

UNIVERSIDADE FEDERAL DE PELOTAS
Escola Superior de Educação Física e Fisioterapia
Programa de Pós-graduação em Educação Física



Tese

**Exercícios supervisionados remotamente para pacientes com osteoartrite de
joelho: implicações em desfechos reportados, parâmetros funcionais e na
arquitetura e qualidade muscular**

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PELOTAS, 2025

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Tese apresentada ao Programa de Pós-Graduação em Educação Física da Escola Superior de Educação Física e Fisioterapia da Universidade Federal de Pelotas, como requisito parcial à obtenção do título de Doutor em Educação Física.

Orientadora: Prof. Dr^a Cristine Lima Alberton

PELOTAS, 2025

Universidade Federal de Pelotas / Sistema de Bibliotecas
Catalogação da Publicação

C331e Carvalho, Maurício Tatsch Ximenes

Exercícios supervisionados remotamente para pacientes com osteoartrite de joelho: implicações em desfechos reportados, parâmetros funcionais e na arquitetura e qualidade muscular [recurso eletrônico] / Maurício Tatsch Ximenes Carvalho ; Cristine Lima Alberton, orientadora. — Pelotas, 2025.
458 f.

Tese (Doutorado) — Programa de Pós-Graduação em Educação Física, Escola Superior de Educação Física e Fisioterapia, Universidade Federal de Pelotas, 2025.

1. Modalidades de Fisioterapia. 2. Ultrassonografia. 3. Exercício Terapêutico. 4. Telerreabilitação. I. Alberton, Cristine Lima, orient. II. Título.

CDD 615.8

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implicações em desfechos reportados, parâmetros funcionais e na arquitetura e
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Tese aprovada, como requisito parcial para obtenção do grau de Doutor em Educação Física, Programa de Pós-Graduação em Educação Física, Escola Superior de Educação Física e Fisioterapia, Universidade Federal de Pelotas.

Data da defesa: 28 de março de 2025.

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Resumo

CARVALHO, Maurício Tatsch Ximenes. Exercícios supervisionados remotamente para pacientes com osteoartrite de joelho: implicações em desfechos reportados, parâmetros funcionais e na arquitetura e qualidade muscular. Orientadora: Cristine Lima Alberton. 2025. p.458 Tese (Doutorado) - Programa de Pós-Graduação em Educação Física, Escola Superior de Educação Física e Fisioterapia, Universidade Federal de Pelotas, Pelotas, Brasil.

Esta tese investigou duas abordagens para disponibilização de exercícios a pacientes com osteoartrite (OA) de joelho, assim como as repercussões da OA de joelho na arquitetura e qualidade muscular. Foram três objetivos principais. O primeiro foi avaliar a efetividade da estimulação elétrica neuromuscular (EENM) combinada ao exercício em desfechos reportados pelos pacientes, por meio de uma revisão sistemática com metanálise, que encontrou evidências insuficientes para implementação na prática clínica. Embora alguns estudos indicaram redução da dor, são necessários mais estudos de qualidade para confirmar o uso clínico da EENM combinado ao exercício. O segundo objetivo consistiu em revisar a aplicabilidade clínica das medidas ultrassonográficas do quadríceps femoral em pacientes com OA de joelho. No estudo, encontramos que os protocolos de ultrassom carecem de padronização, apesar do crescente interesse nas mudanças do quadríceps femoral na OA de joelho, especialmente na espessura muscular e intensidade do eco. Observa-se redução da espessura no vasto medial e piora da qualidade muscular no vasto medial e intermédio (aumento da intensidade do eco). Além disso, a espessura muscular está associada a desfechos reportados pelos pacientes e a performance funcional, enquanto a intensidade do eco se relaciona à performance funcional. O terceiro, e principal, objetivo foi avaliar se a supervisão remota de um programa de fortalecimento muscular é não inferior à presencial para melhora da dor e função física. No ensaio clínico *Remote and In-person Supervised Exercise in Patients with Knee Osteoarthritis* (RISE-KOA), observou-se que um programa de exercícios supervisionados remotamente via videochamadas é não inferior ao formato presencial para melhorar a dor e a função física de pacientes com OA de joelho. Com respostas semelhantes entre os dois formatos (remoto e presencial) em relação a outros desfechos reportados pelos pacientes relativos a condição articular, a performance funcional e a arquitetura e qualidade muscular do quadríceps femoral. Espera-se que esta tese contribua para a padronização da ultrassonografia na prática clínica fisioterapêutica para melhorar a qualidade de avaliação de pacientes com OA de joelho. Assim como, oportunize a ampliação do acesso ao tratamento baseado em exercícios via supervisão remota em tempo real para esses pacientes, especialmente em países em desenvolvimento.

Palavras-chave: Modalidades de Fisioterapia; Ultrassonografia; Exercício Terapêutico; Telerreabilitação.

Abstract

CARVALHO, Maurício Tatsch Ximenes. Remotely Supervised Exercises for Patients with Knee Osteoarthritis: Implications for Patient-Reported Outcomes, Functional Parameters, and Muscle Architecture and Quality. Advisor: Cristine Lima Alberton. 2025. p.458. Thesis (Doctorate) – Graduate Program in Physical Education, School of Physical Education and Physiotherapy, Federal University of Pelotas, Pelotas, Brazil.

This thesis investigated two approaches for delivering exercise programs to patients with knee osteoarthritis (OA) and the effects of OA on muscle architecture and quality. Three main objectives were addressed. The first was to evaluate neuromuscular electrical stimulation (NMES) combined with exercise on patient-reported outcomes through a systematic review with meta-analysis, which found insufficient evidence for its efficacy. Although some studies indicated pain reduction, further high-quality research is needed to confirm the clinical use of NMES combined with exercise. The second objective was to review the clinical applicability of quadriceps femoris ultrasound measures in patients with knee OA. The study revealed that ultrasound protocols lack standardization despite growing interest in quadriceps femoris changes in OA, particularly in muscle thickness and echo intensity. A reduction in vastus medialis thickness and decreased muscle quality in both the vastus medialis and vastus intermedius (increased echo intensity) were observed. Furthermore, quadriceps muscle thickness was associated with patient-reported outcomes and functional performance, while echo intensity correlated with functional performance. The third and primary objective was to assess whether remote supervision of a muscle-strengthening program is not inferior to in-person supervision for improving pain and physical function. In the Remote and In-Person Supervised Exercise in Patients with Knee Osteoarthritis (RISE-KOA) study, remote exercise supervision via video calls was found to be non-inferior to the in-person format for improving pain and physical function in patients with knee OA. Both approaches yielded similar outcomes regarding other patient-reported measures related to the joint condition, functional performance, and quadriceps femoris muscle architecture and quality. This thesis is expected to contribute to the standardization of ultrasound in physical therapy clinical practice to improve the assessment quality of patients with knee OA. Additionally, it may facilitate the expansion of real-time remote supervision of exercise-based treatment, particularly in developing countries.

Keywords: Physical Therapy Modalities; Ultrasound; Therapeutic Exercise; Telerehabilitation.

Agradecimentos

A concretização deste trabalho ocorreu pela dedicação e colaboração de várias pessoas. Em especial agradeço:

- Aos meus pais, Maria Alvarina Dias Tatsch e Djalma Adair Ximenes Carvalho, por terem me incentivado, ao longo de toda a minha formação, a estudar e a lutar pelos meus sonhos;

- Ao Vinicius Costa Prado, meu colega de escola e um amigo para vida toda que me inspira todos os dias pela sua força, persistência e resiliência. Especial agradecimento a esse amigo que sempre me apoiou e vibra junto as minhas conquistas. Amigo que acompanhou todas as minhas batalhas desde a graduação até este momento, a defesa do meu doutorado;

- Ao Cristiano Ferreira Silveira, meu amigo que conheci em Bagé e acompanhou toda a minha jornada assumindo as atividades como professor e doutorando. Agradeço pela parceria e apoio em etapas importantes do meu doutorado, assim como por me incentivar e sempre acreditar em mim;

- Ao Henrique Rockenbach de Almeida, meu namorado e parceiro de vida que vive junto comigo os meus anseios, incertezas e alegrias. Obrigado por fazer os meus dias mais felizes, ser um lugar seguro em meio a tantas demandas e por estar ao meu lado;

- A equipe do estudo RISE-KOA que foi incansável em todas as etapas de coleta de dados. Me sinto particularmente orgulhoso dessa equipe, porque ela foi composta na sua grande maioria pelos meus alunos de graduação. Estudantes que tiveram a sua primeira experiência participando de um ensaio clínico randomizado e foram fundamentais para concretização deste trabalho. Sem eles o estudo não teria acontecido. Remeto um agradecimento especial à Adriana Celina Domingues Avila, Fernanda Silveira de Sena, Luana Gualarte Moreira, Luiza da Silva Cardoso Macedo, Raíssa Pereira Trassante, Jéssica Vargas Dias e Eduarda Carvalho da Silva.

- Ao Breno Berny Vasconcelos e ao Victor Hugo Guesser Pinheiro, colegas do grupo de pesquisa LabNeuro, que participaram das coletas de dados dos estudos. Obrigado pela parceria e comprometimento.

- A Professora Cristine Lima Alberton, minha orientadora de doutorado, que depositou muita confiança em mim, permitindo que minhas ideias fossem concretizadas nos estudos que conduzimos. Sou imensamente grato por sua orientação ao longo de toda a minha jornada no grupo de pesquisa. Desde o início do doutorado, minha preocupação era aproveitar ao máximo essa experiência e o privilégio de ser orientado por uma referência tão importante na ciência do exercício. Sinto orgulho da trajetória que construí, e isso é um reflexo direto da orientação que recebi. Além disso, mesmo enfrentando desafios, como conciliar trabalho, doutorado

e superar dificuldades financeiras, sempre encontrei na minha orientadora alguém que acreditou no meu potencial. Obrigado!

- Aos professores Michele Forgiarini Saccol e Airton José Rombaldi, que participaram da minha banca de qualificação de doutorado e teceram considerações fundamentais para o aprimoramento deste trabalho.

- As professoras Ana Zilda Ceolin Colpo e Mirtes Dalmaso que autorizaram a condução do estudo no Núcleo de Práticas Assistenciais do Hospital Universitário do Centro Universitário da Região da Campanha (URCAMP).

- A equipe de funcionários no Núcleo de Práticas Assistenciais e do Serviço de Radiologia do Hospital Universitário da URCAMP.

- Aos participantes do estudo RISE-KOA que possibilitaram a minha chegada até esse momento da defesa. Foi gratificante observar as mudanças que o exercício promoveu na vida de cada um.

- A todos os pacientes com osteoartrite de joelho que passaram por mim em supervisão de estágio, tanto em unidade básica de saúde como em nível ambulatorial, relatando terem recebido previamente tratamento fisioterapêutico baseado em intervenções passivas. Essas pessoas se viram de inspiração para condução deste estudo, em especial, Cleuza Maria Fagundes dos Santos, que foi paciente dos meus alunos, tornou-se uma grande amiga e foi a principal inspiração para este estudo acontecer. O meu pensamento era: “quero um estudo no interior do estado que disponibilize as pessoas o tratamento recomendado pelas diretrizes internacionais.” Gratidão a todas essas pessoas.

- Por fim, aos professores do Programa de Pós-graduação em Educação Física da Universidade Federal de Pelotas.

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INTRODUÇÃO

A osteoartrite (OA) é uma condição articular multifatorial com alta prevalência e uma das principais causas de incapacidade global (Safiri et al., 2020; Steinmetz et al., 2023). A OA é uma doença que se manifesta primeiramente como uma desordem molecular, levando à degradação da cartilagem, remodelação óssea, formação de osteófitos, inflamação e declínio da função articular (Kraus et al., 2015). Em 2020, 595 milhões de pessoas vivenciavam os sintomas articulares da OA em todo o mundo, refletindo um aumento de 132,2% no total de casos desde 1990 (Yang et al., 2023). As projeções indicam que até o ano de 2050, o número de novos casos, especificamente de OA do joelho, deverá aumentar em 74,9% (Steinmetz et al., 2023). Os sintomas da OA de joelho incluem dor no joelho relacionada à atividade, limitação funcional, rigidez matinal, edema articular e sensação de instabilidade articular (Zhang et al., 2010). A fraqueza e a redução de qualidade muscular dos músculos extensores do joelho são fatores que influenciam na apresentação sintomática desta condição articular (Øiestad et al., 2022; Taniguchi et al., 2023). Neste contexto, somado as alterações musculoesqueléticas e na performance funcional, catastrofização relacionada a dor, redução de qualidade do sono e aumento de sintomas de depressão, ansiedade e estresse são repercussões observadas em pacientes com OA de joelho (Lentz et al., 2020; Suzuki, Iijima e Aoyama, 2020; Zheng et al., 2021; Zhou et al., 2024).

Conforme as principais diretrizes internacionais, o exercício e as estratégias de educação são consideradas a primeira linha de tratamento para o manejo dos sintomas da OA de joelho (Bannuru et al., 2019; Kolasinski et al., 2020). Exercício aeróbico, fortalecimento muscular, ou a combinação dos dois são consideradas intervenções efetivas para melhora de desfechos reportados pelos pacientes, tais como dor e condição funcional (Kolasinski et al., 2020). No entanto, algumas barreiras são reconhecidas ao envolvimento dos pacientes em programas de exercícios tradicionais, incluindo fatores físicos (pacientes relatam dor e limitações funcionais), psicológicos (alguns pacientes acreditam que as atividades físicas são ineficazes, prejudiciais, além de relatarem falta de motivação) e socioambientais (os pacientes vivenciam a falta de aconselhamento e incentivo de profissionais de saúde e têm falta de apoio social) (Kanavaki et al., 2017). Neste cenário, emerge a necessidade de investigar estratégias alternativas para condução do tratamento baseado em exercícios de forma a engajar os pacientes no tratamento, como a combinação do exercício com outras modalidades terapêuticas, tais como a

estimulação elétrica neuromuscular (EENM) ou a mudança no formato de disponibilização presencial do exercício para uma configuração remota.

A EENM é um recurso terapêutico auxiliar para o tratamento de pacientes com OA de joelho, uma vez que reduz o nível de dor no joelho e melhora a rigidez e a mobilidade articular (Sax et al., 2022). Conforme os achados de uma revisão sistemática com metanálise, há evidências de certeza muito baixa que a EENM combinada com exercícios, em comparação com um grupo de controle ativo, aumenta a força muscular isométrica do músculo quadríceps femoral em pessoas com OA do joelho (Bispo et al., 2021). No entanto, esses autores também incluíram estudos que compararam EENM *versus* exercícios, não necessariamente analisando apenas o efeito combinado das intervenções. Além disso, os desfechos primários foram medidas de força e parâmetros funcionais; eles não se concentraram em desfechos reportados pelos pacientes.

Em relação ao formato de supervisão de exercícios para pacientes com OA de joelho, tradicionalmente os profissionais de reabilitação física fornecem tratamentos baseados em exercícios em clínicas de fisioterapia ou no domicílio do paciente (Skou e Roos, 2017). No entanto, nos últimos anos, um crescente corpo de literatura destacou a eficácia da telerreabilitação, que utiliza de tecnologias de informação e comunicação, para disponibilização de tratamento para pacientes com OA de joelho (Aily et al., 2023; Alasfour e Almarwani, 2022; Moutzouri et al., 2024; Nelligan et al., 2021). As vantagens da telerreabilitação incluem custo-efetividade, maior acessibilidade à assistência em saúde, a capacidade de entregar programas de exercícios remotamente, o potencial de superar barreiras geográficas e a redução da carga econômica no sistema de saúde (Fioratti I. et al., 2020; Marques et al., 2022).

