for our eligibility criteria. Eligible people will sign an informed consent form

prior to participation. Then, age, sex, lower limb dominance, history of injuries and level of physical activity will be collected by the researcher.

Group allocation, randomization and blinding

After recruitment, participants will be randomly allocated in one of the two groups: CG; or EG using sealed and opaque envelopes. A person not involved in the study will open and inform the allocated group for participants. The sample will be stratified by sex, since it may influence hip passive stiffness[36].

Interventions

Experimental group

The physiotherapist responsible for the experimental group will be trained a priori. The one-repetition maximum (1RM) test will be performed first for each exercise and these data will be used based on load prescription for the strengthening protocol. The protocol will consist of three sets of eight repetitions with an intensity of 80% of 1RM, with a 2-min rest allowed between sets, aiming muscle hypertrophy.[33] If the participant is able to perform a repetition above the number established in all series in two consecutive training sessions, the load will be increased by 10% of the 1RM.[33] The protocol will be preceded by a warm-up and succeeded by a cool-down (walking at self-selected pace). All strengthening exercises will be performed bilaterally.

The strengthening protocol will consist of: Hip external rotation against the resistance of a pulley mechanism (sitting) [37] ; Hip Extension in Quadruped position with elbows and Knee Flexed [38]; Hip Extension in Quadruped position with Elbows flexed and Knee Extended [38]; hip ER strengthening in ventral decubitus against the resistance of a pulley mechanism[39]; and Hip external rotation in closed kinetic chain[40].

Control group

The CG will be instructed to continue performing their activities of daily living and not to initiate physical activities during the study period. They will not receive any intervention.

Outcome measures

The primary feasibility outcomes are presented in table 2. Secondary measures include passive hip IR ROM, hip and knee kinematics in the transverse and frontal plane, hip and knee kinematics in the transverse and frontal plane. All secondary outcome measures have been shown to be reliable and valid.[17]

Passive Hip IR Range of Motion: Each participant will be positioned in prone position with the pelvis stabilized by Velcro® straps. An inclinometer will be placed 5 cm distal to the tibial tuberosity. To reduce tissue viscoelasticity, the examiner will perform five passive movements of internal and external hip rotation. This limb will then be positioned at 90° of knee flexion and neutral hip rotation. The participant will be instructed to keep the muscles relaxed and allow the movement of hip IR until passive structures interrupt the movement. At this time, a measurement will be taken using an analog inclinometer. The measurement will be discarded and repeated if the assessor perceives any muscle contraction visually or on palpation.

Data for calculating the intraclass correlation coefficients (ICC) for the reliability of the passive hip IR ROM was collected on two occasions with a 1-week interval between them during a pilot study. For six individuals of both sexes, the evaluator achieved excellent test reliability, i.e., ICC values of 0.99 (0.98–0.99).

Transverse Plane Hip Kinematics

A three-dimensional motion capture system consisting of nine cameras (Oqus 3+; Qualisys, Gothenburg, Sweden) will be used to evaluate the hip kinematics at 6 degrees of freedom. Retro-reflective markers will be placed on the lower limbs and pelvis using the Calibrated Anatomical System technique.[41] Static calibration tests will be obtained with the participant in the anatomical position. Kinetic data will be collected using two force plates sampled at 2000 Hz (Advanced Mechanical Technology Inc., Watertown, MA, USA). The joint moments and external joint moments data normalized for body mass (Nm/kg) will be calculated using the three-dimensional inverse dynamics.

The assessor will determine the 60° knee flexion for the single-leg squat test using the dominant lower limb as a reference with a universal goniometer. During the single-leg squat, the participant will be instructed to perform the movement from 0° to 60° of knee flexion and return to the initial position.[42] [43] The speed at which the movement is performed will be determined using a metronome (2-second rise, 2-second descent), and familiarization will be conducted. During the test itself, two sets of three squat repetitions will be performed alternately with a 60-second rest between sets. Participants will be instructed to stand on one leg with the opposite knee flexed to approximately 90° opposite the hip in a neutral position with the hands positioned on the waist slightly above the anterior superior iliac spine.[44]

Measurement of Concentric Torque of Hip ER Muscles

Participants will be positioned on the isokinetic dynamometer in prone positions with the pelvis stabilized with a strap and hips in a neutral position in the sagittal plane. The knee will be tested at 90° of flexion with the contralateral limb extended. The dynamometer axis will be aligned with the tibial tuberosity. The lever will be attached below the medial malleolus. The articular amplitude tested will range between 5° of ER and 25° of IR at a constant velocity of 60°/s to capture the maximum torque generation.[45 46]

Criteria for feasibility

The results of this feasibility trial will indicate if the study as designed is feasible, which will inform the decision of progressing to a full trial. The decision will be one of the following: (1) do not proceed to a full trial; (2) modify the protocol further prior to conducting a full trial; (3) continue with the full trial using the same procedures used in the feasibility trial ; however, monitor the study procedures closely; and (4) continue without modifications, as it is in the feasibility trial, close monitoring is not required.61 The criteria for the feasibility are presented in table 3.

Data analysis

Descriptive statistics will be reported using means, 95% confidence intervals (CIs) and frequencies, considering normal distribution. As it is a feasibility study, level of significance and hypothesis testing regarding treatment efficacy will not be performed. Effect sizes representing between-group differences in the primary and secondary outcomes will be computed, but these effect sizes will not be considered as criteria for sample size estimation for the full trial, nor as criteria to proceed to the full trial because of the inadequate power of the current feasibility study. Estimates for the secondary outcome measures will be presented as means and 95 CIs at all timepoints (i.e., baseline, 8-week and 20-week follow-ups). Between-group differences for secondary outcomes will be compared with their respective minimum important change (MIC) scores, when they are available. Planed analysis will be conducted on software, SPSS version 22. Detailed analysis is described in table 2.

Limitation of the study

As this is a feasibility study, the results of the current study will not provide findings regarding the efficacy of the interventions being tested. The study will only evaluate if this research study is viable as a full trial and inform any recommendations for modification of the protocols for the full trial resulting from the findings of this feasibility trial.

Plan for supervision and monitoring

The study will be conducted and monitored by the lead investigator (HJS) under the supervision of the coauthors (LDM and VCO), with assistance of the research team. All the ethical principles as provided by Declaration of Helsinki will be followed by all the members of this research throughout the study.

Plan for data integrity and management

The research data will be collected by a research assistant who will be trained to collect the research data and manage the data by compiling in a file for individual patient. Participant identifiers (including name, address and contact information) will be removed from the research data and will be stored separately. Data will be entered in Microsoft Excel. Identification of the groups as intervention and CG will be removed from the excel sheet. Research data will be monitored weekly by scrutinising entered data. Any errors in entry will be identified (if any) and amended. Consent forms will be scanned and stored in password-protected computers of the lead researcher and at the University's along with other research data files.

Data analysis plan

Descriptive statistics will be computed to describe the baseline and demographic characteristics of the study participants. As it is a feasibility study, level of significance and hypothesis testing regarding treatment efficacy will not be performed. Effect sizes representing between group differences in change of the primary and secondary outcomes will be computed, but these effect sizes will not be considered as a criteria for sample size

estimation for the full trial, nor as criteria to proceed to the full trial, because of the inadequate power of the current feasibility study. Treatment effects for the secondary outcome measures will be presented as means, standard deviation (SD). Difference between the mean scores of each secondary outcome will be compared with the minimum important change (MIC) values of the outcome measures, if the MIC scores are available. The analysis plans of the primary feasibility objectives are described in table 2.

Ethics and dissemination

The results of the study will be presented in conferences and published in a peer-reviewed journal.

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Table 1 Schedule of enrolment, assessment and interventions

	Study period				
	Enrolment	Allocation	Post Allocation		Final Assessment
Timepoint	$-T_1$	T_0	T_1	T_2	T_3
Eligibility screening	X				
Explain study procedure/provide participant information sheets	X				
Informed consent	X				
Random treatment allocation		X			
Intervention					
Experimental intervention				X	
Control group				X	
Feasibility					
Acceptability of random allocation to one of the two groups	X				
Feasibility of blinding the assessor					X
Eligibility and recruitment rates	X				
Understanding possible contamination between the groups					X
Adherence to intervention					X
Treatment satisfaction					X
Difficulty in understanding the treatments					X
Secondary outcomes					
Passive hip IR range of motion			X		X
Hip kinematics			X		X

605 Table 2 - How will each primary feasibility objective be assessed?

	Objectives	Measures to assess specific objectives	Statistical analysis
1	Feasibility of blinding the assessor	Feasibility of blinding will be assessed by asking the assessor two questions at the end of the follow-up assessment: 1. Did you receive any information that indicated to you which group the participant was assigned to? 2. How did you receive information about group assignment? Assessor's guess regarding group assignment group will be recorded for each participant. The responses will be coded as correct or incorrect guess.	The frequency and relative rates of '*Yes*' and '*No*' as the answer to the first question will be computed, as will the frequency and relative rates of correct and incorrect guesses. Finally, reasons for guesses will be recorded as verbatim and reported.
2	Acceptability of random allocation to a treatment group	Outcome assessor will ask the participants if random allocation to one of the two treatment groups is acceptable to the participants. Responses will be recorded as 'Acceptable', 'Not acceptable' or 'No preference'.	The frequencies of each response will be computed separately for each treatment condition.
3	Understanding possible contamination between the groups	Have you talked to other participants in this study about the intervention they are receiving? Has your attitude towards the intervention changed after talking to the participant (s) in the other group? Are any of the participants in the other group aware of the type of intervention you are receiving in this study?	The frequencies of the participants who responded affirmatively to each question will be computed separately for each treatment condition.
4	Satisfaction of treatment	All the participants of the intervention group will be asked to respond an adapted version of the MedRisk Instrument for Measuring Patient Satisfaction With Physical Therapy Care (MRPS)[47] at 1 week following treatment. The question asked will be: 1 Did my physiotherapist carefully explain the treatments I received? 2 Did my physiotherapist treat me respectfully? 3 Did my physiotherapist answer all my questions? n general, am I completely satisfied with the services I received from my physical therapist? Responses to this question are made on a five-point categorical scale 1='completely disagree'; 2='Disagree'; 3= 'Neutral'; 4=' Agree'; 5=' Completely agree').	The frequency of response for each question will be analyzed
5	Difficulty in understanding the information provided by the physiotherapist.	All the participants will be asked about the difficulty in understanding the information provided by the physiotherapist. The question asked will be, '*How difficult was it for you to understand* the *information provided by the physiotherapist?*' Responses will be provided on a 5-point Likert scale, where 1='*Very easy*', 2='*Easy*', 3='*Neither easy nor difficult*', 4='*Difficult*', 5='*Very difficult*'.	The differences in the difficulty in understanding the information provided will be compared between the two groups.
6	Adverse events	All the participants of the intervention group was asked about any adverse events after treatment. All responses will be recorded verbatim.	The number of adverse events listed will be computed for each treatment condition separately. The responses will be analysed qualitatively (see text).

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	Full trial is not feasible as designed		Proceed to a full trial without modification in the protocol of the feasibility trial	
Criteria	**Full trial is not feasible as designed Modify the protocol prior to a full trial if…**	**Action**	**Monitor the study procedures closely if…**	**Close monitoring is not required if…**
Feasibility of blinding the assessor	Assessor has a >70% correct guess rate on the group allocation.	Identify ways to improve assessor blinding based on the responses or feedback provided by the assessors.	70%–90% blinding is found.	<10% correct guess to the group allocation.
Attrition rate (in both arms)	>30% total drop-outs post-treatment.	Identify possible reasons for dropouts and ways to improve follow-up participation.	15%–30% total drop-outs post-treatment	<15% total drop-outs at post-treatment. www.pedro.org.au)
Contamination of intervention	≥15% contamination between the groups.	Identify reasons for contamination and resolve them.	<15% contamination between the groups.	0% contamination between the groups.
Adherence to treatment	<50% of frequency during the intervention.	Identify reasons for not attending the treatment session in order to increase attendance in the full trial.	50%–80% of frequency during the intervention.	80% or more of frequency during the intervention.
Difficulty scale	≥50% participants in the experimental group rate as a difficult intervention or very	Perform new training to facilitate a language of instruction to the patient		If ≥50% participants in the experimental group

608
609
610 Table 3 - Criteria for feasibility

	difficult.	rate as very easy or easy.
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CAPÍTULO 3. Efficacy of strength training of the hip external rotator muscles on passive stiffness, kinetics and kinematics: A feasibility study

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Abstract

Background. Passive stiffness is determined by the rate of change in resistance torque during angular displacement of a joint in the absence of muscle contraction. Stiffness contributes to the muscle's ability to absorb energy when it is under the action of mechanical forces. Decreased stiffness of the hip external rotator (ER) muscles could result in excessive hip internal rotation (IR) during closed kinematic chain tasks. Movement pattern associated with injuries such as: patellofemoral pain, anterior cruciate ligament injury, and medial tibial stress syndrome.

Objective. Determine the feasibility of undertake a full RCT to evaluate the effect of strengthening on passive stiffness and transverse plane hip kinematics in healthy participants.

Design. Feasibility study of randomized controlled trial with blinded assessor.
Setting. University's physical therapy clinical center.
Participants. Twenty healthy sedentary adults participated in the study.

Methods. Participants was be randomly allocated to an 8-week hip ER muscle strengthening program or will undergo no intervention. The primary outcomes are related to feasibility, including: (1) assessor blinding; (2) eligibility and recruitment rates; (3) acceptability of screening procedures and random allocation; (4) possible between-group contamination; (5) intervention adherence; (6) treatment satisfaction; and (7) difficulty in understanding the provided intervention.

Ethics. The protocol was approved by University's Ethics research committee (protocol number 88004918.2.0000.5108).
Results. Three of the five previously established feasibility criteria were achieved.

Conclusions. This study is feasible for the sedentary population.

Keywords

Stiffness; Muscle; Hip; Kinematics

Introduction

Passive stiffness is determined by the rate of change in resistance torque during angular displacement of a joint in the absence of muscle contraction.[4 5] Stiffness contributes to the muscle's ability to absorb energy when it is under the action of mechanical forces.[48 49] The mechanical properties of the connective tissues provide resistance to joint displacement, exerting complementary action on muscle activation during functional tasks.[6] Adequate passive stiffness may control excessive joint movement, reducing the need for muscle contraction[8] and, consequently, the energy expenditure[50 10 51 52] to promote functional stability during sports and functional tasks.[18 53]

The low capability of hip structures to resist rotational forces during functional tasks is one of the factors related to the occurrence of injuries such as patellofemoral pain,[13 14] anterior cruciate ligament injury,[15] and medial tibial stress syndrome.[16]. In addition, excessive hip internal rotation (IR) may contribute to undesirable movement patterns (i.e., excessive pronation of the subtalar joint[16] and dynamic knee valgus[11]). This is because an excessive hip IR with lower limbs fixed to the ground may move the knee joint center medially in relation the foot,[20] overloading local and non-local tissues [11 19]. The hip joint capability to resist these forces is determined, among other factors, by the passive stiffness of the structures surrounding this joint (i.e. capsule, ligaments, fascia and muscles).[11] Therefore, hip passive stiffness can be considered one of the factors related to injury development, and undesirable movement patterns. In this context, establish effective strategies to increase passive hip stiffness could be helpful to prevent injuries and undesirable movement patterns during functional tasks.

Joint passive stiffness is associated with the cross-sectional area and structure of surrounded tissues of the joint[23]. Therefore, strengthening may be effective on its passive stiffness[24 25 26] because it leads to an increase in the number of sarcomeres in parallel and in the number and size contractile proteins and not contractile as the titin responsible for the sarcomere support. [27 28 29] Previous studies found high association between passive stiffness and muscle strength in the elbow and ankle joints[23 30]. Nevertheless, the effectiveness of strengthening hip external rotator (ER) muscles on joint passive stiffness is still unclear due to small number of high-quality randomized controlled trials. [21 22]

We propose a randomized clinical trial to evaluate the effect of hip ER strengthening on hip passive stiffness and on kinematics in the transverse plane during single-leg squat. However, the study sample consists of healthy and sedentary participants. Healthy participants without a previous complaint may have low adherence to the intervention or low interest in the procedures. Therefore, a prior study is necessary to assess the feasibility of conducting a full study. A feasibility study may have various purposes such as testing study procedures, validity of tools, estimation of the recruitment rate, and estimation of parameters such as the variance of the outcome variable to calculate sample size etc.[54] In the present study, we focused attention on the attrition rate, adherence to the intervention and the evaluator blindness. The identification and correction of possible failures still in the initial phase of the study is fundamental to carry out a complete study of high methodological quality. Therefore, we aimed to determine whether or not it would be feasible to undertake a full RCT to evaluate the effect of strengthening on passive stiffness and hip cinema in the transverse plane in healthy participants.

Methods

Was performed a feasibility trial evaluating the feasibility of conducting an RCT to evaluate the efficacy of strength training of the hip external rotator muscles on hip passive stiffness, kip and knee kinetics and kinematics in coronal and transverse plane.

Research design

We conducted a two-arm, assessor-blinded, feasibility, parallel, randomized clinical trial. We obtained ethical approval by the University's ethics committee (protocol number 88004918.2.0000.5108), and registry of the trial protocol at ClinicalTrials.gov (RBR-6wvd9). We used the SPIRIT (Standard Protocol Items: Recommendations for Interventional Trials) statement [31] during the development of the protocol, and followed the CONSORT (Consolidated Standards of Reporting Trials) statement extension for a pilot and feasibility randomized trials for reporting.[32] Feasibility was to be determined on *a priori* criteria. For the detailed review of the research methods, we refer readers to the published stud protocol.

Participants

Were included individuals of both sexes, 18 years-old or older, healthy and sedentary who have not been submitted to surgical procedures or rehabilitation on the hip or have not suffered any musculoskeletal injury on the lower limbs or trunk in the last six months. We consider as sedentary, individuals who do less than 30 minutes of moderate aerobic physical activity during 5 days a week, or 20 minutes of vigorous aerobic activity during 3 days a week, or less than 2 days a week of resistance training[34]. Were excluded from the study individuals who are unable to perform the passive hip stiffness test or who have pain during any procedure.

Individuals were recruited through advertisements on radio and social media networks. All eligible individuals received information about the study and sign an informed consent form prior to participation. Information including age, sex, lower-limb dominance, history of injury, and physical activity level was collected.

Interventions

Hip External Rotator Strengthening

The physiotherapist responsible for the experimental group was trained a priori. The one-repetition maximum (1RM) test was performed first for each exercise; these data was used based on load prescription for the strengthening protocol. The protocol consist of three sets of eight repetitions with an intensity of 80% of 1RM, with a 2-min rest allowed between sets.[33] If the participant is able to perform a repetition above the number established in all series in two consecutive training sessions, the load was increased by 10% of the 1RM.[33] The protocol was preceded by a warm-up and succeeded by a cool-down (walking at self-selected pace). All strengthening exercises was performed bilaterally.

The strengthening protocol consisted of: Hip external rotation against the resistance of a pulley mechanism (sitting) [37] ; Hip Extension in Quadruped position with elbows and Knee Flexed [38]; Hip Extension in Quadruped position with Elbows flexed and Knee Extended [38];

hip ER strengthening in ventral decubitus against the resistance of a pulley mechanism[39]; and Hip external rotation in closed kinetic chain[40].

Control Group

The CG was instructed to continue performing their activities of daily living and not initiate physical activity during the study period.

Primary outcome measures

The primary outcomes were related to feasibility: recruitment, retention, and treatment adherence of participants, feasibility and blinding of outcome assessments, fidelity of treatment delivery, credibility of, and satisfaction with, treatment. To assess recruitment-related feasibility outcomes, we recorded the numbers of potential participants who were eligible and recruitment rates. Participation-related feasibility outcomes was (1) acceptability of random allocation to a treatment group. Feasibility outcomes related to outcome assessment was (1) feasibility of assessor blinding procedures. Finally, the treatment-related feasibility outcomes were (1) possible contamination between the groups, (2) adherence to the interventions, (4) treatment satisfaction, (5) difficulty in understanding the treatment, and (6) adverse events related to the interventions. Details of these feasibility outcome measures are presented in Supplementary file (Protocol).

Secondary outcome measures

The secondary outcome measures selected were those that had the potential to be primary or secondary outcomes of a potential full clinical trial. Passive Hip IR ROM, hip and knee kinematics in the transverse and frontal plane, hip and knee kinetics in the transverse and frontal plane.

Passive Hip IR Range of Motion: Each participant was positioned in prone position with the pelvis stabilized by Velcro® straps. An inclinometer was placed 5 cm distal to the tibial tuberosity. To reduce tissue viscoelasticity, the examiner performed five passive

movements of internal and external hip rotation. This limb was then be positioned at 90° of knee flexion and neutral hip rotation. The participant was instructed to keep the muscles relaxed and allow the movement of hip IR until passive structures interrupt the movement. At this time, a measurement was taken using an analog inclinometer. The measurement was discarded and repeated if the assessor perceives any muscle contraction visually or on palpation. Three measurements was performed to calculate the mean.

Hip and Knee Kinematics and kinetics: A three-dimensional motion capture system consisting of nine cameras (Oqus 3+; Qualisys, Gothenburg, Sweden) was used to evaluate the hip kinematics at 6 degrees of freedom. Retro-reflective markers was placed on the lower limbs and pelvis using the Calibrated Anatomical System technique.[41] Static calibration tests was obtained with the participant in the anatomical position. Kinetic data was collected using two force plates sampled at 2000 Hz (Advanced Mechanical Technology Inc., Watertown, MA, USA). The joint moments and external joint moments data normalized by body mass (Nm/kg) was calculated using the three-dimensional inverse dynamics.

The assessor determined the 60° knee flexion for the single-leg squat test using the dominant lower limb as a reference with a universal goniometer. During the single-leg squat, the participant was instructed to perform the movement from 0° to 60° of knee flexion and return to the initial position.[42] [43] The speed at which the movement was performed was determined using a metronome (2-second rise, 2-second descent), and familiarization was conducted. During the test itself, two sets of three squat repetitions was performed alternately with a 60-second rest between sets. Participants was instructed to stand on one leg with the opposite knee flexed to approximately 90° opposite the hip in a neutral position with the hands positioned on the waist slightly above the anterior superior iliac spine.[44]

Isometric torque: To perform the isometric test of hip external rotators the participant was placed in bench press with the hips in neutral, the Handheld Dynamometer (microFET2,

Hoggan Health Industries, Inc., West Jordan, UT) was positioned in the participant's leg, 5 cm proximal to the lateral malleolus. The dynamometer was fixed by a Velcro® to a fiery sturgeon. The knee joint was positioned at 90º of flexion and 0º of rotation, with the aid of an inclinometer (Starrett®) positioned 15cm distal to tibial tuberosity.

The participant performed an isometric maximal hip rotation force. The examiner collected the results of 3 replicates, which were later used to calculate the mean. To obtain isometric torque, the mean values recorded on the dynamometer were multiplied by the distance between the medial condyle of the knee and the 5 cm mark proximal to the medial malleolus. The torque value was divided by the body mass of the volunteer to obtain the normalized data (Nm / kg).

Sample size

Sample size estimation was performed to achieve the primary feasibility outcomes goals, as described in the protocol (Protocol reference) and registration documents (clinicaltrials.gov registration number: RBR-6wvd9), and not to detect differences in the secondary, treatment effects outcomes.[35]

Randomization

After recruitment, participants were randomly allocated in one of the two groups: CG; or IG using sealed and opaque envelopes. A person not involved in the study opened and inform the allocated group for participants. The sample was stratified by sex, since it may influence hip passive stiffness[36]

Blinding

The assessor performing all the assessments was blinded to group allocation of the participants throughout the study.

Statistical methods

Baseline characteristics for demographic and clinical data of the participants were reported using descriptive statistics. The plans for analysis of primary outcome measures are presented in Supplementary file 2 (Protocol Reference).

Results

Recruitment-related feasibility outcomes

Twenty tree candidates were invited to participate of the study. Eighty-seven percent (n=20) of invited candidates participated. Of those who did not, 2 (9%) did not attend the collection and 1 (4%) did not meet inclusion criteria. Twenty out of 23 candidates (87%) screened were eligible to participate. All 20 participants (100%) who met the inclusion criteria provided written informed consent and were randomized to one of the study arms. The reasons for all exclusions and losses to follow-up are outlined in the participant flow diagram (Fig. 1).

Participant-related feasibility outcomes

Acceptability of random allocation to a treatment group. Random allocation of the treatment was acceptable to 20 out of 20 individuals (100%).

Outcomes assessment-related feasibility outcomes

Feasibility of blinding the assessor. The assessor did not receive any definitive information about participants' group allocation for any of the participants during the study. The assessor guess was correct for 3 participants (33.33%) in the intervention grump, and for 4 participants (36.36%) in the control group. On questioning, the assessor identified one clues that may have influenced a correct guess: "Attend same building as intervention site".

Treatment-related feasibility outcomes

Contamination. There were no detected instances of contamination between the two groups. Table 2 presents the results of the five separate contamination questions.

When participants were asked if they talked to participants in the other group 4 (36.36%), 6 (66.66%) answered "yes" to the control and intervention groups respectively. The control group did not change their attitude after the conversation, in turn 33.33% of the participants in the intervention group changed. When asked if participants in the other group knew which group, they were in, 4(36.36%); 6 (66.66%) said yes for the control and intervention groups respectively.

Adherence to intervention and treatment satisfaction. Adherence to intervention and treatment (Table 2). The mean attendance at the sessions was 21.11 days out of the 24 possible. 4 (44.4%) participants attended 20 sessions; 1 (11.1%) out of 21; 3 (33.3%) out of 22; and 1 (11.1) out of 23.

Difficulty in understanding the treatment. 7 participants (77,8%) reported that the treatment was “easy” and 2 (22,2%) Very easy was to understand (Table 2).

Adverse events. One participant in IG reported an ankle sprain but it did not time loss to the study. No participants reported adverse events due to the protocol.

Results of secondary outcomes. No significant changes were found between groups in any of the secondary outcomes. However, this is only a partial presentation of the data. The full study will have a larger sample number and may present statistically significant differences. Secondary outcome data are shown in table 4.

Discussion

We aimed to determine whether or not it would be feasible to undertake a full RCT to evaluate the strengthening effectiveness on hip passive stiffness and kinematic in healthy participants. Three of the five a priori feasibility criteria were met, which suggests that a clinical trial to evaluate strengthening effectiveness on hip passive stiffness and kinematic in healthy participants is feasible. This feasibility trial also provided important additional information that inform the design of the full trial.

Primary feasibility outcomes

Blindness and contamination to need to be followed during the full study. One explanation is that the appraiser and the volunteers in his larger major belong to the physiotherapy

department. This causes frequent contact between the parties. Most controlled trials do not adequately examine assessor blinding,[55] even though it is widely considered a very important component of good study design.[56] In the present study, it was difficult to guarantee blinding. One strategy to improve blinding is to guide the evaluator to avoid direct contact with participants during the protocol. To avoid contamination between groups, participants should be advised not to talk about their intervention with other study members.