As ferramentas de telereabilitação, incluem sites, aplicativos móveis, chamadas telefônicas, mensagens de texto ou videochamadas (Shah et al., 2022). Tanto pacientes quanto fisioterapeutas percebem as videochamadas como uma ferramenta eficaz e bem estabelecida para intervenções terapêuticas remotas em tempo real (Alrushud et al., 2022; Hinman et al., 2017). Este método é comumente empregado em consultas de telessaúde e demonstrou ser tão eficaz quanto consultas ambulatoriais presenciais no tratamento de pacientes com OA de joelho (Hinman et al., 2024). No entanto, a eficácia de tal recurso de telerreabilitação para

supervisão de exercícios em programas de reabilitação estendidos (de 12 semanas) não é bem conhecida.

Achados de um estudo indicaram que implementar exercícios remotos por meio de videochamadas ao longo de oito semanas foi mais eficaz do que programas de exercícios baseados em auto-manejo para pacientes com OA de joelho em vários desfechos, incluindo nível de dor, desfechos reportados pelos pacientes relativos a condição articular, desempenho físico, cinesiofobia, estado emocional, fadiga e nível de atividade física (Tore, Oskay e Haznedaroglu, 2022). Por outro lado, os resultados de um recente ensaio clínico randomizado de não-inferioridade indicaram que quatro semanas de exercícios supervisionados em tempo real por meio de videochamadas são não inferiores à mesma intervenção realizada pessoalmente em clínica de reabilitação na redução da dor e na melhoria da qualidade de vida de pacientes com OA de joelho (Tedeschi et al., 2024).

Portanto, até onde sabemos, nenhum estudo na literatura investigou ainda se 12 semanas de exercício remoto supervisionado por videochamadas é não inferior a um programa presencial comparável em dor, função física, outros desfechos reportados específicos da condição articular, bem-estar psicológico, qualidade do sono, performance funcional e arquitetura e qualidade muscular do quadríceps femoral. Nesse contexto, com o aumento da carga global da OA de joelho e o crescente interesse em telerreabilitação, é crucial entender o potencial da supervisão remota usando videochamadas para otimizar estratégias de reabilitação em todo o mundo.

Somado a isso, há uma literatura crescente a respeito das mudanças na arquitetura muscular do quadríceps femoral em pacientes com OA de joelho, incluindo alterações na espessura do músculo, ângulo de penação, comprimento do fascículo e intensidade do eco muscular (Aily et al., 2019; Karapınar et al., 2024; Taniguchi et al., 2021; Whittaker e Stokes, 2011). Nesse contexto, investigar os efeitos do exercício nesses parâmetros ajudará os clínicos a adotar métodos de supervisão remota para abordar mudanças na arquitetura do músculo quadríceps. Estudos atuais indicam que as principais mudanças no músculo quadríceps estão relacionadas à qualidade do músculo e não à estrutura dos músculos (Chopp-Hurley et al., 2020; Taniguchi et al., 2023). Os resultados futuros desta tese aumentarão a compreensão de como o exercício influencia as mudanças na qualidade do músculo, particularmente em relação à redução da infiltração de tecido adiposo intramuscular.

Além disso, a ultrassonografia destaca-se como uma ferramenta valiosa para o monitoramento do quadríceps femoral em uma perspectiva quantitativa e qualitativa em pacientes com dor articular, porque é um método de avaliação musculoesquelética livre de dor e com vantagens como custo-efetividade (Blum et al., 2020; Karapinar et al., 2021; Umay, Gundogdu e Ozturk, 2020). No entanto, até o presente momento, não foi sumarizada a literatura a cerca de três importantes aspectos: os parâmetros mais relevantes de arquitetura muscular implementados para mensurar o músculo quadríceps femoral em pacientes com OA de joelho; se há diferença na arquitetura e qualidade muscular do quadríceps femoral entre pessoas com OA de joelho e indivíduos saudáveis; e a associação entre a arquitetura do quadríceps e a qualidade com os sintomas ou medidas funcionais.

Considerando o racional descrito anteriormente, a presente tese foi estruturada conforme os seguintes objetivos:

1. Avaliar se um programa de EENM combinada ao exercício ou sobreposto a contrações voluntárias é mais efetivo comparado ao exercício de forma isolada em relação a desfechos reportados pelos pacientes.
2. Verificar a aplicabilidade clínica das medidas ultrassonográficas em pacientes com OA de joelho.
3. Investigar se um programa de exercícios supervisionados remotamente é não inferior ao mesmo programa de exercícios em formato presencial em relação ao nível de dor e a função física, assim como em relação a desfechos reportados específicos da condição articular, bem-estar psicológico, qualidade do sono, desempenho funcional e arquitetura e qualidade muscular do quadríceps em pacientes com OA do joelho.

Na estrutura da tese consta o projeto de pesquisa, o relatório do trabalho de campo, quatro artigos científicos e a nota a imprensa. No primeiro artigo, conduzimos uma revisão sistemática com metanálise para investigar a eficácia de uma intervenção combinada, EENM adicionada ao exercício, ou sobreposta a contrações voluntárias em comparação ao exercício em relação a desfechos reportados pelos pacientes em pessoas com OA de joelho. No segundo artigo, descrevemos o estudo de revisão sistemática que abordou a aplicabilidade das medidas ultrassonográficas do quadríceps femoral conforme três objetivos principais: 1) Analisar protocolos de ultrassom para medir a arquitetura do quadríceps em pessoas com OA de joelho; 2) Resumir a literatura sobre as diferenças na arquitetura do quadríceps entre

indivíduos com e sem OA de joelho; e 3) Investigar associações entre a arquitetura do quadríceps e desfechos reportados pelos pacientes específicos da condição ou medidas funcionais em pessoas com OA de joelho. No terceiro artigo, descrevemos o estudo de protocolo do ensaio clínico randomizado de não-inferioridade, RISE-KOA - *Remote and In-person Supervised Exercise in Patients with Knee Osteoarthritis*. No quarto artigo, apresentamos os resultados do ensaio clínico randomizado RISE-KOA, que investigou se um programa de exercícios supervisionados remotamente é não-inferior ao mesmo programa em formato presencial em relação ao nível de dor e a função física. Além disso, avaliamos sua eficácia em melhorar outros desfechos reportados pelos pacientes específicos da condição articular, bem-estar psicológico, qualidade do sono, desempenho funcional e arquitetura e qualidade do músculo quadríceps femoral.

PROJETO DE PESQUISA

**UNIVERSIDADE FEDERAL DE PELOTAS
PRÓ-REITORIA DE PESQUISA, PÓS-GRADUAÇÃO E INOVAÇÃO
ESCOLA SUPERIOR DE EDUCAÇÃO FÍSICA E FISIOTERAPIA
PROGRAMA DE PÓS-GRADUAÇÃO EM EDUCAÇÃO FÍSICA**



Projeto de tese

Respostas a exercícios supervisionados nas modalidades remota e presencial em pessoas com osteoartrite de joelho: um ensaio clínico randomizado de não inferioridade

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PELOTAS, 2023

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Respostas de um programa de exercícios supervisionados nas modalidades remota e presencial em pessoas com osteoartrite de joelho: um ensaio clínico randomizado de não inferioridade

Data da qualificação do projeto: 1º de setembro de 2023

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RESUMO

Carvalho, Maurício Tatsch Ximenes. Respostas de um programa de exercícios supervisionados nas modalidades remota e presencial em pessoas com osteoartrite de joelho: um ensaio clínico randomizado de não inferioridade. Orientadora: Cristine Lima Alberton. 2023. p.XX Projeto de Pesquisa (Doutorado) - Programa de Pós-Graduação em Educação Física, Escola Superior de Educação Física e Fisioterapia, Universidade Federal de Pelotas, Pelotas, Brasil.

A supervisão de exercícios através de recursos online é uma alternativa à modalidade presencial com respostas terapêuticas similares em diferentes perfis clínicos. Especialmente na osteoartrite de joelho (OA), o exercício é uma abordagem recomendada pelas diretrizes internacionais, no entanto, é necessário elucidar a comparabilidade das respostas dos exercícios supervisionados remotamente e presencialmente. Deste modo, o objetivo do estudo é investigar as respostas de um programa de exercícios remotos comparado ao presencial em desfechos reportados pelos pacientes, na arquitetura muscular e na performance funcional de sujeitos com OA de joelho. Serão aleatorizados 68 pacientes com OA de joelho sintomática e radiográfica em dois grupos: de exercícios remotos e presenciais. A intervenção terá duração de 12 semanas e consistirá em exercícios de fortalecimento muscular de extremidades inferiores, os quais serão supervisionados, em um grupo remotamente (por videochamada) e no outro presencialmente (em uma clínica de fisioterapia). Os pacientes realizarão o mesmo programa de tratamento que consistirá em um total de seis exercícios por sessão, em duas sessões semanais, nas primeiras duas semanas e três sessões a partir da terceira semana. No primeiro bloco de tratamento, serão orientados exercícios iniciando pelos grupos musculares dos extensores do joelho, adutores do quadril e flexores plantares, e no segundo bloco, extensores do joelho, abdutores do quadril e flexores do joelho. O monitoramento da percepção de esforço será efetuado pela escala modificada de classificação de esforço de Borg. Antes, após 6, 12 e 18 semanas serão mensurados desfechos reportados pelos pacientes relativos à condição articular como dor, sintomas, atividades diárias, atividades esportivas e de lazer e qualidade de vida; desfechos relativos ao domínio psicológico como à catastrofização da dor, sintomas de depressão, ansiedade e estresse e qualidade do sono. Adicionalmente, serão realizadas as medidas de arquitetura muscular do quadríceps femoral, incluindo a espessura muscular, ângulo de penação e ecointensidade. E, a performance funcional através de testes que englobam as habilidades de levantar e sentar, caminhar e subir e descer escadas. As medidas de arquitetura muscular e os parâmetros funcionais serão realizadas em dois momentos (antes e após 12 semanas). A análise dos dados será conduzida por *Linear Mixed Models* e será apresentada a análise por intenção de tratar e por protocolo. O nível de significância adotado neste estudo será de $\alpha = 0,05$.

Palavras-chave: exercício terapêutico; telerreabilitação; osteoartrite.

ABSTRACT

Carvalho, Maurício Tatsch Ximenes. Responses to supervised remote and in-person exercise in people with knee osteoarthritis: a randomized non-inferiority clinical trial. Supervisor: Cristine Lima Alberton. 2023. p. XX. Thesis (Doctoral degree in Physical Education). Graduation Program in Physical Education, Superior School of Physical Education, Federal University of Pelotas, Pelotas, Brazil.

Exercise supervision through online resources is an alternative to the in-person modality with similar therapeutic responses in different clinical profiles. Especially in knee osteoarthritis (OA), exercise is recommended by international guidelines; however, it is necessary to elucidate the comparability of remote and in-person supervised exercise responses. Therefore, the study's objective is to investigate the responses of a remote exercise program compared to the in-person one on patient-reported outcomes measures (PROMs), muscular architecture, and the functional performance of patients with knee OA. Sixty-eight patients with symptomatic and radiographic knee OA will be randomized into remote and in-person exercise. The intervention will last 12 weeks and consist of muscle-strengthening exercises for the lower extremities, supervised in one group remotely (by video call) and in the other in person (at a physiotherapy clinic). Patients will perform the same treatment program of six exercises per session in two weekly sessions in the first two weeks and three sessions from the third week forward. In the first treatment block, exercises will be guided, starting with the muscle groups of the knee extensors, hip adductors, and plantar flexors, and in the second block, knee extensors, hip abductors, and knee flexors. Perceived exertion will be monitored using the rating of perceived exertion using the Borg scale. Before, after 6, 12 and 18 weeks, PROMs relating to the joint condition will be measured, such as pain, symptoms, daily activities, sports and leisure activities, and quality of life; outcomes related to the psychological domain, such as pain catastrophizing, symptoms of depression, anxiety and stress and sleep quality. Additionally, measurements of the muscular architecture of the quadriceps femoris will be taken, including muscle thickness, pennation angle, and echo intensity. And functional performance through tests that include the skills of standing and sitting, walking and going up and down stairs. Muscular architecture and functional parameters will only be measured in weeks 0 and 12. Data analysis will be conducted using Linear Mixed Models, and analysis will be presented by intention to treat and protocol. The significance level adopted in this study will be $\alpha = 0.05$.

Keywords: therapeutic exercise; telerehabilitation; osteoarthritis.

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1. INTRODUÇÃO

A osteoartrite (OA) é uma condição articular multifatorial com elevada prevalência e incidência ao longo da vida (SAFIRI et al., 2020). Em escala global, em 2020, 595 milhões de pessoas tiveram o diagnóstico de OA, o que corresponde a 7,6% da população global representando um aumento de 132,2% no total de casos desde 1990 (*Global Burden Disease*, 2021). As alterações articulares observadas nesta condição clínica comprometem estruturas como a cartilagem, a região óssea subcondral, os ligamentos, a cápsula articular, a membrana sinovial e os músculos periarticulares (HUNTER E BIERMA-ZEINSTRA, 2019). A apresentação clínica inclui dor, rigidez articular, redução da amplitude de movimento, e declínio funcional acompanhado de fraqueza muscular (SHARMA, 2021). Embora possa ocorrer as manifestações clínicas em outras articulações tais como o quadril, a OA de joelho é a mais prevalente (HALL et al., 2022). Especificamente, a prevalência global de OA de joelho, padronizada por idade, em 2019 foi de 4.376,0 a cada 100.000 indivíduos (IC-95% - 3.793,0 a 5.004,9), um aumento de 7,5% entre 1990 e 2019 (YANG et al. 2023). Além disso, o aumento na carga global da doença constituiu um dos fatores preditivos para o prolongamento dos anos vividos com incapacidade (HUNTER e BIERMA-ZEINSTRA, 2019).

Em sujeitos com OA de joelho, especialmente naqueles com maior severidade clínica e níveis elevados de dor, a condição funcional e a qualidade de vida são classificadas como moderadas ou baixas (COSTA et al., 2023). Neste contexto, há um impacto em domínios de saúde nesta condição articular, além do status funcional, como aspectos psicológicos, incluindo aumento da catastrofização associada a dor, sintomas de estresse, ansiedade, depressão e redução da qualidade do sono (LAPANE et al., 2021; TERRY et al., 2021; ZHENG et al., 2021). Assim, pacientes com sintomas depressivos apresentam maior severidade no quadro de dor, bem como a catastrofização relacionada a dor e a redução da qualidade de sono parecem interferir no nível de atividade física, resultando em menor número de passos por dia (GILBERT et al., 2021; HELMINEN et al., 2020; URITANI et al., 2020).

A apresentação sintomática na OA de joelho está diretamente implicada com a redução da qualidade muscular do vasto medial, que consiste em um preditor

independente de incapacidade e de manifestação de sintomas articulares em longo prazo (TANIGUCHI et al., 2022). Esse declínio musculoesquelético é mediado pela inibição artrogênica muscular e ocorre possivelmente devido à inflamação do complexo articular do joelho (DALLE e KOPPO, 2020). Consequentemente, os achados histológicos são a redução das miofibrilas e o aumento de tecido não-contrátil (adiposidade) no endomísio e perimísio do vasto medial (IKEMOTO-UEZUMI et al., 2017).