Treatment satisfaction were high in intervention group. On a scale of 1 to 5, the participants' average rating was 4.89 for the three priori questions. The significance of satisfaction is emphasized by evidence that satisfied patients are more likely to adhere to treatment, benefit from their care, and have a higher quality of life.[57] [58] In addition the participants found the information's "easy" or "very easy", which meets the a priori feasibility criterion (Ref protocol). For this reason, the guideline pattern should be maintained for the full study. Adherence to treatment was high in the present study. This can be explained by the fact that participants reported satisfaction with treatment and ease of understanding the information.

The attrition rate in the present study was 20%. We have met the criteria previously, but the 15% PEDro (www.pedro.org.au) recommended rate has not been reached. One strategy that can be adopted for the full study is to contact participants in advance to ensure their participation.

Secondary outcomes

In the present study, no significant differences were found for any of the secondary outcomes. However, evaluating the results of interest was not the purpose of this study. We direct our goal by answering the question, "Can this study be done?" As recommended by the National Institute for Health Research (NIHR)(https://www.nihr.ac.uk/). The present study has a small sample number, so it does not have sufficient power to establish the effectiveness of the intervention.[59] This answer is left to the full study, which will have a sufficient sample size to reach the statistical power to answer this question.

Strengths and limitations

The current study has a number of strengths: We guarantee adherence to the intervention; We assessed both blinding and contamination; The study protocol was previously registered; The sample was randomly distributed among the groups.

To our knowledge, this is the first study to examine the feasibility of a clinical trial about strengthening effect over hip passive stiffness. Conducting a feasibility study is an important step before conducting a full clinical trial, especially in a setting where a clinical trial has never been conducted, and that there are no previous experience recommendations.

In the present study, the torque measurement that would initially be performed with the isokinetic dynamometer was replaced by the Handheld Dynamometer (microFET2, Hoggan Health Industries, Inc., West Jordan, UT). This replacement occurred by the fact that the isokinetic dynamometer needed maintenance. However, torque measurement was only a control measure in our study. In addition, the Handheld Dynamometer is widely used in research[60 61 62] and is validated as a strength measurement.[63 64]

Conclusion

We conclude that a clinical trial to evaluate the effect of muscle strengthening on passive stiffness and hip kinematics in the frontal plane is feasible and warranted, although some minor modifications are required.

Figure 1. Participant flow

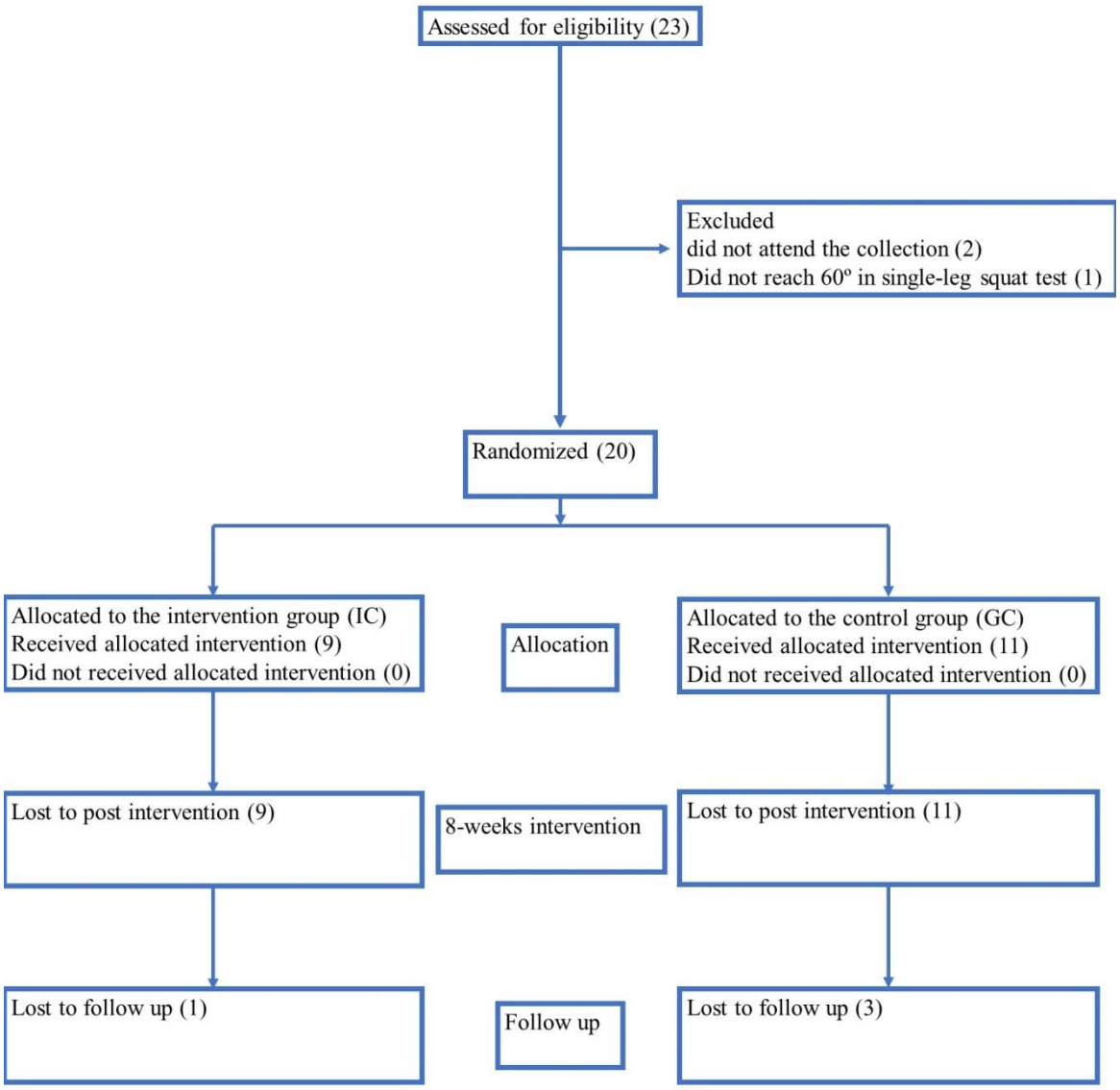

Table 1. Baseline characteristics of the two study groups.

Variable	IG n (9) N (%) or Mean (SD)	CG n(11) N (%) or Mean (SD)
Age (y), mean (SD)	22.00 (2.39)	23.55 (6.65)
Weight (kg), mean (SD)	62.11 (8.82)	57.02 (12.54)
Height (m), mean (SD)	1.65 (0.59)	1.66 (0.10)
Sex (male; female), n (%)	2 (22%); 7 (78%)	4 (36%); 7 (64%)
Passive Hip IR Range of Motion, º	30.85 (19.29)	35.51 (17.87)
Isometric torque, Nm/kg	51.92 (15.23)	57.14 (16.31)
Transverse Plane Hip Kinematics, º	4.05 (0,76)	4.41 (0,68)

CG= Control Group; IG= Intervention Group; Kg= Kilograms; m= Meters; n= number; N= Newton; SD= Standard Deviation; Y= Years; º= Angle; % Percentage

Table 2. Feasibility results for the two study groups.

Feasibility outcomes	Control N (%) or Mean (SD)	Intervention N (%) or Mean (SD)	*P* values	Summary
Assessor's correct guess for group allocation	4 (36,36%)	3 (33,33%)	0.890	Assessor correctly guessed the group allocation slightly more often for the Intervention than the CG.
Acceptability of random allocation to a treatment group	11 (100%)	9 (100%)	1.000	All participants accepted the random allocation of groups.
Understanding possible contamination between the groups				No difference in first and third questions between groups. However, the intervention group tends to change its attitude after talking with participants in the control group.
• Have you talked to other participants in this study about the intervention they are receiving?	4 (36.36%)	6 (66.66%)	0.189	
• Has your attitude towards the intervention changed after talking to the participant (s) in the other group?	0 (0%)	3 (33.33%)	0.043	
• Are any of the participants in the other group aware of the type of intervention you are receiving in this study?	4(36.36%)	6 (66.66%)	0.189	
Adherence to treatment				
n (9)				Participants were adherent to the treatment.
Number of days (SD)		21.11 (1.16)		
Satisfaction.				High satisfaction scores with the intervention were found.
All the participants of the Intervention group will be asked to respond an adapted version of the MedRisk Instrument for Measuring Patient Satisfaction With Physical Therapy Care (MRPS)[47] at 1 week following treatment. The question asked will be:				
• Did my physiotherapist carefully explain the treatments I received?		4.89 (0.33)		
• Did my physiotherapist treat me respectfully?		4.89 (0.33)		
• Did my physiotherapist answer all my questions?		4.89 (0.33)		
Responses to this question are made on a five-point categorical scale 1= 'completely disagree'; 2= 'Disagree'; 3= 'Neutral'; 4= 'Agree'; 5= 'Completely agree').				

Difficulty in understanding the information provided by the physiotherapist. Responses to this question are made on a five-point categorical scale		77.8% of participants reported the information as very easy and 22.2% as easy.
• Very easy	7 (77,8)	
• Easy	2 (22,2)	
• Neither easy nor difficult	0 (0,0)	
• Difficult	0 (0,0)	
• Very difficult	0 (0.0)	

CG= Control Group; IG= Intervention Group; n= number; SD= Standard Deviation; % Percentage

Table 3. Were the feasibility criteria met?

Criteria	Feasibility criteria met?	Recommendations for full trial
Blinding of assessor	No	The evaluator should be oriented to: 1) avoid direct contact with participants during the protocol; 2) Do not attend the intervention site during the protocol.
Attrition rate (in both arms)	Yes	Phone call reminders for the follow up assessment helped reduce the drop-outs, which should be considered in the full trial.
Contamination of intervention	No	Participants should be advised not to comment on their intervention with other study participants.
Adherence to treatment	Yes	The average frequency in the intervention group was 89.9%. Constant telephone contact with participants should be maintained. This strategy was important to maintain a good adherence to the intervention.
Difficulty scale	Yes	Standardized guidelines for intervention should be maintained.

Table 4. Secondary outcomes

Variable	IG n (9) Mean (IC)	CG n (11) Mean (IC)	P
Passive Hip ROMº			
Baseline	30.85 (17.88 – 43.82)	35.51 (23.78- 47.24)	0.582
Post-Intervention	43.03 (34.69 – 51.38)	41.84 (34.30 – 49.39)	0.826
Follow Up	31.52 (26.98 – 36.05)	37.27 (33.17 – 41.37)	0.063
Transverse Plane Hip Kinematicsº			
Baseline	4.05 (2.45 – 5.65)	4.41 (2.97 – 5.86)	0.730
Post-Intervention	5.82 (2.99 – 8.64)	4.33 (1.78 – 6.89)	0.425
Follow Up	5.56 (3.82 – 7.30)	4.31 (2.74 – 5.88)	0.278
Isometric torque Nm/kg			
Baseline	51.92 (40.82 – 63.02)	57.14 (47.10 – 67.18)	0.473
Post-Intervention	62.17 (52.13 – 72. 02)	58.08 (49.00 – 67.17)	0.533
Follow Up	58.89 (50.86 – 66.93)	60.05 (52.7967.32)	0.824
Coronal Plane Hip Kinematicsº			
Baseline	6.34 (3.37 – 9.31)	4.84 (2.16 – 7.53)	0.422
Post-Intervention	7.00 (3.73 – 10.26)	4.59 (1.64 – 7.55)	0.266
Follow Up	6.95 (4.11 – 9.79)	4.97 (4.40 – 7.55)	0.293
Transverse Plane Knee Kinematicsº			
Baseline	4.60 (2.44 – 6.77)	5.25 (3.29 – 7.21)	0.648
Post-Intervention	5.07 (2.58 – 7.56)	4.70 (2.45 – 6.94)	0.818
Follow Up	5.84 (2.97 – 8.72)	4.50 (1.90 – 7.10)	0.478
Coronal Plane Knee Kinematicsº			
Baseline	4.45 (1.47 – 7.43)	3.92 (1.22 – 6.61)	0.784
Post-Intervention	4.99 (2.81 – 7.17)	4.91 (2.94 – 6.88)	0.995
Follow Up	5.09 (2.66 – 7.51)	5.19 (3.00 – 7.39)	0.948
Transverse Plane Hip Kinetics Nm/kg			
Baseline	-0.56 (-1.71 - 0.59)	-0.04 (-1.08 - 1.00)	0.491
Post-Intervention	0.66 (-0.88 - 2.21)	1.40 (0.00 - 2.80)	0.467
Follow Up	0.19 (-0.49 - 0.88)	-0.27 (-0.89 - 0.35)	0.310
Coronal Plane Hip Kinetics Nm/kg			
Baseline	0.23 (-1.31 - 1.78)	-0.24 (-1.64 - 1.15)	0.636
Post-Intervention	-0.26 (-1.64 - 1.11)	0.49 (-0.75 - 1.74)	0.405
Follow Up	-0.71 (-0.95 - -0.48)	-0.50 (-0.72 - -0.29)	0.186
Transverse Plane Knee Kinetics Nm/kg			
Baseline	-0.62 (-1.53 – 0.29)	0.10 (-0.71 – 0.93)	0.228
Post-Intervention	-0.44 (-1.53 – 0.64)	0.59 (0.39 – 1.57)	0.154
Follow Up	0.31 (-0.12 - 0.19)	-0.08 (-0.22 – 0.06)	0.278
Coronal Plane Knee Kinetics Nm/kg			
Baseline	-0.85 (-1.79 – 0.08)	-0.02 (-0.88 – 0.82)	0.189
Post-Intervention	-0.42 (-1.58 – 0.74)	0.46 (-0.59 – 1.51)	0.252
Follow Up	-0.24 (-0.87 – 0.38)	0.23 (-0.33 – 0.80)	0.256

CG= Control Group; IC= Confidence Interval; IG= Intervention Group; IR= Internal rotation; m= Meters; n= number; N= Newton; ROM= Range of Motion; º= Angle; % Percentage

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CAPÍTULO 4. Efficacy of Strength Training of the Hip External Rotator Muscles on passive Stiffness, kinetics **and Kinematics: Study Protocol of a Randomized Controlled Trial**

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Abstract

Background. Passive stiffness is determined by the rate of change of resistance torque during joint angular displacement without muscle contraction. Decreased passive stiffness of the hip external rotator (ER) muscles could result in excessive hip internal rotation (IR) during closed kinematic chain tasks. Some lower-limb injuries are associated with excessive hip IR, such as patellofemoral pain and anterior cruciate ligament injury. However, whether muscle hypertrophy increases passive stiffness and enhances proper movement pattern remains unclear.