Com a finalidade de realizar o tratamento da dor e melhorar a condição funcional, as diretrizes clínicas preconizam o tratamento de pacientes com OA de joelho através de exercícios terapêuticos estruturados e estratégias de educação sobre a condição articular (BANNURU, et al., 2019; KOLASINSKI et al., 2020). Nos últimos anos tem havido crescente interesse nas respostas de exercícios conduzidos através da telerreabilitação, uma vez que esse modo de disponibilização da intervenção utiliza de tecnologias da informação e comunicação para aprimorar o engajamento dos pacientes no tratamento e melhorar desfechos em saúde em condições musculoesqueléticas (AILY et al., 2021; ALLEN et al., 2019; ALLEN, et al., 2018; BARONI et al., 2023; BENNELL et al., 2017; CHEN, OR e CHEN, 2021; HINMAN et al., 2020; MECKLENBURG et al., 2018). As ferramentas utilizadas para assistência fisioterapêutica remota incluem sites, aplicativos móveis, chamadas telefônicas, mensagens de texto e videochamadas (SHAH et al., 2022). Como um modo de disponibilização da intervenção terapêutica em tempo real, as videochamadas são consideradas uma ferramenta viável e bem avaliada na perspectiva dos pacientes e fisioterapeutas (HINMAN et al., 2023; HINMAN et al., 2017). As respostas advindas de exercícios prescritos ou supervisionados por esse recurso, incluem a melhora da dor, da condição funcional reportada pelo paciente no curto e longo prazo, além de repercutir no status funcional e emocional, na cinesiofobia, na fadiga e no nível de atividade física (BENNELL, et al., 2017; TORE, OSKAY e HAZNEDAROGLU, 2023).

Apesar dos achados referidos anteriormente, as respostas de exercícios para pacientes com OA de joelho supervisionados remotamente *versus* presencialmente em desfechos reportados pelos pacientes relativos à condição articular e ao domínio psicológico, e a respeito dos parâmetros funcionais ainda necessitam de elucidação. Os programas de exercícios remotos, na sua maioria, não consideraram a alternância entre os grupos musculares dos membros inferiores durante a realização

do programa de treinamento estruturado, o que consiste em uma lacuna na literatura disponível. Somado a isto, ressalta-se a relevância de investigar um programa de tratamento contemplando o fortalecimento muscular em uma perspectiva mais funcional com a inclusão da sustentação de peso corporal, especialmente ao considerar que tais exercícios, em pacientes com OA, melhoram a força muscular dos extensores do joelho sem acarretar um aumento das forças de contato articular (STARKEY *et al.*, 2022). Ainda, apesar das repercussões dos parâmetros neuromusculares, especialmente o aumento da ecointensidade (redução da qualidade muscular) do quadríceps femoral, na performance funcional de pessoas com OA de joelho, são escassos os estudos sobre os efeitos de intervenções baseadas em exercício neste desfecho (CHOPP-HURLEY *et al.*, 2020; KARAPINAR *et al.*, 2021a; b). A luz da literatura disponível destaca-se a necessidade de investigar as respostas de exercícios remotos em comparação ao presencial, especificamente em relação a qualidade muscular do vasto medial, em vista da relevância de investigar as repercussões de exercícios em déficits neuromusculares, além das repercussões na dor e na condição funcional reportada pelo paciente em pacientes com OA de joelho (TAYFUR *et al.*, 2023).

Por fim, os achados de um recente ensaio clínico randomizado indicaram similaridade nas respostas a um programa periodizado de exercício em circuito, tanto na modalidade online quanto na presencial, em relação a uma série de desfechos, incluindo a arquitetura muscular do quadríceps femoral de pacientes com OA de joelho, no entanto ainda persiste uma lacuna na literatura sobre as repercussões de um programa de exercícios terapêuticos de extremidades inferiores disponibilizado remotamente e presencialmente na ecointensidade muscular do quadríceps femoral neste perfil clínico (AILY *et al.*, 2023). Deste modo, o presente ensaio clínico randomizado visa responder o seguinte questionamento: um programa de exercícios remotos tem respostas comparáveis ao presencial em desfechos reportados pelos pacientes, na arquitetura muscular e na performance funcional de sujeitos com OA de joelho?

1.1.Objetivo geral

Investigar as respostas de 12 semanas de um programa de exercícios remotos comparado ao presencial em desfechos reportados pelos pacientes, na arquitetura muscular e em parâmetros funcionais de sujeitos com OA de joelho.

1.2.Objetivos específicos

Analisar desfechos reportados pelos pacientes relativos à condição articular – dor, sintomas, atividades de vida diária, esportivas e de lazer e qualidade de vida – antes (semana 0), durante (semana 6) e após 12 semanas de exercícios remotos e presenciais em sujeitos com OA de joelho e em um período de *follow-up* (após 18 semanas).

Analisar desfechos reportados pelos pacientes relativos à condição psicológica – catastrofização relacionada a dor, sintomas de depressão, ansiedade e estresse e qualidade do sono – antes (semana 0), durante (semana 6) e após 12 semanas de exercícios remotos e presenciais em sujeitos com OA de joelho e em um período de *follow-up* (após 18 semanas).

Analisar a arquitetura muscular – espessura e qualidade muscular do quadríceps femoral e comprimento do fascículo e ângulo de penação do vasto lateral – antes e após 12 semanas de exercícios remotos e presenciais em sujeitos com OA de joelho.

Analisar parâmetros funcionais – capacidade levantar e sentar da cadeira, mobilidade funcional, velocidade de marcha e capacidade de subir e descer escadas – antes e após 12 semanas de exercícios remotos e presenciais em sujeitos com OA de joelho.

1.3.Hipótese

A hipótese do estudo é a de que as respostas de exercícios de fortalecimento muscular supervisionados remotamente não são inferiores para a melhora de desfechos reportados pelos pacientes, da arquitetura muscular e de parâmetros funcionais à supervisão presencial em sujeitos com OA de joelho.

2. REVISÃO DE LITERATURA

2.1.Osteoartrite de joelho

2.1.1. Definição, dados epidemiológicos e fatores de risco

A osteoartrite é caracterizada pelas alterações articulares que comprometem a cartilagem, a estrutura óssea subcondral, os ligamentos, a cápsula articular, a membrana sinovial e os músculos periarticulares (HUNTER e BIERMA-ZEINSTRA, 2019). Segundo a *Osteoarthritis Research Society International (OARSI)*, esta condição de saúde envolve as articulações móveis, nas quais o estresse celular e a degradação da matriz extracelular são iniciadas por micro e macro-lesões ativadoras de respostas de reparo mal adaptativas, incluindo vias pró-inflamatórias da imunidade inata. Desse modo, o desarranjo molecular, é seguido por respostas como degradação da cartilagem, remodelação óssea, formação de osteófitos, inflamação articular e declínio da função articular (KRAUS et al., 2015).

A prevalência global da OA de joelho é de 22,9% em indivíduos maiores de 40 anos e a incidência de 203 casos a cada 10.000 pessoas por ano (CUI et al., 2020). Somado a isto, além da OA ser mais frequente em mulheres, há aumento da prevalência e da incidência com a idade (CROSS et al., 2014). No entanto, esta condição articular não é atribuída somente ao processo natural do envelhecimento, uma vez que diversos fatores estão implicados no desenvolvimento das manifestações articulares (ALLEN, THOMA e GOLIGHTLY, 2022). Deve-se também incluir a condição musculoesquelética desses pacientes, uma vez que um baixo índice de massa muscular, associado à idade, está implicado com a gravidade do estreitamento do espaço articular na OA de joelho (KIM e HONG, 2022).

Os fatores de risco não modificáveis para o desenvolvimento da OA de joelho são a idade, gênero, etnia, predisposição genética e lesão articular (LESPASIO et al., 2017). Especialmente a lesão articular pode ser considerada um fator de risco modificável, ao considerar que as estratégias de prevenção de lesões alteram a trajetória de desenvolvimento da OA (ARUNDALE et al., 2018; OLIVARES-JABALERA et al., 2021). No entanto, quando há uma lesão articular prévia, este fator de risco é estabelecido como nas lesões do ligamento cruzado anterior (DAVIS et al., 2021). Nesse contexto, mesmo com a lesão articular anterior abordagens terapêuticas podem minimizar o risco aumentado de OA de joelho (DAVIS et al., 2021).

A obesidade, a presença de comorbidades, os fatores biomecânicos, o nível de atividade física e a força muscular estão entre os fatores de risco modificáveis (WERNER et al., 2022). A obesidade geral, a central e a sarcopênica aumentam o risco de desenvolvimento de OA de joelho (MISRA et al., 2019; PARK et al., 2023). Nesse sentido, o maior índice de massa corporal é associado com alterações na biomecânica da marcha nestes pacientes (HARDING et al., 2012). Observa-se o aumento das forças de contato articular, o momento de adução externa do joelho e a tensão diurna da cartilagem (MESSIER et al., 2011; WIDMYER et al., 2013). Embora os mecanismos mecânicos possibilitem observar a associação entre obesidade e OA de joelho, é necessário considerar a influência adicional de fatores metabólicos e inflamatórios (BATUSHANSKY et al., 2022; BERENBAUM, GRIFFIN e LIU-BRYAN, 2017). Somado a isto, há uma complexa interação entre variáveis biomecânicas com questões psicossociais, psicológicas e alterações teciduais observadas na obesidade (ANDRIACCHI et al., 2020).

A respeito das comorbidades, o diagnóstico de OA de joelho coexiste com outras condições clínicas como obesidade, doenças cardiovasculares e diabetes, as quais aumentam o risco da progressão sintomática e radiográfica (LONG et al., 2022). Por outro lado, é necessário considerar os achados de um estudo que incluiu duas coortes de mais de 7000 participantes, no qual foi observado que o diagnóstico de diabetes e doença cardiovascular não aumentou a incidência de OA radiográfica e sintomática (KUUSALO et al., 2021). Portanto, destaca-se que na presença de obesidade, a qual consiste em um fator de risco estabelecido, os efeitos da doença cardiovascular e da diabetes são muito pequenos para desencadear uma manifestação articular. Quando a doença articular é estabelecida, o risco

cardiovascular é maior conforme o grau de incapacidade, o uso de dispositivos auxiliares de locomoção, a limitação da marcha, o tempo de acompanhamento prolongado, a idade mais jovem de início da OA, o número de articulações envolvidas e a severidade da manifestação articular (ATHOW, MORGAN e BROWN, 2023).

Aspectos biomecânicos influenciam o surgimento e a progressão da OA. O alinhamento estrutural em varo das extremidades inferiores aumenta a sobrecarga da articulação tíbio-femoral ao nível medial, enquanto o alinhamento em valgo predispõe a sobrecarga lateral (BROUWER et al., 2007; FELSON et al., 2013; SHARMA, 2001). Essas anormalidades, além da frouxidão em valgo e varo, aumentam a incidência e a progressão da OA (LI et al., 2022). Somado a isto, alterações na biomecânica da marcha são encontradas em pessoas com OA de joelho (TUNEN, VAN et al., 2018). Entre elas, a redução do comprimento da passada e da velocidade de marcha ocorre conforme o grau de severidade da OA, e tais alterações são resultado do declínio na força muscular isométrica do quadríceps femoral (NISHINO et al., 2021). A velocidade de marcha é um dos fatores preditivos do nível de atividade física em pessoas vivendo com OA de joelho (AYDEMIR, HUANG e FOUCHER, 2023; HSU, HSIEH e CHIU, 2022). Ainda, a redução da velocidade de marcha aumenta o risco de mortalidade em pacientes com mais de 60 anos e com OA radiográfica de joelho (MASTER et al., 2020). Especificamente, aqueles pacientes com menor velocidade de marcha ($<0,5\text{m/s}$ na curta distância e $1,2\text{m/s}$ em distâncias padronizadas) apresentam maior risco de mortalidade por todas as causas ao longo de nove anos.

A presença de limitações funcionais em pacientes com OA de joelho ou com alto risco de desenvolvimento são mais comuns em sujeitos com baixo nível de atividade física (MASTER et al., 2021). O sedentarismo é um fator de risco para a apresentação de manifestações ortopédicas como dor e rigidez da articulação do joelho (KANG et al., 2020). Fatores como idade avançada, IMC alto, dor severa no joelho, nível educacional, depressão e fraqueza muscular do quadríceps femoral estão implicados com o não engajamento em atividade física regular nesse perfil clínico (CHANG et al., 2020). No entanto, o nível de atividade física não está implicado na gênese das alterações estruturais na OA de joelho, tanto em sujeitos considerados inativos fisicamente como naqueles que realizam atividade física moderada à vigorosa (GATES et al., 2022; JAYABALAN et al., 2019; QIN et al., 2018).

A respeito da força muscular de quadríceps femoral, os achados de uma revisão sistemática com meta-análise, que incluiu 11 estudos com total de 46819 participantes, indicaram que a fraqueza muscular de extensores de joelho está associada com a OA de joelho sintomática e radiográfica em homens e mulheres (ØIESTAD et al., 2022). Deste modo, é relevante considerar que, embora a fraqueza muscular de quadríceps femoral consista em um marcador preditivo do aumento dos sintomas e do declínio funcional, a redução do espaço articular não é influenciada pela força (CULVENOR et al., 2017). Portanto, a apresentação sintomática da OA não é estritamente associada com alterações estruturais (CULVENOR et al., 2019).

2.1.2. Patogênese e manifestações clínicas

A OA é uma condição complexa, envolvendo diversos fatores biológicos, inflamatórios e metabólicos, que contribuem para patogênese, com repercussões na cartilagem, na estrutura óssea, no líquido sinovial, nos ligamentos, nos meniscos e na estrutura muscular (KATZ, ARANT e LOESER, 2021; LOESER et al., 2012). Os componentes metabólicos e inflamatórios exercem influências diferentes na gênese da apresentação sintomática e das alterações estruturais, uma vez que as citocinas pró-inflamatórias (interleucina-1 β , -2, -4, -6, -8, -17A, -17F, -21, -22, e -23) são associadas com dano estrutural e com a apresentação sintomática. E os marcadores de inflamação metabólica como leptina, adiposina e proteína C reativa apresentam associação somente com a manifestação sintomática. Além disso, as mudanças estruturais observadas na OA são acompanhadas pelo aumento de outros biomarcadores de inflamação metabólica como resistina, apelin-36 e adiponectina (ZHU et al., 2022).

A respeito das manifestações estruturais, alterações como redução do espaço articular e disfunções ósseas como esclerose óssea subcondral e presença de osteófitos são observadas em exames radiográficos (MOBASHERI et al., 2017). As repercussões na cartilagem, nos meniscos, na sinóvia, no osso subcondral e em outros tecidos são observados em imagens de ressonância magnética. No entanto, apesar desses achados estruturais possibilitarem a identificação de alterações típicas na OA de joelho, há uma discordância entre o que é observado nos exames de imagem e a apresentação sintomática, principalmente com relação aos desfechos reportados pelos pacientes (BENSALMA et al., 2022).

As manifestações clínicas, baseadas nos critérios do *American College of Rheumatology*, são dor articular somado a três das seguintes condições: idade >50 anos, rigidez <30 min, crepitação, sensibilidade óssea, aumento ósseo e nenhum calor palpável (ALTMAN et al., 1986a). Assim, destaca-se que embora tais critérios sejam baseados em referência tradicional, ainda são utilizados como marcadores da apresentação sintomática destes pacientes (SCHIPHOF et al., 2019).

Além dos aspectos clínicos e funcionais, os fatores psicológicos coexistem com as manifestações típicas da OA de joelho, visto que 19,9% das pessoas vivendo com a referida condição articular apresentam sintomas de depressão com um risco relativo de 1,17 de desenvolver depressão em comparação a sujeitos sem disfunção articular (STUBBS et al., 2016). Entre as condições implicadas com a manifestação de depressão nestes pacientes, destacam-se a presença de fatores de risco para OA de joelho, alto nível de dor e declínio funcional (ZHENG et al., 2021). Além do mais, os sintomas depressivos são considerados um dos fatores prognósticos que predizem um pior quadro de dor (HELMINEN et al., 2020).

A OA de joelho é influenciada pelo aumento do índice de massa corporal e, mais especificamente, o tecido adiposo, o qual atua como um órgão endócrino, exerce um papel importante na deflagração dos sintomas articulares. O tecido adiposo subcutâneo e visceral aumenta a carga mecânica, metabólica e inflamatória do joelho. Assim como, a adiposidade intra-articular exerce um papel importante nas manifestações da OA. Por fim, o tecido adiposo intramuscular repercute na força muscular e nas habilidades funcionais de pacientes com OA de joelho (CHANG et al., 2018). Deste modo, a estrutura muscular influencia na patogênese da OA e tem sido implicada no desenvolvimento e na progressão desta condição articular por meio de mecanismos teciduais e moleculares (KRISHNASAMY, HALL e ROBBINS, 2018).

2.1.3. Repercussões na qualidade muscular

O desenvolvimento e a progressão da OA de joelho são caracterizados pelo declínio na composição dos músculos periarticulares, sobretudo o quadríceps femoral (MOHAJER et al., 2022). Nesse sentido, destaca-se que a redução da qualidade muscular é superior às mudanças na dimensão muscular, uma vez que a infiltração de tecido adiposo no quadríceps femoral é associada negativamente com

desfechos reportados pelos pacientes e com a função física (KUMAR *et al.*, 2014; PEDROSO *et al.*, 2019). Assim, a fraqueza de quadríceps femoral na OA de joelho pode ser atribuída a alteração da arquitetura muscular (KARAPINAR *et al.*, 2022). Especificamente, a redução da qualidade muscular do vasto medial tem um impacto negativo no torque muscular extensor do joelho, independentemente da gravidade da OA (TEOLI *et al.*, 2022). Mesmo em estágios precoces da OA do joelho, é possível detectar um aumento de 7,2% de tecido adiposo no vasto medial, o que oferece uma caracterização do perfil musculoesquelético desses pacientes com baixa sensibilidade e alta especificidade (TANIGUCHI *et al.*, 2023).

Entre as ferramentas utilizadas para mensuração das características musculares do vasto medial e do quadríceps femoral destaca-se a ressonância magnética e a ultrassonografia musculoesquelética (KARAPINAR *et al.*, 2021a; TANIGUCHI *et al.*, 2023). As medidas musculares com a ultrassonografia são precisas, reprodutíveis e amplamente utilizadas em diferentes perfis clínicos como em pacientes com fibromialgia, artrite reumatoide e após cirurgia de reconstrução do ligamento cruzado anterior (GARCIA *et al.*, 2020; UMay, GUNDOGDU e OZTURK, 2020; YOSHIDA *et al.*, 2022). Na OA de joelho, caracteriza-se como uma ferramenta complementar à avaliação funcional e que pode ser implementada independente do nível de dor relatado pelo paciente (NÚÑEZ *et al.*, 2019). Deste modo, a força muscular não é o único fator implicado na habilidade funcional desses pacientes, de forma que as medidas musculares advindas da ultrassonografia cinesiológica são fundamentais para uma observação mais completa da condição musculoesquelética desses pacientes (NÚÑEZ *et al.*, 2019).

A qualidade muscular, mensurada através da ultrassonografia, é observada através do parâmetro ecogenicidade ou eointensidade (PARIS e MOURTZAKIS, 2021a). A intensidade do eco muscular consiste na média do brilho, intensidade do pixel, gerado pela incidência da onda sonora no tecido muscular. A infiltração de tecido adiposo e fibroso intra e intermuscular é representado na imagem ultrassonográfica pelo aumento da intensidade média do pixel, em visto disso quanto maior a ecogenicidade, pior a qualidade muscular (NAGAE *et al.*, 2023). A mensuração precisa da ecogenicidade ocorre por meio da inspeção visual ou através de softwares como o Image J (Figura 1) com base em uma região de interesse (ROI).

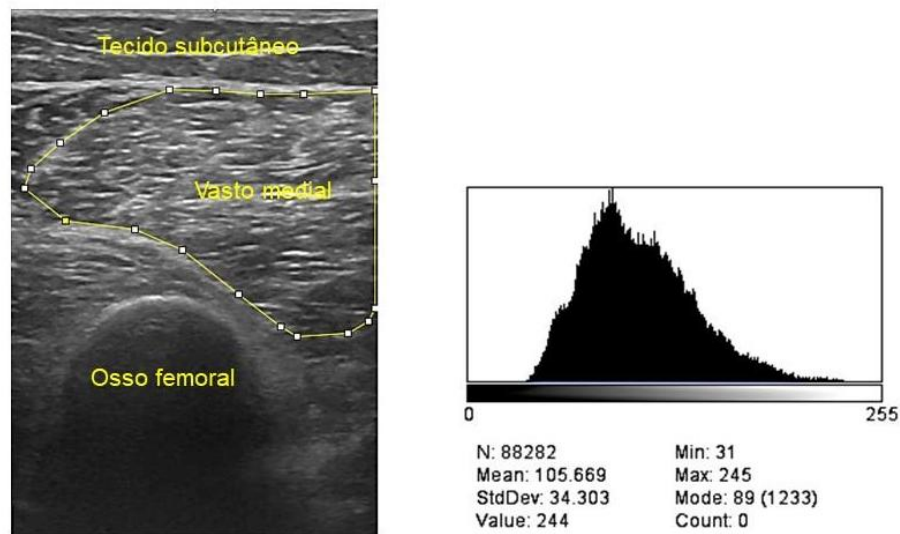


Figura 1. Média da ecogenicidade muscular do vasto medial gerado pelo software *Image J*.

Nos pacientes com OA de joelho, o declínio funcional é atribuído às mudanças na ecogenicidade muscular. Assim, ao considerar que o declínio funcional coexiste com as modificações na qualidade muscular, intervenções em reabilitação devem ser direcionadas visando a melhora deste desfecho (CHOPP-HURLEY et al., 2020). Ao considerar o quadríceps femoral em sua totalidade (reto femoral, vasto intermédio, vasto medial e vasto lateral) sabe-se que há um aumento seletivo da ecogenicidade do vasto medial em pacientes com OA de joelho comparado a sujeitos saudáveis (TANIGUCHI et al., 2021). Especificamente, o ponto de corte de 80,4 u.a. é indicativo do declínio na qualidade muscular. Por fim, o aumento da ecogenicidade do vasto medial prediz a piora da incapacidade funcional e dos sintomas na OA de joelho ao longo de três anos, deste modo a qualidade muscular do vasto medial repercute diretamente na apresentação sintomática neste perfil clínico (TANIGUCHI et al., 2022).

As alterações na composição muscular não se limitam ao vasto medial, pois no vasto lateral de pessoas vivendo com OA de joelho observa-se modificação nos tipos de fibras musculares, tais como menor proporção de fibras do tipo I e mais fibras híbridas do tipo IIa/x comparado a sujeitos saudáveis (NOEHREN et al., 2018). Além disso, há menos células satélites, concomitante com a maior expressão de genes pró-fibróticos e deposição de matrix extracelular (elemento não contrátil nas

fibras musculares). Tais alterações são sugestivas do declínio na qualidade muscular de pacientes com OA de joelho.

2.2.Exercícios remotos na osteoartrite de joelho

O exercício é fortemente recomendado no tratamento de pacientes com OA de joelho, conforme as diretrizes do *American College of Rheumatology* e da *Osteoarthritis Research Society International* (BANNURU, et al., 2019; KOLASINSKI et al., 2020b). Embora não haja evidência de superioridade de uma modalidade de exercício em relação a outra, e algumas lacunas ainda persistam na literatura em relação à dose ideal (duração, intensidade e frequência), os pacientes com OA de joelho beneficiam-se de exercícios terapêuticos principalmente com relação ao manejo da dor e a melhora da condição funcional. Em uma recente *network* meta-análise, os exercícios agrupados em treinamento no meio aquático, exercícios em bicicleta estacionária, treinamento de força, programas de exercícios tradicionais e Yoga mostraram-se efetivos no manejo terapêutico da OA de joelho (MO et al., 2023).

Tradicionalmente os exercícios são implementados em formato presencial, no entanto, a modalidade remota é uma alternativa viável e de baixo custo no tratamento de sujeitos com OA de joelho, sem a necessidade de deslocamento do paciente até um serviço de fisioterapia (HARRIS et al., 2023). Conforme os achados de uma revisão sistemática, exercícios remotos não são menos efetivos em comparação ao tratamento fisioterapêutico presencial, e nos ensaios clínicos, os quais incluíram a adição da comunicação do profissional para discutir e personalizar os exercícios observou-se melhora no escore de dor (MCHUGH et al., 2022). No entanto, em outra revisão sistemática os resultados indicaram que apesar das repercussões sobre o controle da dor, a efetividade de exercícios transmitidos online é limitada para melhora da condição funcional em comparação com programas convencionais de reabilitação (XIE et al., 2021).

O estudo de Kloek et al. (2018) demonstrou que exercícios remotos, implementados ao longo de 12 semanas, melhoram a condição clínica de pacientes com OA de joelho com achados similares aos das consultas presenciais. Deste modo, tecnologias digitais são utilizadas para disponibilizar o programa de exercícios, incluindo sites, aplicativos móveis, redes sociais e videoconferência

(SHAH et al., 2022). As consultas fisioterapêuticas por videochamadas possibilitam a avaliação e a elaboração do programa de tratamento de pessoas com OA. Embora esta modalidade de disponibilização da intervenção terapêutica seja suscetível a problemas técnicos relacionados a conexão de áudio e vídeo, tais problemas são rapidamente resolvidos e não interferem na efetividade da consulta em fisioterapia (ROSS et al., 2023).

A disponibilização de serviços de saúde online é caracterizada pelo termo *telehealth* que consiste na prestação de serviços de saúde, de forma síncrona ou assíncrona, usando de tecnologias da informação e comunicação para a disponibilização de informações válidas para o diagnóstico, tratamento e prevenção de doenças e lesões, para pesquisa e avaliação, e para formação continuada de profissionais da saúde, com a finalidade de promover a saúde da comunidade. Neste contexto, a telerreabilitação consiste em uma série de práticas em saúde conduzidas por profissionais de reabilitação via recursos digitais e de comunicação (BRENNAN et al., 2010). As referidas práticas aumentam o engajamento dos pacientes no autocuidado, assim como contribuem para melhora de desfechos em saúde em pacientes com condições musculoesqueléticas (BARONI et al., 2023). Neste cenário, embora haja um número expressivo de estudos com telerreabilitação, motivados pelo cenário da pandemia de COVID-19, esta modalidade já era utilizada para o tratamento de pacientes com OA de joelho (ODOLE e OJO, 2013).

A respeito dos achados de ensaios clínicos randomizados envolvendo exercícios remotos na OA de joelho, a descrição abaixo compreendeu as seguintes categorias. (1) Exercícios remotos em formato totalmente online; (2) Exercícios remotos incluindo contato com os pesquisadores via telefone ou virtual por videochamada; (3) Exercícios remotos incluindo contato pessoal com os pesquisadores.

2.2.1. Exercícios remotos em formato totalmente online

Em um estudo realizado por Allen et al. (2018) a efetividade de um programa de exercícios remotos (*Internet-Based Exercise Training* (IBET)) foi investigada em comparação a uma abordagem fisioterapêutica presencial nos sintomas articulares relatados pelo paciente. A medida deste desfecho foi conduzida através do índice *Western Ontario and McMaster Universities Osteoarthritis Index* (WOMAC), que

permite mensurar a severidade dos sintomas da OA. Os autores analisaram se as respostas destes dois programas, após quatro e 12 meses de acompanhamento, foram superiores a um grupo controle, no qual os participantes estavam em uma lista de espera. O programa IBET foi composto por exercícios personalizados com base em escore de dor, função e atividade atual, recomendações de progressão dos exercícios com base em medidas seriadas de dor e função, exibição de vídeos com os exercícios, lembretes automatizados para manter a aderência dos participantes e rastreamento de progresso. Os participantes foram encorajados a realizar o programa de exercícios por 12 meses, no mínimo três vezes na semana, o qual incluía exercícios de fortalecimento muscular, alongamentos e atividades aeróbicas. Os pacientes direcionados ao grupo de atendimentos presenciais receberam um programa de fisioterapia tradicional com ênfase em exercícios domiciliares por oito sessões durante quatro meses, incluindo outras modalidades terapêuticas necessárias conforme avaliação individualizada de cada participante. Os resultados do estudo indicaram que não houve diferença significativa, nem clinicamente relevante, na maioria dos desfechos analisados incluindo os sintomas articulares, entre os grupos que receberam as intervenções. Esse achado reforça a efetividade similar entre a abordagem fisioterapêutica presencial e a realizada remotamente.

Em outro ensaio clínico randomizado, os pesquisadores investigaram a eficácia de um programa de automanejo com duração de 24 semanas (NELLIGAN *et al.*, 2021). Esse programa consistia em um site contendo informações sobre a OA de joelho, um protocolo de exercícios estruturados e um guia para aumentar a atividade física. Além disso, foi utilizado um sistema automático de mensagens para incentivar a aderência ao exercício. Esse protocolo foi comparado a um grupo que recebeu acesso ao site com informações sobre a OA de joelho, a importância do exercício e da atividade física, mas sem as informações estruturadas sobre o programa de fortalecimento muscular e o guia de atividade física. Os resultados revelaram diferenças significativas entre os grupos no que diz respeito ao escore de dor e função, favorecendo o grupo que recebeu o regime de exercícios de fortalecimento não supervisionado e orientação de atividade física por meio de mensagens de texto automatizadas.

Quadro 1. Características dos programas de exercícios remotos em formato totalmente online

Autor, ano de publicação e país	Amostra	Intervenção	Desfechos	Resultados
Allen et al. (2018) Estados Unidos	Sujeitos com OA de joelho radiográfica e sintomática conforme os critérios clínicos do <i>American College of Rheumatology</i> Grupo de exercícios remotos: <u>Internet-based exercise training (IBET)</u> 142 participantes - 65,3 ± 11,5 anos Grupo de fisioterapia: 140 participantes - 65,7 ± 10,3 anos Grupo de lista de espera: 68 participantes - 64,3 ± 12,2 anos	<u>Grupo de exercícios remotos vs. fisioterapia tradicional vs. lista de espera</u> <u>Grupo de exercícios remotos – Internet-based exercise training (IBET)</u> - Exercícios: Personalizados com base em escores de dor e função (exercícios de fortalecimento de extremidades inferiores, alongamento e recomendações de atividades aeróbicas); - Duração: 12 meses; - Frequência: 3x/semana (fortalecimento e alongamento) e diariamente (atividades aeróbicas); - Intensidade: não reportada. - Duração da sessão: não reportado. - Progressão dos exercícios: conforme escore de dor e função; - Orientação dos exercícios: exibição de vídeos e fotos por aplicativo; - Aderência: lembretes automáticos; <u>Grupo de fisioterapia</u> - Exercícios focados na função dos músculos do core e nas extremidades inferiores e conforme as necessidades de cada paciente;	Condição funcional reportada através do WOMAC (escore total) após quatro e 12 meses	O escore WOMAC não diferiu entre os grupos (exercícios remotos vs. fisioterapia tradicional vs. lista de espera) após 4 e 12 meses. Os exercícios remotos não foram inferiores à fisioterapia tradicional.

		- Exercícios: fortalecimento muscular, flexibilidade, amplitude de movimento e aeróbicos; - Duração: 4 meses; - Frequência: 3x/semana (fortalecimento muscular); diariamente (amplitude de movimento); recomendações para atividades aeróbicas até um total de 150 min por semana; - Intensidade: não reportado. - Duração da sessão: não reportado. - Progressão dos exercícios: não reportado; - Orientação dos exercícios: na clínica de fisioterapia e no domicílio. - Intervenções concomitantes: terapia manual, modalidades eletrofísicas e prescrição de palmilhas conforme necessidade. <u>Grupo de lista de espera</u> - Não receberam intervenção durante o período do estudo.		
Nelligan et al. (2021) Austrália	Sujeitos com OA de joelho conforme critérios clínicos (idade ≥ 45 anos, dor no joelho relacionada a atividade e rigidez matinal ≤ 30 minutos). Grupo intervenção: <i>My Knee Exercise Website Plus Text Messages</i> 103 participantes – $60,3 \pm 8,2$ anos	<u>Grupo intervenção vs. controle</u> <u>Grupo intervenção: <i>My Knee Exercise Website Plus Text Messages</i></u> - Exercícios: 5 a 6 exercícios de fortalecimento de extremidades inferiores; - Duração: 24 semanas;	Dor (na última semana) pela Escala Numérica de dor após 24 semanas. Condição funcional (na última semana) pela subescala de função física do WOMAC após 24 semanas.	Houve melhora do escore de dor e função favorecendo o grupo intervenção.