Objective. This study will investigate the effect of hip ER muscle strengthening on be passive hip IR range of motion and hip kinematics in the transverse plane during a single-leg squat.

Design. This will be a 2-arm prospectively registered randomized controlled trial with a blinded assessor.

Setting. University outpatient physical therapy center in Diamantina, Brazil.

Participants. Eighty healthy sedentary adults will participate in the study.

Intervention. Participants will be randomly allocated to an 8-week hip ER muscle strengthening program (n = 40) or will undergo no intervention (n = 40).

Measurements. Primary outcomes will be passive hip IR range of motion and transverse plane hip kinematics assessed by a blinded assessor at 8- (post-intervention) and 20-week follow-ups.

Limitations. The therapists and participants will not be blinded.

Conclusions. This study will aim to provide evidence of the efficacy of hip ER muscle strengthening on passive hip stiffness and transverse plane hip kinematics during a single-leg squat.

keywords

Passive stiffness; External rotator; Hip kinematics

Introduction

Muscle stiffness is a mechanical property related to their resistance to deformation and can be represented graphically by the slope of the stress-strain curve.[65] The area below the stress-strain curve represents the amount of energy that can be absorbed by a particular muscle during stretching, resting, or contraction.[66] Therefore, stiffness contributes to the muscle's ability to absorb energy when it is under the action of mechanical forces.[48 49] In other words, the mechanical properties of the connective tissues provide resistance to joint displacement, exerting complementary action on muscle activation during functional tasks.[6] Adequate passive stiffness may control excessive joint movement, reducing the need for muscle contraction[8] and, consequently, the energy expenditure[50 10 51 52] to promote functional stability during sports and functional tasks.[18]

Decreased hip stiffness could result in excessive hip internal rotation (IR) during closed-chain activities such as running, jumping, and squatting.[11] Excessive hip IR may contribute to undesirable movement patterns (i.e., excessive pronation of the subtalar joint[16] and dynamic valgus of the knee[11]) that are frequently linked to musculoskeletal injuries[13 16] such as patellofemoral pain,[13 14] anterior cruciate ligament injury,[15] and medial tibial stress syndrome.[16] Bittencourt et al (2012)[3] identified that, during the single-leg squat, an excessive frontal plane knee projection angle is predicted by an interaction between hip abductors weakness and a high passive hip IR range of motion (ROM), a measurement related to passive joint stiffness.[17] Moreover, during landing, an excessive frontal plane knee projection angle may occur due to an interaction between shank-forefoot alignment, hip abductors weakness and high passive hip IR ROM. According to Souza et al (2014),[1] passive hip IR ROM partially predicts the rearfoot kinematics during walking and standing

and is directly related to subtalar joint pronation. Therefore, interventions to increase passive hip stiffness may be necessary to prevent undesirable movement patterns which could lead to overload and, consequently, injury.

Joint stiffness depends on the cross-sectional area and the structure of the tissues surrounding the joints.[23] Longitudinal studies have suggested that strengthening may effectively increase passive hip stiffness and influence hip resting position.[24 25 26] Some authors found a strong correlation between passive stiffness and muscle strength in the elbow and ankle joints.[23 30] The structural changes that occur in the muscle tissue owing to hypertrophy could be a decisive factor for the increase in passive muscle stiffness.[24 25 26] However, this assumption is not supported owing to the low methodological quality of previous studies, and whether hip muscle strengthening effectively increases passive hip stiffness and improves hip kinematics remains unclear. This study will aim to investigate the effects of hip ER muscle strengthening on passive hip stiffness and transverse plane hip kinematics during a single-leg squat.

Methods

Study Design

This will be a two-arm prospectively registered randomized controlled trial with a blinded assessor.

Study Setting

The study will be developed at a university outpatient physical therapy center in Diamantina, Brazil.

Eligibility Criteria

Healthy and sedentary individuals of both sexes who were 18 years of age or older were included upon meeting the following inclusion criteria: 1) at least 25° of hip IR and 5° of hip external rotation (ER); and 2) had not undergone previous surgical procedures or rehabilitation of the hip or suffered any musculoskeletal injury on the lower limbs or trunk in the previous 6 months. Sedentary individuals will be defined as those who complete less than 30 min of moderate aerobic physical activity on 5 days a week, 20 min of vigorous aerobic activity on 3 days a week, or resistance training on less than 2 days a week.[34] Individuals who are unable to perform the passive hip IR range of motion test or experience pain during any procedure will be excluded.

Procedures

Individuals will be recruited through advertisements on radio and social media networks. All eligible individuals will receive information about the study and sign an informed consent form prior to participation. Information including age, sex, lower-limb dominance, history of injury, and physical activity level will be collected. Passive hip IR range of motion and transverse plane hip kinematics assessed the last 8-week follow-up (i.e., 8

weeks after randomization for the post-intervention assessment) and at the 20-week follow-up (i.e., 5 months after the end of the intervention). The assessments will be performed at the 8-week follow-up to investigate the immediate effects and will be repeated at the 20-week follow-up to investigate the potential reversibility of the estimates.

Outcome Measures

Each participant will undergo the following tests: (1) passive hip IR ROM, (2) transverse plane hip kinematics, and (3) hip ER isometric torque. The primary outcomes will be passive hip IR ROM and transverse plane hip kinematics. As secondary outcomes, we will analyze the kinematics of the hip in the frontal plane and of the knee in the frontal and transverse planes. Moreover, we will analyze the frontal and transverse plane kinetics of the hip and knee. Hip ER isometric torque will be used as a control outcome to verify the efficiency of the strengthening protocol.

Passive Hip IR Range of Motion

Each participant will be positioned in prone position with the pelvis stabilized by Velcro® straps. An inclinometer will be placed 5 cm distal to the tibial tuberosity. To reduce tissue viscoelasticity, the examiner will perform five passive movements of internal and external hip rotation. This limb will then be positioned at 90° of knee flexion and neutral hip rotation. The participant will be instructed to keep the muscles relaxed and allow the movement of hip IR until passive structures interrupt the movement. At this time, a measurement will be taken using an analog inclinometer. The measurement will be

discarded and repeated if the assessor perceives any muscle contraction visually or on palpation. Three measurements will be performed to calculate the mean; this value will be normalized to the participant's body weight.[17] A pilot study will investigate intra-assessor reliability.

Hip and Knee Kinematics and kinetics

A three-dimensional motion capture system consisting of nine cameras (Oqus 3+; Qualisys, Gothenburg, Sweden) will be used to evaluate the hip kinematics at 6 degrees of freedom. Retro-reflective markers will be placed on the lower limbs and pelvis using the Calibrated Anatomical System technique.[41] Anatomical markers will be positioned by the same assessor on the anterior superior iliac spine, posterior superior iliac spine, great trochanter, medial and lateral femoral epicondyle, medial and lateral malleoli, and medial and lateral aspects of the 1st and 5th metatarsals. In addition, clusters of non-collinear markers will be attached to the shank and thigh. Static calibration tests will be obtained with the participant in the anatomical position. Kinetic data will be collected using two force plates sampled at 2000 Hz (Advanced Mechanical Technology Inc., Watertown, MA, USA). The joint moments and external joint moments data normalized for body mass (Nm/kg) will be calculated using the three-dimensional inverse dynamics.

The assessor will determine the 60° knee flexion for the single-leg squat test using the dominant lower limb as a reference with a universal goniometer. During the single-leg squat, the participant will be instructed to perform the movement from 0° to 60° of knee flexion and return to the initial position.[42] [43] The speed at which the movement is performed

will be determined using a metronome (2-second rise, 2-second descent), and familiarization will be conducted. During the test itself, two sets of three squat repetitions will be performed alternately with a 60-second rest between sets. Participants will be instructed to stand on one leg with the opposite knee flexed to approximately 90° opposite the hip in a neutral position with the hands positioned on the waist slightly above the anterior superior iliac spine.[44]

Measurement of Concentric Torque of Hip ER Muscles

Participants will be positioned on the isokinetic dynamometer in prone positions with the pelvis stabilized with a strap and hips in a neutral position in the sagittal plane. The knee will be tested at 90° of flexion with the contralateral limb extended. The dynamometer axis will be aligned with the tibial tuberosity. The lever will be attached below the medial malleolus. The articular amplitude tested will range between 5° of ER and 25° of IR at a constant velocity of 60°/s to capture the maximum torque generation.[45] [46]

Random Allocation

The participants will be randomly allocated to one of the following two groups: 1) no intervention (control group [CG]), or 2) hip ER strengthening (experimental group [EG]). The allocations will be made using sealed opaque envelopes in a random numerical sequence. A researcher not involved with the study will open each envelope and inform the participants of their group assignments. The sample will be stratified by sex, since this factor could influence passive hip stiffness.[36]

Blinding

The assessor will be trained a priori for all study measurements and be blinded to the study group assignments. Only the assessor will be blinded in the study because of the nature of our comparators. Figure 1 shows the study design.

Interventions

Hip External Rotator Strengthening

The physiotherapist responsible for the experimental group will be trained a priori. The one-repetition maximum (1RM) test will be performed first for each exercise; these data will be used based on load prescription for the strengthening protocol. The protocol will consist of three sets of eight repetitions with an intensity of 80% of 1RM, with a 2-min rest allowed between sets.[33] If the participant is able to perform a repetition above the number established in all series in two consecutive training sessions, the load will be increased by 10% of the 1RM.[33] The protocol will be preceded by a warm-up and succeeded by a cool-down (walking at self-selected pace). All strengthening exercises will be performed bilaterally.

The strengthening protocol will consist of: hip lateral rotation against the resistance of a pulley mechanism (sitting)[37] (Figure 2), hip extension in quadruped on elbows with knees flexed[38] (Figure 3), hip extension in quadruped on elbows with knees extended[38] (Figure 4), strengthening of hip ER in ventral decubitus against the resistance of a pulley mechanism[39] (Figure 5), and hip lateral rotation in a closed kinetic chain[40] (Figure 6).

Control Group

The CG will be instructed to continue performing their activities of daily living and not initiate physical activity during the study period.

Statistical Methods

Sample Size Calculation

The sample size calculation was performed using the G*Power 3.1 software based on the kinematics data of Araújo et al (2017).[22] Eighty participants are needed (40 in each group) considering a statistical power of 80%, alpha of 5%, and 20% dropout rate.

Reliability Passive Hip IR

Data for calculating the intraclass correlation coefficients (ICC) for the reliability of the passive hip IR was collected on two occasions with a 1-week interval between them during a pilot study. For six individuals of both sexes, the evaluator achieved excellent test reliability, i.e., ICC values of 0.99 (0.98–0.99).

Analysis of Treatment Effects

A statistical analysis will be performed following the intention-to-treat analysis principles. First, the normality of the data will be tested using the Kolmogorov-Smirnov test and the homoscedasticity of the data will be tested using the Levene test. Then, considering normal

distribution, the independent t-test will be used to determine if groups are similar at baseline in terms of age, height, body mass index, isometric torque, passive hip IR, and transverse plane hip kinematics. Finally, repeated-measures analysis of variance will be performed to investigate inter- and intragroup effects on our primary and secondary outcomes of interest at the 8- and 20-week follow-ups. All data will be analyzed at an alpha level of 0.05. Significant differences detected on analysis of variance will be examined again with a Bonferroni post hoc analysis with the corrected alpha level of 0.05 for multiple comparisons. The effect size will be calculated and set to small (0.2), medium (0.5), and large (0.8).[67] All statistical analyses will be performed with SPSS version 22, and the results will be presented as means and 95% confidence intervals (CIs).

Ethics

Participants will be informed about the study and sign a consent form prior to participating. This study was approved by the University's Ethics Committee (CAAE-88004918.2.0000.5108) and prospectively registered at www.ClinicalTrials.gov (RBR-6wvd9t). Possible modifications to the protocol will be reported to the ethics committee as well as the study registry.