	Grupo controle: <i>My Knee Education Website</i> 103 participantes – 59,0 ± 8,5 anos	• Frequência: 3x/semana; • Dose: 3 séries de 10 repetições; • Intensidade. • Programa 1 (5 exercícios – intensidade de 5 a 6/10 na escala de percepção de esforço (EPE); • Programa 2 (6 exercícios – intensidade de 7 a 8/10 na escala de percepção de esforço (EPE); • Duração da sessão: 20 a 30 min; • Progressão dos exercícios: modificação da posição e por aumento da carga. • Orientação dos exercícios: descrição dos exercícios escritas e vídeos. • Aderência: No “<i>My Knee Exercise Website</i>” possui informações para aderência dos participantes. Mensagens automáticas semanais ao longo de 24 semanas. • Intervenções concomitantes: educação em saúde sobre a OA e um guia de atividade física. <u>Grupo controle: <i>My Knee Education Website</i></u> • Material educativo em um website (informações sobre dor no joelho, OA de joelho, e a importância do exercício e da atividade física).		

OA= Osteoartrite; WOMAC= Western Ontario and McMaster Universities Osteoarthritis Index;

2.2.2. Exercícios remotos incluindo algum contato dos pesquisadores via telefone ou virtual por videochamada

A videochamada é uma das possibilidades de disponibilização das consultas fisioterapêuticas para prescrição de exercícios terapêuticos. No estudo conduzido por Bennell et al. (2017), os autores investigaram a efetividade de dois programas combinados de intervenção online, os quais consistiram em um programa de exercícios prescritos via videoconferência e um treinamento online de habilidades para enfrentamento da dor combinado a um material educativo para pacientes com dor crônica no joelho. Em comparação a pacientes que receberam somente o material educativo, a intervenção online com exercícios domiciliares e treinamento para habilidades de enfrentamento da dor melhorou o escore de dor e função três meses após o início do estudo e os efeitos foram sustentados nove meses após o início da intervenção em comparação ao grupo que recebeu apenas o material educativo. Além disso, as mudanças observadas excederam a diferença mínima clinicamente relevante no escore de função.

As consultas por videochamada podem ser utilizadas para prescrição do exercícios e posterior realização do programa de treinamento de forma independente ou como uma ferramenta para supervisão fisioterapêutica simultânea. Neste contexto, ao comparar um programa de exercícios de fortalecimento muscular de extremidades inferiores no qual um grupo foi acompanhado simultaneamente por videochamada e o outro recebeu um folheto com as orientações dos exercícios foi observada melhora em diversos parâmetros, incluindo a condição funcional reportada pelo paciente, dor, estado funcional e emocional, cinesiofobia, fadiga e nível de atividade física favorecendo o grupo de telereabilitação por videochamada (TORE, OSKAY e HAZNEDAROGLU, 2023).

Utilizando de ligações telefônicas como meio de comunicação com os pacientes, o estudo de O'Brien et al., (2018) implementou um protocolo de seis meses baseado em ligações telefônicas motivacionais incluindo recomendações para perda de peso e orientações para prática de atividade física comparado a um grupo de cuidados usuais para pacientes com OA de joelho. O desfecho primário do estudo foi a intensidade da dor na escala numérica de 11 pontos. Não houve diferença significativa entre os grupos em relação a intensidade da dor e a perda de

peso ao longo de seis meses. No entanto, é necessário considerar que apenas 34% dos participantes do estudo completaram o programa de tratamento, aspecto que interferiu na magnitude do efeito da intervenção. Os achados deste estudo destacam a necessidade de elucidar os fatores que influenciam a adesão dos pacientes ao programa de treinamento por meio de ligações telefônicas.

Visando a disponibilização de um programa de tratamento individualizado para pacientes com OA de joelho, no estudo de Hinman et al. (2020) o objetivo foi determinar a eficácia de exercícios orientados via telefone por fisioterapeutas na dor e função em comparação a um programa de orientações sobre a condição articular. O programa de exercícios, estruturado de forma individualizada, contemplou uma lista de 14 exercícios de fortalecimento muscular, entre os quais os participantes foram encorajados a realizar de cinco a seis três vezes por semana. Após um acompanhamento de seis meses, foi observada melhora na condição funcional referida pelos sujeitos do estudo sem alteração significativa na dor. No entanto, a relevância clínica desses achados é incerta, visto que a melhora funcional não alcançou a diferença mínima clinicamente relevante.

Em período menor de intervenção, em outro ensaio clínico randomizado, foi comparado os efeitos de seis semanas de um programa de exercícios remotos e outro programa de automanejo classificado como tratamento usual (GOHIR et al., 2021). O tratamento, disponibilizado via aplicativo de celular, foi composto por exercícios em cadeia cinética aberta e fechada, os quais foram prescritos visando o fortalecimento neuromuscular dos membros inferiores, o estímulo a estabilidade central e o equilíbrio. O desfecho primário do estudo foi a mudança do *baseline* até seis semanas na dor auto-referida nos últimos sete dias. Os participantes foram incentivados a manter a adesão ao tratamento via e-mails diários, notificações de smartphones, ou pelo fisioterapeuta via chat ou telefone. A intervenção online baseada em exercícios promoveu redução da dor do *baseline* até seis semanas em comparação ao tratamento usual. No entanto, a melhora no escore de dor não alcançou a diferença mínima clinicamente relevante.

Quadro 2. Características dos programas de exercícios remotos incluindo algum contato dos pesquisadores via telefone ou virtual por videochamada.

Autor, ano de publicação e país	Amostra	Intervenção	Desfechos primários	Resultados
Bennell et al. (2017) Austrália	Sujeitos com dor crônica no joelho: ≥ 50 anos, dor por mais de 3 meses, dor durante a caminhada (score ≥ 4 na END) e declínio funcional leve ou moderado pela subescala do WOMAC. Grupo intervenção: <i>Internet-delivered treatments</i> 74 participantes – $60,8 \pm 6,5$ anos Grupo controle: 74 participantes – $61,5 \pm 7,6$ anos	<u>Grupo intervenção vs. controle</u> <u>Grupo intervenção – <i>Internet-delivered treatments</i></u> - Exercícios: fortalecimento muscular de extremidades inferiores; - Duração: 3 meses; - Frequência: 3x/semana; - Intensidade: 5/10 na escala de percepção de esforço (EPE); - Duração da sessão: não reportado. - Progressão dos exercícios: pela variação dos exercícios, repetições, carga ou dificuldade de atingir um nível máximo de dez repetições; - Orientação dos exercícios: a prescrição dos exercícios foi realizada por videochamadas ao longo de 12 semanas (semanas 2, 3, 4, 6, 8, 10, e 12) além da disponibilização da descrição dos exercícios e vídeos demonstrativos. Intervenções concomitantes: - Orientados a praticar habilidades de enfrentamento da dor diariamente (PainCOACH); - Material educativo para acesso no momento de lazer sobre exercício, atividade física, controle da dor,	Dor ao caminhar pela Escala Numérica de Dor após 3 e 9 meses. Condição funcional nas últimas 48 horas pela subescala de função física do WOMAC após 3 e 9 meses.	Houve melhora no escore de dor e função favorecendo o grupo intervenção após três meses comparado ao grupo controle. Esses achados foram sustentados após nove meses.

		emoções, alimentação saudável, terapias complementares e medicamentos.		
		<u>Grupo controle:</u> Os participantes do grupo controle receberam o mesmo material educativo do grupo intervenção.		
Tore, Oskay e Haznedaroglu, (2023) Turkia	Sujeitos com diagnóstico de OA de joelho leve ou moderada conforme os critérios do <i>American College of Rheumatology</i>. Sujeitos com independência funcional sem a necessidade de dispositivos auxiliares para marcha, possuindo celular, tablet ou computador com conexão à internet, e capaz de usar um desses dispositivos sem assistência. Grupo intervenção 24 participantes – 55,87±7,24 anos Grupo controle: 24 participantes – 55,79 ± 6,76 anos	<u>Grupo intervenção vs. controle</u> <u>Grupo intervenção</u> - Exercícios: fortalecimento muscular de extremidades inferiores incluindo exercícios isométricos e isotônicos seguidos por alongamento; - Duração: 8 semanas; - Frequência: 3x/semana; - Intensidade: não reportado. - Duração da sessão: 45 a 60 minutos. - Progressão dos exercícios: pela duração e repetição dos exercícios. - Orientação dos exercícios: os exercícios foram supervisionados por videochamadas utilizando a plataforma <i>Zoom meetings</i>. Intervenções concomitantes: Não houve intervenções concomitantes. <u>Grupo controle:</u> Os participantes do grupo controle receberam o mesmo programa de	Performance funcional - Teste de sentar e levantar da cadeira de 30 segundos. Prontidão para atividade física - <i>Physical Activity Readiness Questionnaire for Everyone</i>. Escore de dor, sintomas, função física, atividades esportiva e de lazer e qualidade de vida relacionada ao joelho – KOOS Questionnaire. Severidade da dor – Escala Numérica de Dor.	O grupo intervenção apresentou melhor performance funcional, nível de atividade física, escores dos questionários KOOS e QUIPA (melhor qualidade de atendimento fisioterapêutico) e satisfação com o tratamento fisioterapêutico comparado ao grupo controle. O grupo intervenção apresentou maior redução nos escores de nível de dor, sintomas de depressão e ansiedade, fadiga e cinesiofobia quando comparado ao grupo controle.

		exercícios através de um folheto explicativo para realização independente.	Nível de atividade física – IPAQ-SF. Nível de ansiedade e depressão – HADS. Qualidade do atendimento fisioterapêutico – QUIPA. Cinesiofobia – Escala TAMPA de cinesiofobia. Aderência do paciente ao tratamento – EARS. Nível de fadiga – Escala de severidade da fadiga. Satisfação do paciente com o tratamento.	
O'Brien et al. (2018) Austrália	Sujeitos com história de dor devido a OA de joelho por mais de 3 meses, com sobrepeso e obesidade (IMC >27 kg/m ² e <40 kg/m ²), nível de dor 3/10 na escala numérica de dor, nível moderado de interferência em	<u>Grupo intervenção vs. controle</u> <u>Grupo intervenção</u> Tratamento: <i>Get Healthy Information and Coaching Service</i> por 6 meses.	Nível de dor – Escala Numérica de dor após 2, 6, 10, 14, 18, 22 e 26 semanas.	Uma intervenção de gerenciamento de peso e estilo de vida saudável por telefone não melhorou a intensidade da dor em pacientes com osteoartrite do

	atividades de vida diária e acesso a telefone. Grupo intervenção - 63,0±11,1 anos Grupo controle – 60,2±13,9 anos	- Composição da intervenção: 10 sessões de <i>coaching</i> personalizadas via telefone, ministradas por <i>coaches</i> de saúde qualificados pela universidade, incluindo nutricionistas, fisiologistas do exercício e fisioterapeutas, durante um período de 6 meses. - O apoio fornecido foi baseado em diretrizes nacionais de dieta e atividade física. - Frequência das chamadas telefônicas: 6 chamadas (entre 10 e 15 minutos) nas primeiras 12 semanas e demais ligações para manutenção da adesão ao programa. <u>Grupo controle:</u> - Participantes em lista de espera para uma consulta ortopédica sem envolvimento em intervenções baseadas em exercício.		joelho que estão com sobrepeso ou obesos.
Hinman et al. (2020) Austrália	Pacientes conforme critérios clínicos para OA de joelho, tais como: (1) ≥45 anos; (2) dor no joelho relacionada à atividade e (3) rigidez matinal no joelho ≤30min. Critérios adicionais foram dor no joelho (semana anterior) ≥4 na Escala Numérica de Dor; e dor por ≥3 meses.	<u>Grupo intervenção vs. Controle</u> <u>Grupo intervenção – Aconselhamento sobre exercícios e suporte</u> - Exercícios: 5 a 6 exercícios de fortalecimento muscular. - Duração: 6 meses; - Frequência: 3x/semana;	Dor no joelho pela Escala Numérica de dor e função física (WOMAC Index, range 0–68) após 6 meses.	O aconselhamento e o apoio sobre exercícios realizados por fisioterapeutas por telefone melhoraram modestamente a função física, mas não o desfecho primário de dor no joelho em 6 meses.

	Grupo intervenção: 62,4 ± 9,1 anos. Grupo controle: 62,5 ± 8,1 anos,	• Intensidade: exercícios prescritos em intensidade reportada como “difícil” ou “muito difícil”. • Duração da sessão: não reportado, porque os participantes realizavam de forma independente. • Progressão dos exercícios: mudança da resistência de faixa elástica, posição durante os exercícios e tempo de execução. • Orientação dos exercícios: Ligações telefônicas de (de 4 a 10) ao longo de 6 meses para aconselhamento dos exercícios e monitoramento do progresso. • Intervenções concomitantes: Um modelo opcional de plano de autogerenciamento pessoal, instruções e fotos demonstrando exercícios em casa e um diário de saúde para registrar a adesão ao exercício e sintomas no joelho foram fornecidos. <u>Controle – Serviço usual</u> • O grupo controle recebeu atendimento usual via <i>Musculoskeletal Help Line</i>, incluindo informações sobre OA, estratégias de autogerenciamento, recursos comunitários, suporte emocional e orientação sobre serviços de saúde. Os participantes tiveram uma ligação inicial, com possibilidade de chamadas adicionais, se necessário.		

Gohir et al. (2021). Reino Unido	Pacientes com 45 anos ou mais, com diagnóstico clínico de OA de joelho (sintomática e radiográfica). Grupo intervenção: 65,2±9,7 anos. Grupo controle: 68±8,6 anos.	<u>Grupo intervenção vs. Controle</u> <u>Grupo intervenção – Exercícios por aplicativo e suporte por chat assíncrono ou contato via telefone.</u> • Exercícios: Instruções de exercícios de cadeia aberta e fechada focadas no fortalecimento neuromuscular dos membros inferiores e na estabilidade e desempenho do core, bem como no aprimoramento do equilíbrio. • Duração: 6 semanas; • Frequência: não reportado (realização assíncrona dos exercícios). • Intensidade: ajustada conforme o que o paciente reportava: exercício muito fácil, bom ou muito difícil. • Duração da sessão: não reportado, porque os participantes realizavam de forma independente. • Progressão dos exercícios: os exercícios progrediram conforme graus de complexidade, carga e dificuldade em relação à resposta de cada participante. • Orientação dos exercícios: via aplicativo. • Intervenções concomitantes: abordagem educacional focada em conceitos básicos da OA, seu tratamento, autogerenciamento dos sintomas, os benefícios da mudança comportamental e a manutenção de um estilo de vida saudável.	Nível de dor pela Escala Numérica de dor após 6 semanas	O programa de tratamento baseados em exercícios via aplicativo foi superior aos cuidados usuais em relação a melhora do nível de dor.

		<u>Controle – cuidado usual</u> Os pacientes foram orientados a seguirem o tratamento prévio para OA de joelho.		

OA= Osteoartrite; WOMAC= Western Ontario and McMaster Universities Osteoarthritis Index;

2.2.3. Exercícios remotos com a inclusão de contato pessoal com os pesquisadores.

Em um ensaio clínico randomizado com uma configuração de tratamento tradicional, todos participantes receberam orientações para realizar exercícios em cinco visitas presenciais ao longo de seis meses (Bennell et al., 2017). A prescrição do tratamento consistia na realização de quatro a seis exercícios de fortalecimento de extremidades inferiores três vezes por semana. Em um dos grupos do estudo, os participantes receberam adicionalmente seis sessões de treinamento por telefone visando a aderência ao tratamento e o estímulo a autoeficácia. Os achados do estudo indicaram que após seis meses de acompanhamento não houve diferença entre os grupos na dor e no escore de função. Os dois grupos apresentaram melhora significativa e clinicamente relevante nesses desfechos, e essa melhora foi mantida após 18 meses, aspecto que evidencia que a abordagem por telefone não promoveu benefícios adicionais ao tratamento presencial. Esses achados são semelhantes aos de outro estudo, com grupo controle ativo, no qual mensagens motivacionais não aumentaram a aderência ao tratamento baseado em exercícios de fortalecimento muscular em um acompanhamento de dois anos (Baker et al., 2020).

Em estudo conduzido por Kloeck et al., (2018) com pacientes com OA de joelho e quadril, uma intervenção combinada (*Blended Physical Therapist*) contemplando recurso online para condução do exercício (*e-exercise*) ao longo de 12 semanas e 5 consultas com um fisioterapeuta foi comparada à fisioterapia tradicional com encontros presenciais ao longo de todo o tratamento. Considerando os desfechos primários condição funcional, reportada pelo paciente e mensurada por meio de teste funcionais, e nível de atividade física. Não foi observada diferença entre os grupos no curto (após 12 semanas) e longo prazo (após um ano) na condição funcional e no nível de atividade física. Ambas as intervenções foram efetivas na melhora dos desfechos primários do estudo. Somado a estes achados, conforme a percepção de fisioterapeutas e de pacientes com OA de joelho é necessário aumentar a aceitabilidade das pessoas ao cuidado por meio de recursos digitais e uma das formas de facilitar este processo é incluir consultas presenciais em programas de reabilitação remota (Weber et al., 2023).

Ao considerar o tratamento presencial com suporte por chamadas de telefone, em estudo conduzido por Chen et al. (2019) no decorrer de 12 semanas, pacientes

com OA de joelho receberam duas horas de orientações a respeito da realização de exercícios por fisioterapeutas nas semanais iniciais de tratamento (semanas 0, 2, 4 e 6) e suporte por chamadas de telefone combinado a um programa de educação em saúde, enquanto o grupo controle recebeu somente o programa de educação em saúde. Os achados do estudo indicaram que os exercícios domiciliares foram efetivos para o manejo da dor, redução da rigidez, melhora da condição funcional (força muscular de membros inferiores, equilíbrio e mobilidade) e melhora da qualidade de vida de pacientes com OA de joelho comparado a pacientes que receberam somente um programa de educação em saúde. Neste contexto, considerando o desfecho nível de atividade física, em outro ensaio clínico randomizado, o qual os autores utilizaram uma intervenção multifacetada pelo mesmo período de 12 semanas, incluindo uso de dispositivo de monitoramento, aplicativo de celular e aconselhamento por fisioterapeuta via telefone até a oitava semana e subsequente continuidade do tratamento até a semana 12. Foi observada melhora no nível de atividade física dos participantes do estudo em comparação a um grupo de sujeitos que não receberam o tratamento nas 12 semanas e iniciaram posteriormente (LI et al., 2020).

Em outro estudo, pacientes com dor crônica no joelho, sendo a maioria deles com OA de joelho, receberam, durante 12 semanas, um programa de tratamento via aplicativo com suporte de um pesquisador (MECKLENBURG et al., 2018). Os participantes foram incentivados a realizar exercícios guiados por sensores, ler materiais educativos, registrar seus sintomas, fazer terapia cognitivo-comportamental, trabalhar na perda de peso (para aqueles com sobrepeso) e realizar atividades aeróbicas. Enquanto isso, o outro grupo recebeu apenas orientações básicas de cuidado para o joelho. Ambos os grupos continuaram com seu regime de tratamento usual. Os resultados mostraram que os participantes que seguiram o programa de tratamento via aplicativo experimentaram melhorias na dor no joelho, na função física e na rigidez articular em comparação ao grupo que apenas recebeu as orientações. Além disso, eles também mostraram menos interesse em cirurgia e uma melhor compreensão de sua condição de saúde em comparação com o grupo controle.

Com base na premissa de que os programas de reabilitação para pacientes com OA de joelho devem ser adaptados às necessidades individuais de cada pessoa, Allen et al. (2021) investigaram a efetividade de uma intervenção baseadas

em exercícios e realizada em etapas, entre as quais, na primeira os sujeitos do estudo recebiam um programa de exercícios online e ao não atingir os critérios de melhora de dor e função evoluíam para a segunda etapa, composta por três meses de ligações telefônicas semanais com estímulo para realização de atividade física. Sem a melhora dos sintomas, os participantes evoluíam para uma terceira etapa composta por exercícios presenciais com um fisioterapeuta. A referida intervenção foi comparada a um grupo controle que recebeu somente um programa de educação sobre a condição articular por e-mail. Embora as mudanças observadas após a intervenção não tenham alcançado a diferença mínima clinicamente relevante, os resultados revelaram uma melhora nos sintomas articulares no grupo que passou pela intervenção em etapas, em comparação aos indivíduos que receberam apenas o programa educativo.

Quadro 3. Características dos programas de exercícios remotos incluindo algum contato pessoal com os pesquisadores.

Autor, ano de publicação e país	Amostra	Intervenção	Desfechos primários	Resultados
Bennell et al. (2017) Austrália	Participantes com idade $\geq$ a 50 anos, com relato de dor no joelho $\geq$ 4 na Escala Numérica de Dor, pacientes conforme os critérios do <i>American College of Rheumatology</i> para OA de joelho e classificados como sedentários ou insuficientemente ativos. Grupo tratamento fisioterapêutico e sessões de coaching por telefone 84 participantes – $61,1 \pm 6,9$ anos Grupo tratamento fisioterapêutico 84 participantes – $63,4 \pm 7,8$ anos	<u>Grupo intervenção vs. controle</u> <u>Grupo intervenção</u> – Tratamento fisioterapêutico e sessões de coaching por telefone <i>Tratamento fisioterapêutico</i> - Exercícios: 4 a 6 exercícios (3 focados nos extensores do joelho, 1 para abdutores de quadril e dois opcionais, conforme avaliação). - Duração: continuidade da intervenção por 12 meses. - Frequência: 3x/semana. - Intensidade: não reportado. - Duração da sessão: não reportado, porque o participante realizava de forma independente. - Progressão dos exercícios: ajustada conforme o tipo de exercício, a carga, o número de repetições e a dificuldade. - Orientação dos exercícios: os exercícios foram prescritos presencialmente e acompanhados ao longo de 5 encontros presenciais (semanas 1, 3, 7, 12 e 20).	O desfecho primário foi a dor no joelho pela Escala Numérica de Dor e a função física pelo escore WOMAC avaliados em 6 meses.	A abordagem de sessões de <i>coaching</i> por telefone não aumentou os benefícios no controle do nível dor e função física em relação aos exercícios prescritos por fisioterapeuta para OA de joelho.

		Intervenções concomitantes: - Estratégia educacional sobre a OA de joelho. - Abordagem com objetivos para aumento do nível de atividade física. Intervenções concomitantes: Sessões de <i>Coaching</i> - 6 sessões de coaching em 6 meses (+ até 6 extras), baseado na Metodologia <i>HealthChange®</i> para melhorar adesão ao tratamento. <u>Grupo fisioterapia:</u> • Os participantes do grupo fisioterapia receberam o mesmo programa de exercícios sem as sessões adicionais de <i>coaching</i>.		
Baker et al. (2020) Estados Unidos	Participantes ≥50 anos, diagnóstico autodeclarado de OA de joelho, dor no WOMAC ≥4 (0–20) ou dor no joelho na maioria dos dias no último mês/ano. Grupo intervenção	Programa de exercício para o grupo intervenção e controle. • Exercícios: Agachamentos, step-ups, inclinações pélvicas, abdução de quadril, extensão e flexão de joelho com carga no tornozelo. • Duração: 6 semanas. • Frequência: 2 vezes por semana. • Intensidade: Ajustada individualmente para atingir um	Aderência auto-reportada ao exercício	Naqueles com osteoartrite do joelho que participaram de um programa de exercícios, lembretes motivacionais frequentes por telefone não aumentaram a aderência aos exercícios de treinamento de força.

	52 participantes – 65,8 ± 6,6 anos Grupo controle 52 participantes – 64,5 ± 8,3 anos	nível de esforço "moderadamente difícil" na escala de Borg, com 2 séries de 8 a 15 repetições. • Duração da sessão: Não especificada. • Progressão dos exercícios: Ajuste da carga conforme a escala de Borg para manter a intensidade adequada. • Orientação dos exercícios: Supervisionados por fisioterapeuta ou fisiologista do exercício em grupo, com um programa domiciliar complementar, incluindo materiais instrucionais, pesos progressivos e registros de treino. <u>Grupo intervenção</u> Programa <i>Boston Overcoming Osteoarthritis through Strength Training Telephone-Linked Communication</i> • Objetivo: incentivar motivação e adesão ao programa de exercícios por 2 anos. • Componentes: avaliação do exercício, definição de metas, aconselhamento sobre barreiras, gestão de lapsos e alertas de dor/lapsos prolongados (>4 semanas).		

		• Base teórica: Teoria social cognitiva, autoeficácia e modelo transteórico. • Frequência das ligações: Semanais (nos primeiros 6 meses) e mensais (nos 18 meses seguintes). • Contato: Ligações agendadas, com até 2 novas tentativas na mesma semana em caso de falha. • Suporte adicional: Mensagens mensais automatizadas e sessão extra em caso de adoecimento. <u>Grupo controle</u> • Por 24 meses, os participantes receberam uma mensagem telefônica mensal automatizada lembrando-os de fazer treinamento de força e completar o registro de exercícios, no entanto, sem mensagens motivacionais.		
Kloek et al. (2018) Holanda	Participantes com 40 a 80 anos diagnosticados com osteoartrite de quadril ou joelho de acordo com os critérios do <i>American College of Rheumatology</i>. Grupo <i>e-exercise</i> - 63.8 ± 8.5 anos. Grupo fisioterapia usual - 62.3 ± 8.9 anos.	<u>Grupo intervenção vs. controle</u> <u>Grupo intervenção – e-exercise</u> • Exercícios: exercício como caminhada ou cíclico combinado com 4 exercícios de força e estabilidade. • Duração: 12 semanas. • Frequência: a cada semana, o participante foi solicitado a	Função física foi avaliada pela subescala “função na vida diária” pelos instrumentos Hip OA Outcome Score (HOOS); The Knee Injury and OA Outcome Score (KOOS), e o teste Timed Up and Go. Nível de atividade física diária pelo instrumento the Short Questionnaire to Assess	Não foram observadas diferença entre o programa <i>e-exercise</i> e os cuidados usuais de fisioterapia em relação a função física e a atividade física diária.

		realizar 2 exercícios assistidos por vídeo em 3 dias diferentes. • Intensidade: não reportado. • Duração da sessão: não reportado, porque o participante realizava de forma independente. • Progressão dos exercícios: o número de repetições dos exercícios foi aumentado gradualmente a cada 4 semanas. • Orientação dos exercícios: em cinco sessões presenciais e por aplicativo. Intervenções concomitantes: - Estímulo ao aumento gradual da atividade física. - Vídeo educacionais sobre etiologia da OA, controle da dor, controle de peso, motivação, medicação e influências sociais na dor. <u>Grupo fisioterapia usual:</u> Fisioterapia usual no estudo foi definida como qualquer tratamento fornecido pelo fisioterapeuta. Os fisioterapeutas foram encorajados a conduzir o tratamento de acordo com a diretriz holandesa de OA.	Health-Enhancing Physical Activity (SQUASH).	
Chen et al. (2019) China	Participantes ≥60 anos, com dor no joelho frequente (entre 3 e 7 na Escala	<u>Grupo intervenção vs. controle</u> Grupo intervenção – Participantes participaram de sessões de 2h com	Intensidade da dor e rigidez articular pelo escore WOMAC	Um programa de exercícios em domicílio combinado a educação em saúde reduziu significativamente os sintomas de

	Numérica de dor) e cognição preservada. Grupo intervenção – 68,9 ± 7,8 anos de idade. Grupo controle – 68,8 ± 6,96 anos de idade.	fisioterapeutas por 12 semanas (0, 2, 4, 6), em grupos de 6–12 pacientes, com 1h de educação em saúde e 1h de exercícios. • Exercícios: 9 exercícios para realização domiciliar com ênfase na função de membros inferiores e equilíbrio. • Duração: 12 semanas. • Frequência: 3x/semana. • Intensidade: Não especificada. • Duração da sessão: 30 a 40 minutos. • Progressão dos exercícios: Não especificada • Orientação dos exercícios: encontros presenciais de orientação e os participantes foram instruídos a preencher um diário de exercícios em casa para lembrá-los de fazer seus exercícios em casa. • Intervenções concomitantes: Ligações nas semanas 1, 3, 5, 7 e 9 para monitorar progresso e adesão, incentivando os exercícios. • 4 módulos sobre manifestações clínicas, fatores de risco, diagnóstico, tratamento, cuidados, benefícios do exercício e manejo domiciliar. <u>Grupo controle</u>		OA de joelho (dor e rigidez) em pacientes idosos em comparação a uma intervenção que envolveu apenas educação em saúde.

		Os participantes do grupo de controle receberam o mesmo número de sessões de educação em saúde, acompanhamentos por telefone e os mesmos materiais em papel que os participantes do grupo de intervenção, mas sua educação em saúde e materiais em papel não incluíam informações relacionadas a exercícios.		
Li et al (2020) Canada	Pacientes ≥ 50 anos ou com diagnóstico médico de OA do joelho que tiveram dor ou desconforto na região do joelho por mais de 28 dias no último ano. <u>Grupo de tratamento imediato – 26 participantes</u> 65$\pm$8 anos de idade <u>Grupo de tratamento tardio – 25 participantes</u> 64,8$\pm$9 anos de idade	<u>Grupo de tratamento imediato e grupo de tratamento tardio</u> <u>Grupo de tratamento imediato</u> Características da intervenção: Sessão presencial, uso de Fitbit Flex-2 e aconselhamento telefônico com fisioterapeuta (PT). - Sessão presencial: 20 min de educação em grupo e 30 min de aconselhamento individual em locais específicos. - Fitbit Flex-2: Dispositivo para rastreamento de passos, esforço físico e tempo ativo; não resistente à água. - FitViz: Aplicativo baseado na web para acompanhar metas de atividade física. - Definição de metas: Planejamento com metas para atividade física. - Acompanhamento: 4 ligações quinzenais para revisão de metas de atividade física e uso	Tempo médio diário de atividade física moderada a vigorosa medido por um sensor (SenseWear Mini (BodyMedia Inc))	A diferença média ajustada no tempo gasto em atividade física moderada a vigorosa entre os grupos após a intervenção em 13 semanas foi de 13,1 minutos por dia (IC 95% 1,6 a 24,5), favorecendo o grupo de tratamento imediato.

		do dispositivo Fitbit Flex-2 e do aplicativo FitViz; uso contínuo do Fitbit e FitViz sem aconselhamento dos fisioterapeutas (semanas 9-12). • Contato adicional: E-mails permitidos para dúvidas após semana 8. <u>Grupo de tratamento tardio</u> Os participantes receberam a mesma intervenção na semana 14. Durante o período de espera, eles receberam e-mails mensais com notícias sobre OA não relacionadas à atividade física.		
Mecklenburg et al (2018) Estados Unidos	Participantes com idade superior a 18 anos com história de dor no joelho por pelo menos 1 mês nos últimos 12 meses. <u>Grupo intervenção</u> 46 ± 12 anos de idade <u>Grupo controle</u> 47 ± 12 anos de idade	<u>Grupo intervenção vs. controle</u> <u>Grupo intervenção: programa Hinge Health (12 semanas)</u> <u>Características do programa</u> • Tablet com app e sensores Bluetooth para exercícios. • Acompanhamento por um profissional e suporte por meio de um fórum no aplicativo. • Participação 100% remota durante o tratamento, com lembretes por mensagem/e-mail.	Score de dor e função física pelas subescalas do KOOS.	O programa Hinge Health proporcionou melhorias significativas na dor e na função física em participantes com dor crônica no joelho, superando o grupo controle que recebeu apenas educação e tratamento usual por 12 semanas.