Discussion

Potential Study Impact and Significance

The single-leg squat is often used by clinicians for general assessments of biomechanical function[68] and rehabilitation outcome[69] and the identification of a potential injury risk factor.[70 71] For instance, excessive knee valgus during the single-leg squat is reportedly associated with lumbar stress injury,[71] pelvic frontal plane drop, and excessive hip adduction with patellofemoral pain.[72 73] In addition, hip IR is described as a risk factor for patellofemoral pain and anterior cruciate ligament injury.[74 75]

During closed chain activities as the single-leg squat, joint motions of the lower limb are interdependent, and excessive movements from one joint may overload non-local tissues in the kinematic chain.[11 19] Tri-planar hip movements are common during unipodal squats such as flexion, adduction, and internal hip rotation. This occurs due to the external forces applied in the body, such as ground reaction forces.[76] This movement is resisted by actions of the hip extensor, abductor, and external rotator muscles, respectively.[20 77 78] Excessive hip IR can move the knee joint center medially from the foot. Considering that the foot is fixed to the ground, the consequence is an IR of the shank and subtalar joint pronation, resulting in other compensations such as dynamic knee valgus and pelvic frontal plane drop. [20]

Hip external rotator strength is often associated with increased hip IR during closed-chain activities.[79] A strong assumption is that tissues with high passive hip stiffness may play an important role in restricting this movement.[11] In contrast, tissues with low levels of stiffness deform in large quantities due to the application of a small-magnitude external force, absorbing little amounts of energy and allowing excessive joint movements.[11] Passive joint stiffness is associated with the cross-sectional area of the surrounding muscle. Based on this assumption, muscle hypertrophy[21 80 81 82 25] could increase passive stiffness and possibly

hip IR restriction, consequently reducing overload in the musculoskeletal system during closed-chain activities such as single-leg squat, jumping, walking, and running.[3 1]

Ocarino et al (2008)[21] reported a significant change in the resting point of the elbow joint after 8 weeks of elbow flexor muscle strengthening. However, that study did not identify a significant change in the passive resistance torque of the elbow flexors after the intervention. These findings may be due to the fact that the study protocol had a small number of exercises that may have been insufficient to cause changes in muscle structure. Similarly, Araújo et al (2017)[81] observed a change in the resting position of the hip joint but no change in the passive resistance torque of the hip ER after strengthening of the hip and trunk muscles. Moreover, no changes were observed in the kinematic variables of the hip and knee joints in the transverse plane during the step-down task. However, due to the small sample size, the statistical power was low (i.e., 0.40). A larger number of participants would be required to demonstrate significant changes in these variables. Therefore, a high-quality methodological study with a suitable sample number is required to identify the effect of muscle strengthening on passive hip stiffness and transverse plane hip kinematics.

The results of this study will contribute to clinical practice. Our findings could contribute to the decision-making process regarding the most efficient exercise prescriptions for decreasing passive hip stiffness and, consequently, change movement biomechanics.

Contribution to the Physical Therapy Profession and Patients

The present study's findings may be useful for physical therapists and their patients because they may identify interventions that increase hip stiffness and influence decreased

hip IR during closed-chain activities. Since excessive hip IR is associated with musculoskeletal system overload and injury,[3 1 20] the results of this study may rule out more effective strategies to correct lower-limb kinetics and kinematics during functional activities. And finally, our findings may improve prevention and rehabilitation approaches.

Study Strengths and Weaknesses

The main strength of this study is that it is a randomized controlled trial with concealed allocations and a blinded assessor. The sample size was calculated to provide adequate statistical power to detect intergroup differences in the primary outcome. The physical therapists responsible for supervising the strengthening protocol will have similar clinical experience and receive prior training. The main limitation of our study is that the participants and therapists will not be blinded to the group allocations.

Future Research

The results of this study may contribute to future studies comparing the effects of muscle strengthening programs at different joint amplitudes on passive stiffness and IR magnitude during functional tasks.

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Figures

Figure 1

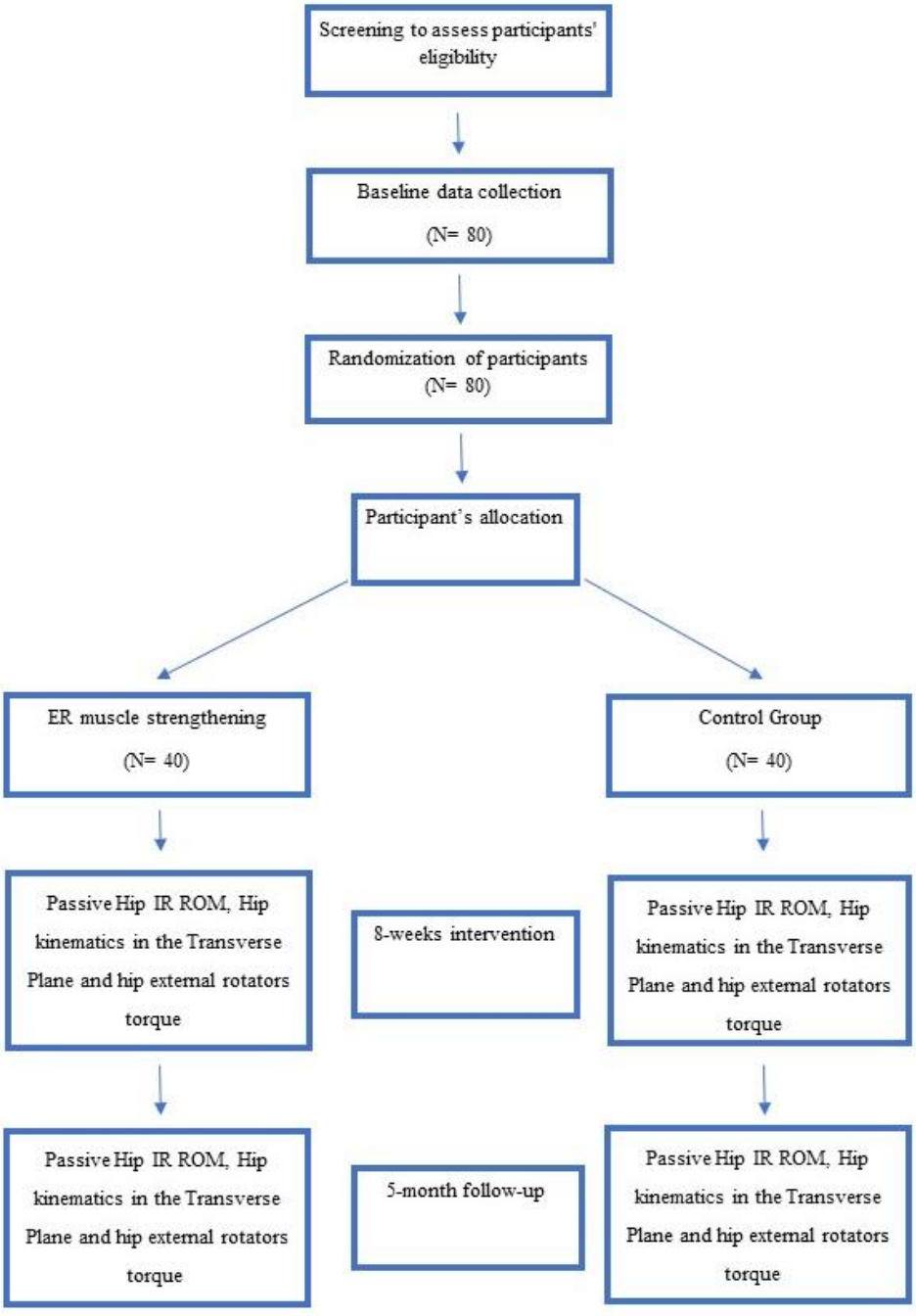


Figure 2

Figure 3

Figure 4

Figure 5

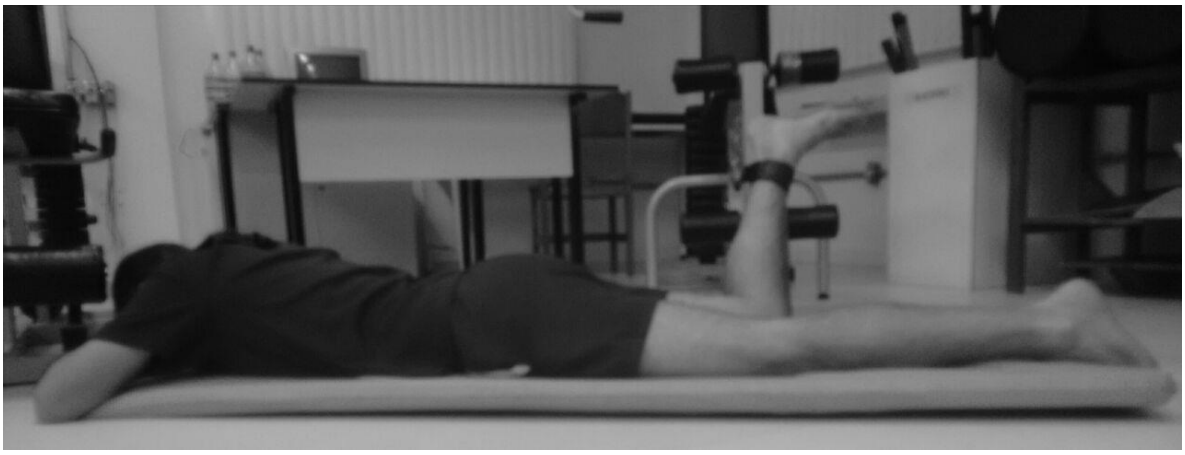


Figure 6

CAPÍTULO 5. CONSIDERAÇÕES FINAIS

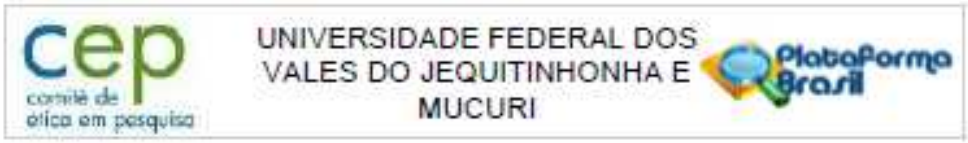
O presente trabalho apresenta os passos necessários para a condução de um RCT com a maior chance de assertividade. Foram apresentados os dados preliminares do estudo, com enfoque em desfechos relacionados a viabilidade do trabalho e corrigir possíveis erros metodológicos. Os resultados dos desfechos de interesse não são suficientes para estabelecer a eficácia da intervenção devido ao pequeno número amostral. Estabelecer a eficácia da intervenção com um número amostral tão restrito, nos levaria ao erro do tipo I. Dessa forma a eficácia poderia ser superestimada ou subestimada devido ao pequeno pode amostral. Essa análise deve ficar a cargo do estudo completo com um número amostral adequado.

No cálculo amostral prévio foi estabelecido um número amostral de 80 participantes para que se alcance um poder estatístico suficiente para detectar mudanças nos desfechos primários. O estudo permanece em fase de coleta de dados e recrutamento de participantes. Até a presente data foram coletados dados de 35 participantes. Os dados apresentados no estudo de viabilidade podem ser de grande importância na sequência do estudo. Poderá ser corrigida a contaminação entre os grupos e o não cegamento do avaliador. Além disso, nos alerta para a taxa de atrito do estudo. O estudo terá continuidade após a defesa da dissertação. Os resultados apresentados pelo estudo de viabilidade serão fundamentais para o seguimento do estudo. Serão tomadas as medias citadas anteriormente para garantir o cegamento e evitar a contaminação entre os grupos. Dessa forma o estudo completo terá mais chance de assertividade.

O Protocolo do Estudo Clínico Aleatorizado foi submetido a revista Physical Therapy. Os dois artigos seguintes serão submetidos logo em seguida.

8. ANEXOS

8.1 ANEXO 1 Parecer do Comité de Ética e Pesquisa



PARECER CONSUBSTANCIADO DO CEP

DADOS DO PROJETO DE PESQUISA

Título da Pesquisa: Efeito do Fortalecimento Muscular em Diferentes Amplitudes de Movimento Sobre a Rigidez Passiva de Rotadores Laterais do Quadril e Cinemática de Membros Inferiores de Adultos Saudáveis e Sedentários ¿ Um Estudo Clínico Randomizado.

Pesquisador: Luciana De Michelis Mendonça

Área Temática:

Versão: 2

CAAE: 86004918.2.0000.5108

Instituição Proponente: Universidade Federal dos Vales do Jequitinhonha e Mucuri

Patrocinador Principal: Financiamento Próprio

DADOS DO PARECER

Número do Parecer: 2.719.752

Apresentação do Projeto:

O projeto intitulado "Efeito do Fortalecimento Muscular em Diferentes Amplitudes de Movimento Sobre a Rigidez Passiva de Rotadores Laterais do Quadril e Cinemática de Membros Inferiores de Adultos Saudáveis e Sedentários Um Estudo Clínico Randomizado." trata-se de um projeto de pesquisa que visa identificar o efeito do fortalecimento muscular de RL de quadril em diferentes amplitudes de movimento sobre a rigidez passiva de rotadores laterais do quadril e cinemática de membros inferiores durante agachamento.

Objetivo da Pesquisa:

Geral:

- Identificar o efeito do fortalecimento muscular de rotadores laterais de quadril em diferentes amplitudes de movimento sobre a rigidez passiva e força muscular de RL do quadril, e biomecânica corporal durante a tarefa de agachamento unipodal.

Específicos:

- Avaliar o efeito do fortalecimento dos músculos rotadores laterais em posição encurtada sobre a amplitude de movimento passiva de rotação medial do quadril.
- Avaliar o efeito do fortalecimento dos músculos rotadores laterais realizado em toda a amplitude de movimento sobre a a amplitude de movimento passiva de rotação medial do quadril.