		• Antes de iniciar o tratamento os participantes passaram por um treinamento presencial para conhecer o programa. • Metas semanais: ✓ 3 sessões de exercícios guiados por sensor. ✓ Leitura de 1-2 artigos educativos. ✓ Registro de sintomas (≥ 2 vezes). ✓ Terapia cognitivo-comportamental (algumas semanas). ✓ Foco na perda de peso (se necessário). ✓ Monitoramento de ≥ 3 sessões aeróbicas (30 min cada). • Acesso contínuo ao tratamento usual. <u>Grupo controle</u> • Os participantes receberam três componentes de educação, apresentadas digitalmente, que também fazem parte do <i>Hinge Health</i>. Esses artigos discutiram a importância do autocuidado, como lidar com contratempos na dor no joelho e como gerenciar a comunicação e os		

		relacionamentos ao viver com dor crônica no joelho.		
Allen et al (2021) Estados Unidos	Participantes com diagnóstico de OA de joelho, e dor autorrelatada ≥ 3 (escala de 0 a 10) no joelho nas últimas duas semanas. Grupo intervenção – 230 participantes – $59,9 \pm 9,9$ anos de idade. Grupo controle – 115 participantes – $60,2 \pm 11,1$ anos de idade.	<u>Grupo intervenção vs. controle</u> <u>Grupo intervenção: programa <i>STepped Exercise Program for patients with Knee OsteoArthritis</i> (STEP-KOA).</u> <u>Características do programa</u> • Step 1 - Programa de exercícios online para osteoartrite de joelho (OA) por 3 meses. • Cada nível de exercício incluía alongamento, fortalecimento e exercícios aeróbicos, com vídeos e imagens demonstrativas. Os participantes deveriam realizá-los pelo menos três vezes por semana. • Step 2 - Coaching telefônico quinzenal para superar barreiras à atividade física (caso não haja resposta ao Step 1). • Step 3 - Sessões presenciais de fisioterapia (se	Dor, rigidez e função do joelho pelas subescalas do questionário WOMAC	Os participantes do grupo STEP-KOA relataram melhorias modestas no resultado primário (WOMAC) no acompanhamento de 9 meses (44), em relação ao grupo de controle

		não houver resposta ao Step 2 após 3 meses). <u>Grupo controle</u> • O grupo controle recebeu materiais educacionais sobre osteoartrite pelo correio a cada duas semanas por 9 meses, baseados em diretrizes estabelecidas.		

OA= Osteoartrite; WOMAC= Western Ontario and McMaster Universities Osteoarthritis Index;

2.2.4. Desfechos em programas de exercícios online

As principais ferramentas aplicadas em estudos com intervenções remotas voltadas a sujeitos com OA são relativas ao nível de dor e a condição funcional reportada pelos pacientes, por meio de instrumentos padronizados para esta finalidade. Na diretriz para ensaios clínicos randomizados da OARSI a inclusão desses parâmetros como desfechos primários é fortemente recomendada visando analisar a efetividade de intervenções direcionadas para este perfil clínico na perspectiva do paciente (MCALINDON et al., 2015).

Neste contexto, é necessário considerar que alguns elementos da condição funcional não são completamente capturados baseados somente no relato do paciente, o que sinaliza a relevância da inclusão de medidas funcionais objetivas para análise completa do perfil funcional do paciente. Particularmente quanto a habilidade de transferência da posição sentada para em pé, velocidade de caminhada e subir e descer escadas (DOBSON et al., 2013).

Quanto a parâmetros de bem-estar psicológico, embora a literatura disponível contemple a saúde emocional como um fator relevante em pacientes com OA de joelho em razão do impacto na condição articular, ainda persiste uma lacuna na literatura a respeito da comparabilidade dos efeitos de intervenções remotas e presenciais em parâmetros como catastrofização relacionada a dor, sintomas de ansiedade, estresse e depressão e qualidade de sono (REZAKHANI MOGHADDAM et al., 2019).

Por fim, a deterioração da qualidade muscular do quadríceps femoral especialmente a do vasto medial, mensurada por ultrassonografia, ao interferir na apresentação sintomática e no nível de incapacidade de sujeitos que vivem com OA de joelho, destaca-se como um parâmetro objetivo de acompanhamento da condição muscular periarticular, além de uma medida preditora de manifestações clínicas (TANIGUCHI et al., 2022). A utilização da ultrassonografia é relevante por possibilitar uma medida livre de desconforto articular para o paciente e que confere informações a respeito da dimensão e qualidade estrutural do músculo. No entanto, as repercussões de um programa de exercícios de fortalecimento muscular de extremidades inferiores na qualidade muscular do quadríceps femoral ainda não foram elucidadas, principalmente quanto a comparabilidade do efeito em dois

modelos de disponibilização da intervenção: remota e presencial. Especialmente para verificar se a intervenção remota é não-inferior à presencial.

Por fim, destaca-se que a maioria dos estudos sobre telereabilitação para pacientes com OA de joelho descritos nos Quadros 1, 2 e 3 foi conduzida em países desenvolvidos, com participantes que possuem letramento digital e alto nível educacional e socioeconômico. Esse cenário levanta o questionamento: quais perfis de pacientes realmente se beneficiam das intervenções remotas? Assim, torna-se essencial a realização de ensaios clínicos randomizados para preencher lacunas na literatura, especialmente no que se refere à implementação da telereabilitação em países em desenvolvimento. Visto que as desigualdades sociais limitam o acesso de indivíduos com menor nível educacional e socioeconômico a abordagens terapêuticas recomendadas por diretrizes internacionais.

3. MATERIAIS E MÉTODOS

3.1. Desenho do estudo

Será conduzido um estudo experimental, caracterizado como um ensaio clínico randomizado de não-inferioridade com dois grupos paralelos, em um único centro e com cegamento de avaliadores de desfecho. O desenho, a condução e a descrição do estudo serão realizados conforme as seguintes recomendações: *OARSI Clinical Trials Recommendations e a Standard Protocol Items: Recommendations for Interventional Trials* (SPIRIT) (SCHULZ et al., 2010; MCALINDON et al., 2015).

3.2. Participantes

A população-alvo do estudo será sujeitos assistidos pelo Sistema Único de Saúde e com diagnóstico clínico de OA de joelho da cidade de Bagé e região. Os participantes serão recrutados a partir da lista de espera da Clínica Escola de Fisioterapia do Hospital Universitário Doutor Mário Araújo do Centro Universitário da Região da Campanha (URCAMP), Campus Bagé – RS, além da divulgação do estudo em redes sociais e Unidades Básicas de Saúde da cidade de Bagé. O termo de anuência será encaminhado para assinatura dos responsáveis para futura condução do estudo nas dependências da instituição (Apêndice A).

Inicialmente, através de ligação telefônica, um pesquisador fará um primeiro contato com os voluntários para analisar a conformidade com os critérios de elegibilidade iniciais, na sequência será marcada a avaliação presencial. Os critérios iniciais de seleção presencialmente serão história de dor e redução da função do joelho, idade ≥ 45 anos e dor por mais de 3 meses. Além disso, uma triagem radiográfica será realizada com a finalidade de identificar o grau da OA de joelho. Os participantes que não possuírem um exame com a classificação radiográfica, ou em caso de a radiografia ter sido realizada em período maior que 12 meses, um novo exame será solicitado no setor de radiologia do Hospital Universitário da URCAMP. Os critérios de inclusão e exclusão definitivos serão verificados na primeira consulta presencial para recrutamento dos participantes na Clínica Escola de Fisioterapia do Hospital Universitário Doutor Mário Araújo da URCAMP. Os participantes, ao

aceitarem participar do estudo, receberão uma explicação detalhada do pesquisador responsável pelo recrutamento, presencialmente, sobre todas as etapas, incluindo informações sobre os objetivos, as medidas de desfecho, os riscos, benefícios e sobre a confidencialidade das informações coletadas. A coleta de dados iniciará somente após a assinatura do Termo de Consentimento Livre e Esclarecido (TCLE) (Apêndice B).

3.2.1. Critérios de inclusão

Serão selecionados pacientes com OA de joelho sintomática, com diagnóstico radiográfico de OA de joelho unilateral ou bilateral e classificados nos graus II ou III conforme os critérios de *Kellgren and Lawrence* (KELLGREN e LAWRENCE, 1957). Além disso, os pacientes deverão ter escore médio de dor ≥ 3 na última semana na escala numérica de dor, rigidez matinal < 30 minutos e crepitação articular (Altman et al., 1986). Considerando o formato das intervenções no presente estudo, os participantes deverão também ter marcha independente e acesso à internet.

3.2.2. Critérios de exclusão

Pacientes com doenças inflamatórias sistêmicas, incluindo artrite reumatoide, espondilite anquilosante e lúpus eritematoso sistêmico; doenças neurológicas com repercussões motoras e doenças cardíacas instáveis; história de artroplastia total de joelho ou cirurgia nas extremidades inferiores; índice de massa corporal (IMC) ≥ 35 kg/m² e tratamento fisioterapêutico ou participação em um programa de exercícios supervisionados nos últimos seis meses.

3.3. Intervenção

A intervenção do estudo é definida como um protocolo de exercícios de fortalecimento muscular de extremidades inferiores. O programa será implementado nos dois grupos do estudo com a supervisão de um fisioterapeuta. O comparador será o formato de disponibilização da intervenção, uma vez que em um grupo a supervisão será presencial e no outro será online.

3.3.1. Protocolo de exercício terapêutico

Os participantes selecionados para o estudo receberão um programa de exercícios, conduzido no decorrer de 12 semanas, com duração de aproximadamente 40 min, duas vezes na semana, nas primeiras duas semanas, e três vezes a partir da terceira semana até o término do protocolo. Um grupo de participantes será supervisionado remotamente por videochamada (grupo de exercícios remotos) e outro presencialmente (grupo de exercícios presenciais).

O protocolo será composto por seis exercícios de fortalecimento muscular de extremidades inferiores, os quais serão orientados alternando-se os grupos musculares. Os exercícios, no primeiro bloco de tratamento, abordarão os extensores do joelho, os adutores do quadril e os flexores plantares, e no segundo bloco, os extensores do joelho, os abdutores do quadril e os flexores do joelho. O protocolo de exercícios será implementado em formato individualizado, deste modo o profissional responsável pela intervenção supervisionará um paciente a cada encontro e adaptações poderão ser realizadas conforme as características funcionais de cada participante. O fisioterapeuta responsável pela intervenção registrará todo o programa de exercícios descrevendo quaisquer adaptações necessárias ao longo das semanas de treinamento. Os sujeitos do estudo serão encorajados a realizar os movimentos em cadeia cinética aberta e fechada em amplitude de movimento completa, e naqueles sujeitos que referirem dor ≥ 3 ao movimento na escala numérica de dor (END), os exercícios serão orientados em menor amplitude de movimento. A marcha estacionária antecederá o primeiro bloco de treinamento e finalizará o programa de exercícios.

A intensidade do exercício será monitorada de forma que os participantes completem, nas duas primeiras semanas de tratamento 2 séries de 8-12 repetições nos exercícios dinâmicos e 5-8 repetições de 20 segundos nos isométricos, e nas seguintes com uma série adicional. A carga do próprio corpo, uma carga externa imposta por faixa elástica e a posição do exercício ao longo do protocolo serão ajustados para manter a percepção de esforço no índice 5 na escala modificada de classificação de esforço de Borg (0-10) da semana um até a sete, e no índice 7 da semana oito até a 12 (American College of Sports Medicine, 2009) (Quadro 4, 5, 6). O intervalo entre as séries será de 1 min e entre os exercícios será de 30 s. Entre o

primeiro e o segundo bloco de fortalecimento muscular terá um intervalo de 1 min nas primeiras seis semanas, e de 30 s nas semanas seguintes. O paciente executará de forma completa as séries e repetições dos exercícios para cada grupo muscular dentro do bloco antes de prosseguir para o próximo. Em todos os exercícios, os fisioterapeutas responsáveis pela intervenção passarão orientações para progressão (Quadro 7). No quadro 8 consta a ilustração dos exercícios do protocolo.

Quadro 4. Periodização do programa de exercícios nas 12 semanas de acompanhamento (semana 1 e 2).

Semana 1 e 2 – 2x/semana		
Bloco 1		
Marcha estacionária - 30 s		
Grupo muscular e exercício	Volume	Intensidade
Extensores de joelho		
Ativação isométrica do quadríceps femoral	2 x 5-8 reps iso 20s. com de 1 min entre séries	Borg 5
Adutores de quadril		
Ativação isométrica dos adutores do quadril	2 x 5-8 reps iso 20s com intervalo de 1 min entre séries	Borg 5
Flexores plantares		
Flexão plantar Nível 1.	2 x 8-12 reps com intervalo de 1 min entre séries	Borg 5
Intervalo entre blocos: 1 min		
Bloco 2		
Extensores de joelho		
Extensão de joelhos Nível 1.	2 x 8-12 reps com intervalo de 1 min entre séries	Borg 5
Abdutores de quadril		
Abdução contra a parede (<i>Wall Push</i>) Nível 1.	2 x 5-8 reps iso 20s com intervalo de 1 min entre séries	Borg 5
Flexores de joelho		
Flexão de joelho Nível 1.	2 x 8-12 reps com intervalo de 1 min entre séries	Borg 5
Marcha estacionária - 30 s		

Quadro 5. Periodização do programa de exercícios nas 12 semanas de acompanhamento (semana 3 a 7).

Semana 3 a 7 – 3x/semana		
Bloco 1		
Marcha estacionária por 30 segundos		
Grupo muscular e exercício	Volume	Intensidade
Extensores de joelho		
Extensão de joelhos Nível 2.	3 x 8-12 reps com intervalo de 1 min entre séries	Borg 5
Adutores de quadril		
Adução de quadril em pé Nível 1 – semanas 3 e 4. Nível 2 – semanas 5, 6 e 7.	3 x 8-12 reps com intervalo de 1 min entre séries	Borg 5
Flexores plantares		
Flexão plantar Nível 2 – semanas 3 e 4. Nível 3 – semanas 5, 6 e 7.	3 x 8-12 reps com intervalo de 1 min entre séries	Borg 5
1 minuto de intervalo ao final do primeiro bloco		
Bloco 2		
Extensores de joelho		
Agachamento na parede Nível 1 – semanas 3 e 4. Nível 2 – semanas 5, 6 e 7.	3 x 8-12 reps com intervalo de 1 min entre séries	Borg 5
Abdutores de quadril		
Abdução contra a parede (<i>Wall Push</i>) Nível 1 – semanas 3 e 4. Nível 2 – semanas 5, 6 e 7.	3 x 5-8 reps iso 20s com intervalo de 1 min entre séries	Borg 5
Flexores de joelho		
Flexão de joelho Nível 1 - semanas 3 e 4. Nível 2 - semanas 5, 6 e 7.	3 x 8-12 reps com intervalo de 1 min entre séries	Borg 5

Marcha estacionária por 30 segundos

Quadro 6. Periodização do programa de exercícios nas 12 semanas de acompanhamento (semana 8 a 12).