- Avaliar o efeito do fortalecimento dos músculos rotadores laterais em posição encurtada sobre a rigidez passiva de RL do quadril.
- Avaliar o efeito do fortalecimento dos músculos rotadores laterais em toda a amplitude de movimento sobre a rigidez passiva de RL do quadril.
- Avaliar o efeito do fortalecimento dos músculos rotadores laterais em posição encurtada sobre a avaliação cinética e cinemática 3D do agachamento unipodal.
- Avaliar o efeito do fortalecimento dos músculos rotadores laterais realizado em toda a amplitude de movimento a avaliação cinética e cinemática 3D do agachamento unipodal.
- Avaliar o efeito do fortalecimento dos músculos rotadores laterais em posição encurtada sobre o pico de torque e trabalho muscular dos músculos RL do quadril.
- Avaliar o efeito do fortalecimento dos músculos rotadores laterais realizado em toda a amplitude de movimento sobre o pico de torque e trabalho muscular dos músculos RL do quadril.
-Identificar a influência da força e rigidez passiva de RL do quadril sobre a biomecânica de MMII e tronco durante avaliação 3D do agachamento unipodal.

Avaliação dos Riscos e Benefícios:

Os riscos para participação no presente estudo são mínimos. O participante poderá apresentar dor muscular de baixa intensidade após a realização do teste de força muscular e durante o protocolo de fortalecimento muscular. Caso ocorra, para minimizar a dor, será realizada termoterapia pelo pesquisador e será orientado alongamento em leve escala. A possibilidade de constrangimento durante o estudo será minimizado pelos seguintes métodos: Os protocolos de avaliação e fortalecimento muscular serão realizados em local reservado contendo apenas os pesquisadores responsáveis pelo estudo; os dados do estudo serão utilizados unicamente para fins acadêmicos, podendo serem publicados em forma de artigos científicos e apresentação em eventos acadêmicos. A identidade do participante será preservada.

Benefícios:

A participação no presente estudo trará benefícios diretos e indiretos. Os benefícios diretos serão através de melhoras biomecânicos e funcionais promovidos pelo fortalecimento e aumento da rigidez passiva dos RL do quadril. Como benefícios indiretos os resultados desta pesquisa poderão contribuir para auxiliar o profissional de fisioterapia na implementação de protocolos de fortalecimento de RL do quadril e mais eficazes para aumento da rigidez passiva de RL do quadril e melhora do padrão de movimento durante tarefas funcionais.

Comentários e Considerações sobre a Pesquisa:

Desenho:

Estudo clínico randomizado, com o avaliador cego

Hipótese:

Hipótese nula – O fortalecimento dos músculos RL do quadril em toda a amplitude de movimento, em posição encurtada e a continuidade das atividades de vida diárias apresentam o mesmo efeito sobre o aumento da rigidez passiva do quadril; melhora do desempenho no teste de agachamento unipodal e aumento do pico de torque e trabalho muscular do RL do quadril. Hipótese alternativa – O fortalecimento dos músculos RL do quadril é mais eficiente para diminuir a amplitude de movimento de rotação medial passiva do quadril; melhorar desempenho no teste de agachamento unipodal e aumentar o pico de torque e trabalho muscular do RL do quadril quando comparado a continuidade das atividades de vida diárias.

Metodologia Proposta:

Medida do torque passivo de resistência durante o movimento de rotação medial do quadril- O participante será posicionado no dinamômetro isocinético em decúbito ventral (DV), com os quadris em neutro no plano sagital, o joelho 90° de flexão e a pelve estabilizada.O eixo do dinamômetro será alinhado à tuberosidade tibial, a alavanca fixada proximal ao maléolo medial do tornozelo. A alavanca movimentará o membro inferior(MI) do participante em uma velocidade constante de 5°/s.Serão realizadas 5 repetições do movimento de rotação, para acomodação viscoelástica e familiarização com o procedimento. Em seguida, serão realizadas três repetições do teste. A amplitude de movimento será de 5° de rotação lateral do quadril até 25° de rotação medial. Para garantir que o participante esta relaxado será utilizada eletromiografia. Amplitude de movimento passiva de rotação medial do quadril Participante posicionado em DV, o MI será posicionado a 90° de flexão de joelho e neutro de rotação do quadril. Um inclinômetro será posicionado 5 centímetros distal à tuberosidade da tíbia, serão realizados 5 movimentos passivos de rotação do quadril, em seguida o participante será orientado a manter a musculatura relaxada e permitir a movimentação até que estruturas passivas interrompam o movimento. Serão realizadas 3 medidas sem contração muscular para cálculo da média. Agachamento unipodal- O participantes será orientado a realizar o agachamento partindo de extensão completa de joelho até 60° de flexão de joelho e a retornar à posição inicial. Serão realizadas 2 séries de 3 repetições, de forma alternada, com repouso de 60 segundos entre as séries. Será utilizado o sistema de captura de movimento em 3D (Qualisys modelo Oqus 3+, Gothenburg, Suécia). Serão utilizados 26 marcadores reflexivos em pontos anatômicos pré definidos e clusters de rastreamento com 4 marcadores cada, posicionados nas coxas e pernas. Será realizada uma coleta estática, e dinâmica, constituída de 2 séries de 3 repetições de agachamento unipodal. Medida do torque concêntrico

dos músculos rotadores laterais do quadril- Participantes posicionados no dinamômetro isocinético em DV, pelve estabilizada com uma cinta, quadris em posicionamento neutro no plano sagital. O joelho do membro testado em 90° de flexão e o contralateral estendido. O eixo do dinamômetro será alinhado com a tuberosidade tibial. A alavanca será fixada abaixo do maléolo medial. A ADM testada será de 5° de rotação lateral a 25° de rotação medial, em uma velocidade constante de 60°/s. Dinamometria manual/torque isométrico - O participante será orientado a se posicionar em DV com os quadris em neutro, o dinamômetro manual posicionado na perna do participante, 5 cm proximal ao maléolo lateral. A articulação do joelho será posicionada em 90° de flexo-extensão e 0° de rotação com auxílio de um inclinômetro. O participante realizará uma força máxima no sentido de rotação lateral do quadril. O avaliador coletará os resultados de 3 repetições, que serão posteriormente utilizadas para o cálculo de uma média.Fortalecimento de rotadores laterais do quadril - Os participantes serão inicialmente distribuídos entre 2 grupos. 1) Grupo controle. 2) Fortalecimento muscular de RL do quadril em toda a amplitude de movimento(ADM) disponível (GTA). Após o fim da primeira fase do estudo o grupo controle será convidado a integrar o grupo 3, fortalecimento muscular de RL do quadril em posição encurtada(GPE). O protocolo será composto por 3 séries de 8 repetições com uma intensidade de 60% de uma repetição máxima e 2 minutos de repouso entre as séries 3 vezes por semana durante 8 semanas. Caso o participante realize 1 repetição acima do número estabelecido em todas as séries em 2 sessões de treinamento consecutivas,a carga será aumentada em 10%. O GTA realizará o protocolo em toda a ADM disponível e o GPE apenas no terço final da ADM.Os testes e avaliação serão repetidos ao fim das 8 semanas de treinamento e 3 meses após o fim do treinamento.

Critério de Inclusão:

- Adultos jovens, sedentários e saudáveis com 18 anos ou mais, que possuírem amplitude de movimento de rotação medial do quadril de no mínimo 25° e rotação lateral do quadril de no mínimo 5°.
- Realizar menos que 30 min cinco dias por semana de atividade aeróbica de moderada intensidade, 20 minutos em três dias por semana de atividade aeróbia de intensidade vigorosa.
- Realizar menos de 2 dias por semana de atividades de fortalecimento ou resistência muscular.
-Não ter sido submetido a procedimentos cirúrgicos ou reabilitação no quadril ou sofrido lesão musculoesquelética nos membros inferiores/tronco nos últimos 6 meses.

Critério de Exclusão:

- Incapacidade de realizar os testes.
- Presença de contração muscular durante a realização do teste de rigidez passiva de RL do

quadril.
- Dor relatada durante o procedimento que impeça sua correta execução.
Metodologia de Análise de Dados:
A análise estatística será realizada seguindo os princípios da análise de intenção de tratar. A normalidade dos dados será testada por meio do teste de kolmogorov-smirnov e será testada a homocedasticidade dos dados. Será utilizado o teste t independente para determinar se há diferenças entre os grupos no baseline para idade, altura, índice de massa corporal (IMC), sexo, força muscular e rigidez passiva. Os dados para calcular os coeficientes de correlação intraclasse (ICCs) para a confiabilidade dos testes de resistência isométrica e amplitude de movimento passiva de rotação medial do quadril serão coletados em 2 ocasiões, com 1 semana de intervalo entre as coletas, durante um estudo piloto. Será realizada a ANOVA com medidas repetidas para identificar diferenças entre a médias pré e pós intervenção e após o acompanhamento de 3 meses para as variáveis força muscular e rigidez passiva de RL do quadril e rotação medial do quadril durante o agachamento unipodal. Todos os dados serão analisados em um nível alfa de 0,05. Diferenças significativas da ANOVA serão examinadas novamente com uma análise hoc hoc de Bonferroni, com o nível alfa corrigido de 0,05 para comparações múltiplas. Todas as análises estatísticas serãorealizadas com o SPSS V.22. e dados de resultados apresentados como media de desvio padrão.

Considerações sobre os Termos de apresentação obrigatória:
Todos os termos obrigatórios, a saber: o Projeto, a Folha de rosto, o TCLE, o cronograma e as cartas de autorização, para uso dos espaços onde serão realizados os procedimentos da pesquisa,foram devidamente apresentados.

Recomendações:
- Segundo a Carta Circular nº. 003/2011/CONEP/CNS, de 21/03/11, há obrigatoriedade de rubrica em todas as páginas do TCLE pelo sujeito de pesquisa ou seu responsável e pelo pesquisador, que deverá também apor sua assinatura na última página do referido termo.

- Relatórios deverão ser apresentados ao CEP: parciais em 09/2019, 09/2020 ao término do estudo em 09/2021. Considerase como antiética a pesquisa descontinuada sem justificativa aceita pelo CEP que a aprovou.

Conclusões ou Pendências e Lista de Inadequações:
O projeto atende aos preceitos éticos para pesquisas envolvendo seres humanos preconizados na

Resolução 466/12 CNS.

Considerações Finais a critério do CEP:

Este parecer foi elaborado baseado nos documentos abaixo relacionados:

Tipo Documento	Arquivo	Postagem	Autor	Situação
Informações Básicas do Projeto	PB_INFORMAÇÕES_BÁSICAS_DO_PROJETO_1060939.pdf	05/06/2018 15:10:06		Aceito
TCLE / Termos de Assentimento / Justificativa de Ausência	TCLE.pdf	05/06/2018 15:09:34	Hytalo de Jesus Silva	Aceito
Projeto Detalhado / Brochura Investigador	EfeitodoFortalecimentoMuscularemDiferentesAmplitudesSobreaRigidezPassivadeRotadoresLateraisdoQuadril.pdf	05/06/2018 15:09:19	Hytalo de Jesus Silva	Aceito
Brochura Pesquisa	ProtocoloFortalecimento.pdf	18/04/2018 15:14:22	Hytalo de Jesus Silva	Aceito
Declaração de Instituição e Infraestrutura	AutorizacaoLDM.jpg	18/04/2018 15:08:20	Hytalo de Jesus Silva	Aceito
Declaração de Instituição e Infraestrutura	AutorizacaoClinica.jpg	18/04/2018 15:07:41	Hytalo de Jesus Silva	Aceito
Folha de Rosto	FolhadeRosto3.pdf	18/04/2018 15:07:04	Hytalo de Jesus Silva	Aceito
Declaração de Instituição e Infraestrutura	OficiodeAutorizacaoUsodoLAM.pdf	18/04/2018 14:57:42	Hytalo de Jesus Silva	Aceito
Cronograma	Cronograma.docx	18/04/2018 14:53:12	Hytalo de Jesus Silva	Aceito

Situação do Parecer:
Aprovado

Necessita Apreciação da CONEP:
Não

DIAMANTINA, 18 de Junho de 2018

Assinado por:
Simone Gomes Dias de Oliveira
(Coordenador)

8.2. ANEXO 2 – Normas da Revista Physical Therapy

Original Research

Original research articles are scientific reports of all types of original research that are directly relevant to physical therapy and rehabilitation science and that have the potential for significant impact on (1) the practice of physical therapy and rehabilitation and/or (2) the health of individuals or the community. Maximum word count, excluding abstract=4,000 words; maximum number of tables and figures=6 (total); references should number no more than 75. Special requirements based on type of original research.

Reviews

PTJ is interested in systematic reviews, scoping reviews, and meta-analyses. Maximum word count, excluding abstract=4,500 words; maximum number of tables and figures=6 (total); references should number no more than 100. Special requirements for reviews.

Perspectives

Perspectives expound on topics such as a specific clinical approach to patient care (on either a theoretical or practical basis) or address professional issues in rehabilitation and health care. Perspectives are not classic literature reviews. Often written by thought leaders, they contain new ideas, interpretations, and opinions and are intended to inform and advance rehabilitation science, physical therapist practice, and education in important ways. Maximum word count, excluding abstract=4,500 words; maximum number of tables and figures=6 (total); references should number no more than 75. *There are no headings in perspective abstracts.*

Points of View

Points of View (POV) are brief thought pieces on timely issues of concern to physical therapy, rehabilitation, and related disciplines and that relate to health care delivery systems, health policy, or patients and members of society who are interested in health and well-being. POVs frequently include calls to action. *POVs are by invitation only.*

Authors interested in writing a POV may contact the managing editor at janreynolds@apta.org. Maximum word count =1,600 words; maximum number of tables and figures=2 (total); references should number no more than 25.

Trial Protocols

Trial protocols are essential for study conduct, review, and reporting. Publication of protocols increases research quality and transparency, as they allow for timely dissemination of high-quality trial designs, prevention of study duplication, and improved

interpretation of study findings. Furthermore, protocol articles can provide additional rationale, background, and organization of the clinical trial beyond what is commonly available in trial registries. PTJ encourages authors to follow the CONSORT Guidelines. **PTJ** considers publication of protocols for trials that have the potential for substantial impact on the field of rehabilitation. The proposed study must be from a randomized clinical trial that: is prospectively registered in a recognized clinical trials registry, has current institutional review board (IRB) approval, is not yet published, has fewer than 50% of participants enrolled, and has no fatal flaws in the methods. Maximum word count, excluding abstract=3,000 words; maximum number of tables and figures=6 (total); references should number no more than 75. Special requirements for protocols.

Clinical Practice Guidelines

Roadmap for Publishing Clinical Practice Guidelines in PTJ explains **PTJ**'s submission requirements for clinical practice guidelines (CPGs). Proposals for CPGs must be submitted through **PTJ**'s ScholarOne submission site. Questions about submitting CPGs should be directed to the managing editor at janreynolds@apta.org.

Linking Evidence and Practice (LEAP)

LEAP articles highlight the findings of a recent Cochrane systematic review (SR) that provides evidence for recommendations *relevant to physical therapist clinical decision making*, and, using a brief case, illustrate the application of those recommendations. Only Cochrane SRs with searches completed within the past 3 years should be used. SRs that do not provide recommendations due to insufficient evidence should not be used. Author teams with both research and clinical expertise are encouraged; one team member should be a physical therapist. *LEAPs are by invitation only*. Authors interested in writing a LEAP may submit their proposed topic to ptjreviews@apta.org. Maximum word count =2,500 words; maximum number of tables and figures=4 (total); references should number no more than 50. Special requirements for LEAP.

Case Reports

PTJ publishes a limited number of case reports on potentially transformational interventions of a clinical, educational, or administrative nature. Reports should emphasize novelty and innovation, addressing clinical conditions or approaches that have not been previously described in the published rehabilitation literature. PTJ only publishes case reports that clearly inform and advance practice, administrative, or educational methods or suggest testable hypotheses for future research. Case reports should not be used to test hypotheses or establish cause-and-effect relationships. Clinical case reports will not be

considered for review if randomized controlled trials (RCTs) have been published on the topic, unless the author can make the case for novelty. A hypothesis-driven, single-subject design research study should be submitted to PTJ as a research report. Maximum word count, excluding abstract=2,000 words; maximum number of tables and/or figures=3 (combined total); references should number no more than 20. Special requirements for case reports.

Letters to the Editor

PTJ Letters to the Editor provide reader perspectives on articles published in PTJ and should be submitted within 6 months of the article's publication. Special requirements for letters.

Special Requirements for Original Research

Below are the unique submission requirements for specific types of original research. For general submission requirements, and for all other types of original research, please refer to How to Prepare a Manuscript for Submission.

Clinical Trials

As defined by the International Committee of Medical Journal Editors (ICMJE), a clinical trial is any research project that prospectively assigns human participants to intervention or comparison groups to determine a cause-and-effect relationship between an intervention and an outcome. The World Health Organization (WHO) states, "A clinical trial is any research study that prospectively assigns human participants or groups of humans to one or more health-related interventions to evaluate the effects on health outcomes. Clinical trials may also be referred to as interventional trials. Interventions include but are not restricted to drugs, cells and other biological products, surgical procedures, radiologic procedures, devices, behavioral treatments, process-of-care changes, preventive care, etc. This definition includes Phase I to Phase IV trials."

Trial Registration

All clinical trials with patient-level outcome measures must be **prospectively registered** (ie, BEFORE enrollment begins) in a trial registry. For further guidance, refer to "Is This a Clinical Trial? And Should It Be Registered?" Upon submission, authors are required to:

1. Specify where the trial is registered (information about trial registration and registries) and provide the trial's unique registration number in their cover letter.

2. Include in their cover letter a statement regarding when enrollment began.

CONSORT Requirements

PTJ endorses the transparent reporting of clinical trials and the CONSORT (Consolidated Standards Of Reporting Trials) statement and its extensions. Authors are required to follow these guidelines and to include the "modified the CONSORT flow diagram for randomized, controlled trials of nonpharmacologic treatment" within the manuscript. For guidance, refer to the checklist for randomized trials of nonpharmacologic treatment (http://www.consort-statement.org/extensions/interventions/non-pharmacologic-treatment-interventions/). It is essential that reports of trials provide sufficient details on interventions so that readers can judge the applicability and clinical relevance of results. Authors are encouraged to provide a trial treatment manual as an online-only appendix.

TIDieR

PTJ

has adopted TIDieR (Template for Intervention Description and Replication). For guidance, authors of manuscripts reporting on evaluative studies of interventions (including clinical trials) are encouraged to refer to the TIDieR checklist.

Special Formatting

Title. For randomized trials, add the subtitle "Randomized, Controlled Trial" to the full title of your manuscript.

Abstract. Structure: Background, Objective, Design, Setting, Patients, Intervention, Measurements, Results, Limitations, Conclusions (see Haynes).

Body of Manuscript. Word limit: 4,000 words (excluding abstract and references).

Sections: Introduction, Methods, Results, and Discussion.

References. No more than 75

Diagnostic Studies

Sensitivity and specificity alone are insufficient for diagnostic studies. The likelihood ratio (LR) with confidence interval (CI) must be reported, along with an interpretation of the clinical relevance of the findings.

STARD Requirements

PTJ endorses the **Sta**ndards for **R**eporting of **D**iagnostic accuracy (STARD) (http://www.equator-network.org/reporting-guidelines/stard/). Authors are required to follow these guidelines and to include a STARD flow diagram;within the manuscript. For guidance, refer to the STARD checklist.

Special Formatting

Title. Identify the article as a study of diagnostic accuracy somewhere in the title.
Abstract. Structure: Background, Objective, Design, Setting, Patients, Measurements, Results, Limitations, Conclusions (see Haynes).
Body of Manuscript. Word limit: 4,000 words (excluding abstract and references). Sections: Introduction, Methods, Results, and Discussion.
References. No more than 75

Measurement Property Evaluation Studies

Studies that evaluate measurement properties must make a clear and compelling argument for how the findings would have a substantial impact on clinical practice.

As indicated by the objectives of the study, authors should report appropriate test results, including:

- Estimates of reliability in the same units as the test to aid in clinical interpretation (eg, for quantitative data, the ICC with 95% CI are appropriate, along with single score error estimates such as the SEM; for nominal and ordinal level data, the kappa or weighted kappa are commonly used)
- Evidence for content, criterion-based, and/or construct validity
- Information on the interpretability and clinical meaningfulness of measurements
- Interpretation of change scores

COSMIN Requirements

PTJ has adopted COnsensus-based Standards for the selection of health Measurement INstruments (COSMIN). For guidance, refer to the COSMIN checklist.

Note: Cross-cultural instrument translations are not within the scope of PTJ unless the authors can make the case that the work has the potential for significant impact on physical therapist practice or rehabilitation science.

Special Formatting

Abstract. Structure: Background, Objective, Design, Methods, Results, Limitations, Conclusions.
Body of Manuscript. Word limit: 4,000 words (excluding abstract and references). Sections: Introduction, Methods, Results, and Discussion.
References. No more than 75

Observational and Prognostic Studies
STROBE Guideline

PTJ endorses the STrengthening the Reporting of OBservational studies in Epidemiology (STROBE) statement (http://www.strobe-statement.org/index.php?id=strobe-home). Authors are required to follow these guidelines and to include a flow diagram within the manuscript. For guidance, refer to the most appropriate checklist (cohort, case-control, or cross-sectional design):

TIDieR

PTJ has adopted the Template for Intervention Description and Replication (TIDieR). For guidance, refer to the TIDieR checklist.

Special Formatting

Abstract. Structure: Background, Objective, Design, Methods, Results, Limitations, Conclusions (see Haynes).
Body of Manuscript. Word limit: 4,000 words (excluding abstract and references). Sections: Introduction, Methods, Results, and Discussion.
References. No more than 75

Qualitative Studies

SRQR Requirements

PTJ requires authors to follow the Standards for Reporting Qualitative Research (SRQR).

Special Formatting

Abstract. Structure: Background, Objectives, Design, Methods, Results, Conclusions.
Body of Manuscript. Word limit: 4,000 words (excluding abstract and references).
Sections: Introduction, Methods, Results, and Discussion.
References: No more than 75

Quality Improvement Studies

SQUIRE Requirements

PTJ endorses the Standards for QUality Improvement Reporting Excellence (SQUIRE) (http://www.squire-statement.org). For guidance, refer to the SQUIRE checklist.

Special Formatting

Abstract. Structure: Background, Purpose, Design, Methods, Results, Limitations, Conclusions (see Haynes).

Body of Manuscript. Word limit: 4,000 words (excluding abstract and references).
Sections: Introduction, Methods, Results, and Discussion.

References. No more than 75

Single Subject Research

Single-subject research designs allow conclusions to be drawn about the effects of treatment based on the responses of a patient or patients under controlled conditions. Single-subject research is often confused with case reports; however, single-subject designs have 2 core elements that distinguish them from case reports: repeated measurements, and design phases.

SCRIBE Guideline

PTJ endorses the SCRIBE guideline (see "The Single-Case Reporting Guideline In BEhavioural Interventions [SCRIBE] 2016 Statement"). For guidance, refer to the SCRIBE checklist.

Special Formatting

Abstract. Structure: Background, Objective, Design, Methods, Results, Limitations, Conclusions (see Haynes).
Body of Manuscript. Word limit: 4,000 words (excluding abstract and references). Sections: Introduction, Methods, Results, and Discussion.
References. No more than 75

Other Original Research

For other types of original research, please refer to How to Prepare a Manuscript for Submission.

Special Requirements for Reviews
PRISMA Guidelines

PTJ endorses the Preferred Reporting Items for Systematic reviews and Meta-Analyses (PRISMA) statement (http://www.prisma-statement.org). Authors submitting systematic reviews and meta-analyses are required to follow these guidelines and to include a flow diagram within the manuscript. For guidance, refer to the checklist.

PTJ also considers scoping reviews. A scoping review, or scoping study, is a form of knowledge synthesis that addresses an exploratory research question aimed at mapping key concepts, types of evidence, and gaps in research related to a defined area or field by systematically searching, selecting, and synthesizing existing knowledge (Colquhoun, Levac, O'Brien et al, 2014). A typical systematic review aims to answer a specific question

or series of questions according to a rigid set of a priori delimiting factors detailed in the protocol, whereas a scoping review has a broader approach, generally with the aim of mapping literature and addressing a broader research question.

Special Formatting

Title. For studies that are meta-analyses or systematic reviews, add that descriptor as the subtitle at the end of the title.

Abstract. Structure: Background, Purpose, Data Sources, Study Selection, Data Extraction, Data Synthesis, Limitations, Conclusions (see Haynes).

Body of Manuscript. Word limit: 4,500 words (excluding abstract and references). Please provide the manuscript word count on the abstract page of your manuscript. Sections: Introduction, Methods, Results, and **Discussion.** The Methods section subheadings should be: Data Sources and Searches; Study Selection; Data Extraction and Quality Assessment; Data Synthesis and Analysis.

References. No more than 75

Special Requirements for Trial Protocols

PTJ considers publication of protocols for trials that have the potential for substantial impact on the field of rehabilitation. The proposed study **must be from a randomized clinical trial that:**

- Is prospectively registered in a recognized clinical trials registry
- Has current institutional review board (IRB) approval
- Is not yet published
- Has fewer than 50% of participants enrolled
- Has no fatal flaws in the methods

SPIRIT Requirements

PTJ endorses the SPIRIT statement (http://www.spirit-statement.org). Authors are required to follow these guidelines and are encouraged to refer to the checklist for guidance.

TIDieR

PTJ has adopted the Template for Intervention Description and Replication (TIDieR). For guidance, authors of manuscripts reporting evaluative studies of interventions—or describing interventions, as in a protocol—are encouraged to refer to the TIDieR checklist.

CONSORT

PTJ encourages authors to follow the CONSORT (Consolidated Standards Of Reporting Trials) guidelines.

Letter of Assurance

Authors are required to submit a letter assuring **PTJ** that no part of the study protocol has been previously published or is under consideration for publication elsewhere.

Special Formatting

Title. Provide a descriptive title identifying the study design, population, interventions, and, if applicable, trial acronym.
Abstract. Structure: Background, Objective, Design, Setting, Participants, Intervention, Measurements, Limitations, Conclusions.
Body of Manuscript. Word limit: 3,000 words (excluding abstract and references). Sections: Introduction (background and clear rationale for the need for the study, primary and secondary objectives, description of trial design), Methods (description of participants, interventions outcomes, assignment of interventions; description of data collection, management, analysis, monitoring and auditing), Ethics (informed consent, research ethics approval, confidentiality, role of the funding agency), and Discussion (potential impact and significance of study, strengths and weaknesses, contribution to the physical therapy/rehabilitation profession).
References. No more than 75

Special Requirements for LEAP (Linking Evidence and Practice)

Abstract

Use the wording of abstracts found in previous LEAP articles, changing only the relevant final sentence(s) to fit your topic.

Background/Introduction

Start with a brief description of the condition, usual treatment, and rationale for the intervention. End the section by introducing the systematic review (SR) and its purpose, inclusion criteria, and main outcomes. Include the search date of the SR (rather than the publication date) to indicate how up to date the SR is.

Take Home Message

Provide a brief description of the SR results, then refer to the Table (see below). In the take home message, include:

- Number of included trials
- Number of participants
- Any brief, relevant description of the included trials
- Data for the main outcomes of the SR
- When summarizing the evidence from the SR, indicate the authors' interpretation of the quality of the evidence, if available. In more recent Cochrane SRs, authors grade the strength of evidence based on the GRADE Working Group recommendations as high, moderate, low, or very low.

Case

Provide a case that applies the results of the SR. The case may be wholly factual, adapted from an actual case, or a representation of a typical patient with the relevant condition. Do

not include the level of detail that might be important if this was a case report. Include the following headings in this order:

"Can [intervention] help [the patient]?"

- Briefly describe the patient's condition.
- Only data essential to the case and how it relates to the SR should be included.

"How did the results of this systematic review apply to [the patient]?"

- Frame the question related to the case using a PICO format—population, intervention(s), comparator(s), outcome(s).
- Using the PICO format (patient relevance, intervention relevance, comparison relevance, outcome relevance), address how useful or relevant the SR results are for the purpose of synthesizing an intervention plan for this patient.
- Describe the clinician's specific recommendation for intervention(s) for the patient based on the SR results.

"How well do the outcomes of the intervention provided to the patient match those suggested by the systematic review?"

Briefly describe the patient's outcomes, including the clinical importance of any changes in relevant measures.

"Can you apply the results of this systematic review to your own patients?"

- Provide a brief summary of the types of patients to whom the results of the SR apply in general.
- In some cases, discussion of additional material may be of relevance, such as pertinent SRs of other interventions for the condition being discussed, or the results of trials published subsequent to the **search date** of the SR.

"What can be advised based on the results of this systematic review?"

Include a brief summary of recommended intervention(s) relevant to those reported in the SR.

Table of Key Results

Include the following details in this order:

Overview

- Search date, number of included trials and number and characteristics of participants.
- Details about the intervention(s) such as frequency, intensity, duration (eg, "4 studies – 3 times/week; 10 studies – 1 time/week") and comparators.

Main outcomes of the review

- In general, divide the results according to comparisons that were made (eg, Treatment A versus placebo; Treatment A versus treatment B). Indicate how many trials and participants each reported outcome is based on, the risks of bias, and, if available, the overall quality of evidence based on the GRADE Working Group recommendations.
- Report the size of the treatment effects for each outcome with significant differences favoring one treatment over another. These effects should be reported in units that clinicians can easily interpret; for example, they could be differences in proportions improved (for dichotomous outcomes) or mean differences (for continuous measures) (eg, pain scores).
- Provide an indication of the absolute benefit that could be expected from the treatment for each outcome.
- If the effect is presented as a standardized mean difference, revert it back into a clinically understandable unit. If this is not possible, please provide criteria for interpreting these (eg, Cohen criteria: small, medium, large effect; minimal detectable change [MDC] or minimal clinically important difference [MCID].

Special Requirements for Case Reports

PTJ endorses the CARE guidelines for clinical case reports. Authors are required to follow these guidelines in writing the manuscript.

Case report submissions must include a patient consent form(s) (if the case is patient-based). In addition to submitting signed patient consent forms, authors of case reports who practice in the United States should include a statement about meeting the HIPAA (Health Insurance, Portability, and Accountability Act) requirements of the institution for disclosure of protected health information.

Special Formatting

Abstract. Structure: Background and Purpose, Case Description, Outcomes, Discussion
Body of Manuscript. Word limit: 2,000 words (excluding abstract and references). To condense information to meet the word limit, **PTJ** recommends that authors use tables whenever possible to provide important details (history, examination, intervention, and outcome information for clinical case reports; program elements and materials for educational/administrative case reports).
References. No more than 20

Special Requirements for Letters to the Editor

PTJ Letters to the Editor (e-Letters) are considered for publication when they relate to an article published in **PTJ**. Letters commenting on an article must be submitted within 6 months of the article's publication.

Letters to the Editor should be submitted as an Letter to the Editor at https://mc.manuscriptcentral.com/ptjournal.

Letters are reviewed by the Editors. If approved, the Letter is published in the next available issue, with only minimal copyediting for grammar or punctuation. Authors of the articles being discussed may be alerted and encouraged to respond.

Fast-Track Review

Manuscripts reporting on original research that has the potential to make a strong and immediate impact on the field of rehabilitation are considered for fast-track peer review (14 days from submission to first decision). Only manuscripts in the Original Research category are considered for fast tracking. Authors must request fast track review prior to submission by sending the abstract and a rationale for why their paper should be fast tracked to ptjreviews@apta.org. Please put FAST TRACK in the subject line.

Editorial Policies

Ethics Statement

Authors should observe high standards with respect to publication ethics as set out by the Commission on Publication Ethics (COPE). Falsification or fabrication of data, plagiarism, including duplicate publication of the authors' own work without proper citation, and misappropriation of the work are all unacceptable practices. Any cases of ethical misconduct are treated very seriously and will be dealt with in accordance with the COPE guidelines.

Redundant, Duplicate, or Simultaneous Publication

PTJ reviews and considers a manuscript for exclusive publication with the understanding that the manuscript, or any substantial portion of the manuscript (as judged by the Editor in Chief), has not been published previously and is not under consideration for publication elsewhere, whether in print or electronic form.

This policy does not usually preclude consideration of (1) a manuscript that has been rejected by another journal or (2) a complete report that follows publication of a preliminary report or pilot study. Press reports on papers presented at a scientific meeting usually will not be considered to constitute prior publication, but such reports should not be

amplified by additional data or copies of tables and illustrations (see also Prior Disclosure and Media Embargo Policy).

Redundancy in publications occurs when the work of 2 or more papers from the same author overlaps substantially. Authors submitting manuscripts to **PTJ**, are asked to include in their cover letter an explanation of any prior submission or publication (eg, published article, article in press, manuscript under review, posting of results in registries) that includes data from the same subjects studied in the submitted manuscript. Previous publication of a small fraction of the content of a manuscript does not necessarily preclude its being published in **PTJ**, but the editors need information about previous publication. Authors must provide a copy of related papers—that is, submitted or published papers that deal with the same data, in part or in full, that are reported in the manuscript being submitted to **PTJ**. These materials will be confidential and will be viewed only by the editors.

Duplicate Publication is the publication of the same paper or substantially similar papers in the same journal or in more than one journal. **PTJ**'s Editorial Board holds that publication more than once of the same study results, regardless of whether the wording is the same or different, is rarely justified. Articles previously published in another language will not be considered for publication in **PTJ**.

The Editorial Board reserves the right to consult with other journals about the content of the papers in question. Furthermore, **PTJ** may decide to take one or more of the following actions: (1) Immediately reject the manuscript without review. (2) Decline to consider any manuscripts from the author(s) for a period of time. If a paper is accepted and published before evidence of duplication is discovered, **PTJ** probably will publish a notification of redundant or duplicate publication, with or without the author's explanation or approval. Typically, **PTJ** will request that the authors write a letter acknowledging the duplicate publication. The Editorial Board may notify appropriate institutions, ranging from national databases to the authors' academic departments or university administrators, at its discretion.

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Disclosure of Commercial/Financial Associations and Conflict of Interest

All funding sources supporting the work should be acknowledged. During the submission process, authors will be required to enter this information.

PTJ has adopted the International Committee of Medical Journal Editors (ICMJE) initiative to standardize a format for disclosing competing interests. For more information, please refer to the JAMA editorial at http://jama.jamanetwork.com/article.aspx?articleid=185138. Each author is required to complete the ICMJE Uniform Disclosure Form for Potential Conflicts of Interest. This information will be held in confidence by the Editor in Chief during the review process and, if the paper is accepted for publication, will be shared with readers as appropriate. We thank authors for their assistance in this effort.

Ethical Approval of Research and Informed Consent

All Research Reports must include a statement that the study complies with the Declaration of Helsinki and that the authors received approval or a waiver from a properly constituted ethics committee. In the cover letter that is submitted with the manuscript, authors should provide the name of the institutional review board (IRB), institutional animal care and use committee, or other similar body that approved the study.

Authors also should submit patient consent forms for photographs or videos. Within the manuscript, authors must include a statement in the "Method" section that they obtained informed consent of participants, when required for protection of human subjects. Along with their signed copyright release forms, authors of Case Reports should submit a signed patient consent form. Case Report authors who practice in the United States should also include a statement about meeting the HIPAA (Health Insurance, Portability, and Accountability Act) requirements of the institution for disclosure of protected health information.

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The Editor in Chief and Editorial Board reserve the right to reject, without full review, any manuscript that does not meet **PTJ**'s requirements. Each manuscript is prescreened by an Editorial Board member team.

Manuscripts that qualify for full review typically are reviewed by 2 content experts, a statistical consultant as appropriate, and an Editorial Board member. Both the reviewers and the Editorial Board members are required to complete a conflict-of-interest statement for each manuscript they review. The initial review takes 37 days on average. The mean number of days in review from submission to final decision is 48.

Once you have submitted your manuscript via ScholarOne, you can check on its progress by visiting the ScholarOne website. If you have any questions during the review period, contact the editorial tracking manager at karendarley@apta.org.

Deposit of Articles to Approved Public Repositories

National Institutes of Health (NIH). Public Access Policy (NOT-OD-05-022) states:

The Director of the National Institutes of Health shall require that all investigators funded by the NIH submit or have submitted for them to the National Library of Medicine's PubMed Central an electronic version of their final, peer-reviewed manuscripts upon acceptance for publication, to be made publicly available no later than 12 months after the official date of publication: Provided, That the NIH shall implement the public access policy in a manner consistent with copyright law.

This policy applies to all articles, including all graphics and supplemental materials generated by the authors, that (1) are accepted for publication on or after April 7, 2008, and (2) arise in whole or in part from direct costs funded by NIH or from NIH staff. The policy also may apply to systematic reviews of randomized controlled trials that were funded by NIH. More information about the policy is available

at http://publicaccess.nih.gov/policy.htm and http://grants.nih.gov/grants/guide/notice-files/NOT-OD-08-033.html.

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Publication Process

Page Proofs

THROUGH NOVEMBER 30: Authors are sent page proofs by email, so it is essential that a current email address is supplied with all manuscripts. These should be checked immediately, and corrections, as well as answers to any queries, should be returned as an annotated PDF via the online proofing system within 7 working days (further details are supplied with the proof). It is the author's responsibility to check proofs thoroughly.

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How to Prepare a Manuscript for Submission

General Requirements

PTJ endorses the Uniform Requirements for Manuscripts Submitted to Biomedical Journals put forth by the International Committee of Medical Journal Editors (ICMJE).

PTJ promotes "people-first" language. That is, patients and subjects should not be referred to by disability or condition (eg, use "patients who have had a stroke" or "patients with stroke," rather than "stroke patients" or "stroke survivors").

Ethics Approval

All manuscripts reporting on studies involving human participants must include a statement that the authors received approval from a properly constituted ethics committee. In the cover letter that is submitted with the manuscript, authors should provide the name of the institutional review board (IRB), institutional animal care and use committee, or other similar body that approved the study.

Raw Data

PTJ works to maintain the highest levels of integrity and accountability. The Editors therefore reserve the right to ask researchers to provide the raw data for their studies during review or at any time up to 5 years after publication in PTJ. This would likely happen only when credibility of the research has been brought into serious question.

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All individuals listed as authors should qualify for authorship and should have participated sufficiently in the work to take public responsibility for appropriate portions of the content. Authors included in the manuscript should meet all of the following conditions: 1) substantial contributions to the conception and design, acquisition of data, or analysis and interpretation of data; 2) drafting the article or revising it critically for important intellectual content; and 3) final approval of the version to be published. Information about author roles and responsibilities must be made clear. Any other contributors to the work who do not qualify for authorship should be listed in an acknowledgement section. For further information about authorship, please refer to the ICMJE guidelines.

Conflict of interest: All authors must make a formal statement at the time of submission indicating any potential conflict of interest that might constitute an embarrassment to any of the authors if it were not to be declared and were to emerge after publication. Such conflicts might include, but are not limited to, shareholding in or receipt of a grant or consultancy fee from a company whose product features in the submitted manuscript or which manufactures a competing product.

PTJ follows the guidelines of the International Committee of Medical Journal Editors and an ICMJE disclosure of potential conflicts of interest (COI) form must be submitted for each author at the time of manuscript submission. Forms must be submitted even if there is no conflict of interest. It is the responsibility of the corresponding author to ensure that all authors adhere to this policy prior to submission. Each other author also must indicate their roles and responsibilities.

A conflict of interest statement must also be included in the manuscript after any "Acknowledgements" and "Funding" sections and should summarize all aspects of any conflicts of interest included on the ICMJE form. If there is no conflict of interest, authors must include 'Conflict of Interest: none declared'.

Statistics

Requirements for addressing clinical relevance. In reporting statistical results, *P* values alone are insufficient. **PTJ** authors are required report the magnitude and/or precision of statistical estimates (eg, 95% CI) to enhance data interpretation and clarify which results potentially have an impact on clinical practice.

Percentages. Report percentages to one decimal place (ie, xx.x %).

Standard deviations. Use "mean (SD)" rather than "mean ± SD" notation. Report confidence intervals (CI) rather than standard errors.

***P* values.** Report exact *P* values to 2 decimal places, except when $P \leq .001$ and in that case $P \leq .001$ is sufficient. *P* values alone are insufficient and must be accompanied with appropriate magnitude and precision estimate.

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