Semana 8 a 12 – 3x/semana		
Bloco 1		
Marcha estacionária por 30 segundos		
Grupo muscular e exercício	Volume	Intensidade
Extensores de joelho		
Extensão de joelho sentado em menor amplitude (até 60°) Nível 1 – semanas 8 e 9. Nível 2 – semanas 10, 11 e 12.	3 x 8-12 reps com intervalo de 1 min entre séries	Borg 7
Adutores de quadril		
Adução de quadril em pé Nível 2 – semanas 8 a 12.	3 x 8-12 reps com intervalo de 1 min entre séries	Borg 7
Flexores plantares		
Flexão plantar Nível 3 – semanas 8 a 12.	3 x 8-12 reps com intervalo de 1 min entre séries	Borg 7
30 segundos de intervalo ao final do primeiro bloco		
Bloco 2		
Extensores de joelho		
Exercício de levantar e sentar Nível 1 – semanas 8 e 9. Nível 2 – semanas 10, 11 e 12.	3 x 8-12 reps com intervalo de 1 min entre séries	Borg 7
Abdutores de quadril		
Exercício de marcha lateral Nível 1 – semanas 8 e 9. Nível 2 – semanas 10, 11 e 12.	20-30 passos laterais em cada direção	Borg 7
Flexores de joelho/extensores de quadril		
Exercício de ponte Nível 1 – semanas 8 e 9. Nível 2 – semanas 10, 11, 12.	3 x 8-12 reps com intervalo de 1 min entre séries	Borg 7

Marcha estacionária por 30 segundos

Quadro 7. Descrição dos exercícios, resistência e progressão.

	Exercício	Descrição	Resistência	Progressão
Extensores do joelho	Ativação isométrica do quadríceps femoral	Paciente sentado, realiza a extensão de joelhos e mantém a contração muscular por 20 segundos.		-
	Extensão de joelhos	Paciente sentado, realiza a extensão de joelho contra a resistência.	Resistência de banda elástica	Nível 1 – banda elástica leve Nível 2 – banda elástica moderada
	Extensão de joelho sentado em menor amplitude (até 60°)	Paciente sentado, realiza a extensão de joelho contra a resistência de 90° a 60°.	Resistência de banda elástica	-
	Agachamento na parede	Paciente em pé, de costas para a parede, realiza o movimento de agachamento.	Massa corporal	Nível 1 – agachamento com sobrecarga articular bilateral Nível 2 – agachamento com sobrecarga bilateral e ênfase no membro inferior sintomático.

	Sentar e levantar da cadeira	Paciente em pé, de costas para a cadeira, realiza o movimento de sentar e levantar da cadeira.	Massa corporal	Nível 1 – agachamento com sobrecarga articular bilateral Nível 2 – agachamento com sobrecarga bilateral e ênfase no membro inferior sintomático.

Flexores do joelho	Flexão de joelho	Paciente em pé realiza o movimento de flexão de joelho contra resistência	Faixa elástica	Nível 1 – banda elástica leve. Nível 2 – banda elástica moderada.
	Exercício de ponte	Paciente em posição supina, joelhos e quadris fletidos, membros superiores apoiados lateralmente, realiza o movimento de elevação pélvica.	Massa corporal	Nível 1 – Exercício com apoio bilateral dos membros inferiores. Nível 2 – Exercício de ponte unilateral (com extensão de joelho).
Adutores de quadril	Ativação isométrica dos adutores do quadril	Paciente sentado, com travesseiro entre os joelhos, realiza a adução do quadril	-	-
	Adução do quadril em pé	Paciente em pé realiza o movimento de adução contra resistência	Faixa elástica	Nível 1 – banda elástica leve Nível 2 – banda elástica moderada.

Abdutores de quadril	Abdução contra a parede (<i>Wall Push</i>)	Paciente em pé de lado contra a parede. Realiza ativação isométrica dos abdutores empurrando a região lateral da coxa contra a parede, enquanto a outra extremidade inferior encontra-se em 15 a 20° de flexão de joelho.	Massa corporal	Nível 1 – Exercício com a extremidade inferior apoiada no solo em 15 a 20° de flexão. Nível 2 – Exercício com a extremidade inferior apoiada no solo em 45° de flexão.
	Exercício de marcha lateral	Paciente em pé realiza passos laterais contra a resistência	Peso corporal	Nível 1 – 20 passos laterais contra a resistência de uma banda elástica moderada. Nível 2 – 30 passos laterais contra a resistência de uma banda elástica moderada.
Flexores plantares	Flexão plantar	Paciente em pé realiza o movimento de flexão plantar	Peso corporal	Nível 1 – Flexão plantar bilateral Nível 2 – Flexão plantar unilateral com membro inferior contralateral em 20° de flexão de joelho.

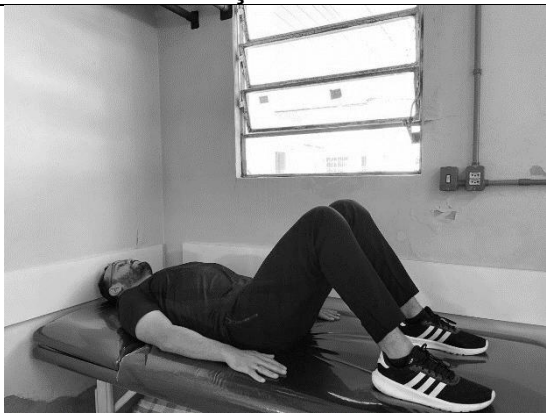
				Nível 3 – Flexão plantar unilateral com membro inferior contralateral em 90° de flexão de joelho.

Quadro 8. Ilustração dos exercícios

Exercício	Ilustração	
	Posição inicial	Posição final
Ativação isométrica do quadríceps femoral		
	Posição inicial	Posição final

Extensão de joelhos		
Extensão de joelho sentado em menor amplitude (até 60°)		
	Posição inicial	Posição final

Agachamento na parede		
Sentar e levantar da cadeira		
	Posição inicial	Posição final

Flexão de joelho em pé		
Exercício de ponte	Posição inicial 	Posição final 
	Posição inicial	Posição final

Ativação isométrica dos adutores do quadril		
Adução do quadril em pé	Posição inicial 	Posição final 
	Posição inicial	Posição final

Abdução contra a parede (Wall Push)



Exercício de marcha lateral

Posição inicial



Posição final



Posição inicial

Posição final

Flexão plantar						
		Posição inicial		Posição final		
Marcha estacionária						

3.3.2. Familiarização dos participantes com a intervenção

Todos os sujeitos incluídos no estudo, subsequentemente às avaliações pré-intervenção e randomização, participarão de uma sessão presencial de familiarização com o programa de exercícios, incluindo orientações específicas sobre o formato de disponibilização da intervenção (remota ou presencial), além de serem orientados sobre o uso da escala modificada de classificação de esforço de Borg durante o tratamento (AMERICAN COLLEGE OF SPORTS MEDICINE, 2009).

No grupo de exercícios remotos, os participantes receberão orientações sobre as videochamadas, com ênfase no posicionamento do dispositivo móvel visando a qualidade da supervisão em tempo real. Na sequência, cada exercício será realizado com orientações para realização segura no domicílio. Como exemplo, manter uma cadeira e uma vassoura por perto para realização dos movimentos em pé para prevenção de quedas, evitar realizar movimento perto de tapetes que possam escorregar. Neste mesmo encontro, as bandas elásticas serão disponibilizadas para os participantes. Esses serão orientados que a cada sessão o fisioterapeuta enviará um link por aplicativo de mensagens para acesso a videochamada e início do programa de exercícios.

No grupo de exercícios presenciais, os participantes também serão familiarizados executando cada exercício com a supervisão do fisioterapeuta e orientados sobre os encontros semanais agendados na clínica de fisioterapia para o tratamento.

3.3.3. Acompanhamento após 12 semanas

Após o período de tratamento supervisionado de 12 semanas, os participantes do estudo, independente do grupo de alocação, serão encorajados a prosseguir o mesmo programa de exercícios em domicílio, sem a supervisão de um fisioterapeuta. Para incitar a continuidade do tratamento, todos os participantes receberão uma cartilha com fotos com a descrição dos exercícios. Neste material os participantes serão orientados a continuar o mesmo programa de tratamento realizado nas últimas semanas com foco nos exercícios sem a necessidade da faixa elástica (Apêndice C).

3.3.4. Critérios para descontinuar a intervenção

Os sujeitos randomizados estarão livres para desistir do tratamento sem nenhuma penalidade a qualquer momento ou motivo. A participação no estudo poderá ser interrompida por motivos de segurança, como orientação médica, complicação de doença preexistente ou agudização de condição clínica que impossibilite a participação no programa de exercício.

Serão monitorados os eventos adversos e categorizados conforme gravidade (leve, moderado ou grave), previsibilidade (esperado ou inesperado) e possível associação com o exercício e o modo de supervisão (definitivamente associados, possivelmente associados ou não associados). Todos os possíveis eventos adversos serão discutidos por pelo menos dois pesquisadores (os pesquisadores principais) e consultores e especialistas na área.

3.3.5. Estratégias para aumentar a aderência ao tratamento

Uma das recomendações da OARSI para desenvolver melhores práticas de exercícios terapêuticos para pessoas com OA de joelho é motivar o paciente a realizar e aderir ao programa de exercícios (HOLDEN *et al.*, 2023). Visando manter os participantes aderentes ao exercício, ao longo do tratamento supervisionado por videochamada ou presencialmente, o profissional abordará tópicos relevantes de educação em saúde sobre o tratamento da OA de joelho baseado em exercício. O fisioterapeuta realizará uma abordagem educativa em tempo real por videochamada no grupo de exercícios remotos, ou presencialmente no grupo de exercícios presenciais em aproximadamente 20 minutos antes no início da sessão de exercícios. Serão conduzidos três momentos de enfoque educativo ao longo do estudo, sendo o primeiro na semana inicial de exercício supervisionado, o segundo na terceira semana, e o terceiro na oitava semana. O pesquisador elaborará uma breve apresentação ilustrada com foco na história clínica do participante e abordará os seguintes tópicos (Apêndice D):

- A. Orientação sobre a osteoartrite de joelho e a importância do exercício no tratamento.

- B. Abordagem centrada na história do paciente facilitando o entendimento sobre a apresentação sintomática da OA de joelho.
- C. Utilização de comunicação simples e positiva para explicar a OA, evitando o desenvolvimento de cinesiofobia.
- D. Explicação sobre os benefícios a longo prazo do exercício, com repercussões na dor e na função, demonstrando que é uma maneira eficaz de lidar com a OA.
- E. Esclarecimento sobre o exercício como tratamento, destacando que não está associado a um maior risco de lesão articular ou substituição articular.
- F. Orientação sobre a diferença entre a dor como sintoma da OA e a dor muscular após o exercício, enfatizando que a dor em curto prazo não indica dano articular.
- G. Abordagem do medo relatado pelos pacientes em relação ao exercício garantindo a segurança do tratamento e atenção especial a quaisquer noções equivocadas sobre a eficácia do exercício terapêutico.

3.3.6. Acompanhamento da aderência ao tratamento

O acompanhamento da aderência ao tratamento será baseado em protocolo de estudo publicado por HINMAN et al. (2017). No grupo de exercícios remotos, a aderência ao tratamento será monitorada por meio do número de videochamadas realizadas semanalmente e pela duração. No grupo de exercícios presenciais, o monitoramento será realizado pela presença dos participantes nos encontros semanais. Na reavaliação presencial após 12 semanas, os participantes receberão uma planilha para registrar semanalmente a realização dos exercícios nas semanas seguintes, e no final, na reavaliação presencial após 18 semanas, o fisioterapeuta irá conferir a aderência ao tratamento. Além disso, um questionário de monitoramento da intervenção será aplicado após 18 semanas com as seguintes perguntas: Você realizou os exercícios? (Sim, Não); Quantas vezes na semana? (uma, duas ou três vezes na semana); você enfrentou dificuldade para realizar os exercícios sozinho (a)? (Sim, Não); você concorda com o programa de exercícios? (Sim, Não); indique o seu grau de satisfação com a intervenção (0 – totalmente insatisfeito; 10 – totalmente satisfeito).

3.3.7. Capacitação da equipe do estudo

A equipe do estudo será capacitada previamente a respeito dos modelos de entrega da intervenção, remota e presencial, para garantir que os participantes do estudo recebam a mesma intervenção. A capacitação iniciará pela disponibilização em ambiente virtual de um material ilustrado abordando os temas essenciais da intervenção.

Posteriormente, o treinamento será realizado presencialmente e por etapas, entre as quais, na primeira serão abordados os conceitos sobre a condição articular e ao programa de intervenção, incluindo a definição da OA de joelho, o papel central dos exercícios no tratamento fisioterapêutico, as formas de conduzir esta abordagem terapêutica tanto em formato presencial quanto remoto e os tópicos da abordagem educativa sobre a OA.

No segundo encontro, a equipe do estudo será capacitada quanto a condução do protocolo nas duas modalidades, vivenciando os exercícios do programa de intervenção presencialmente e por meio de videochamadas. Além disso, serão discutidos cada tópico da abordagem educativa em uma perspectiva teórica e prática. Serão enfatizados tópicos relativos a tomada de decisão frente a possíveis problemas durante as videochamadas como a perda de conexão ou qualidade da transmissão. Em um terceiro encontro será realizado um piloto com pacientes reais para capacitar a equipe.

3.3.8. Intervenções concomitantes durante o estudo

Os participantes serão orientados a não participar de programa de tratamento fisioterapêutico concomitante, incluindo quaisquer modalidades terapêuticas como terapia manual, recursos eletroterapêuticos ou outros programas de exercícios supervisionados. Será permitido que os participantes mantenham tratamento farmacológico para outras condições de saúde, no entanto, serão orientados a evitar tratamento por meio de injeções intra-articulares de glicocorticoides para manejo sintomático da OA de joelho.

3.4.Desfechos

3.4.1. Desfechos primários

Os desfechos primários serão a intensidade média de dor na última semana pela END e a condição funcional reportada pelo paciente utilizando da subescala de atividade de vida diária do questionário *Knee Injury and Osteoarthritis Outcome Score* (KOOS). Os referidos desfechos foram selecionados, pois são fortemente recomendados em ensaios clínicos envolvendo pacientes com OA de joelho (SMITH et al., 2019).

3.4.2. Desfechos secundários

- Desfechos reportados pelos pacientes relativos à condição articular nas semanas 6, 12 e em um follow-up (semana 18): dor, sintomas, atividades esportivas e de lazer e qualidade de vida aferidas pela subescalas do KOOS.
- Desfechos reportados pelos pacientes relativos a aspectos psicológicos nas semanas 6, 12 e em um follow-up (semana 18): catastrofização da dor pela Escala de Pensamento Catastrófico sobre a Dor; sintomas de depressão, ansiedade e estresse pela *Depression, Anxiety, and Stress scale*; e qualidade do sono pelo *Pittsburgh Sleep Quality Index Self-report Questionnaire*.
- Parâmetros funcionais baseados em testes funcionais após 12 semanas: testes de sentar e levantar da cadeira em 30 segundos, *Timed Up and Go*, caminhada rápida de 40m e *Stair Climb*.
- Arquitetura muscular mensurada por ultrassonografia cinesiológica após 12 semanas: espessura e eointensidade do quadríceps femoral, comprimento do fascículo e ângulo de penação do vasto lateral.

3.4.3. Outros desfechos

- Ingestão de medicação analgésica e anti-inflamatória.

3.4.4. Descrição do plano de coleta de dados

A medida dos desfechos será realizada por uma equipe previamente capacitada em relação a cada ferramenta. A coleta de dados ocorrerá em dois dias, entre os quais, no primeiro será realizada uma anamnese visando estabelecer o perfil clínico e sociodemográfico dos participantes presencialmente. Sequencialmente, as medidas ultrassonográficas e os testes funcionais serão realizados. E no segundo dia será realizada uma videochamada para o participante responder os questionários do estudo referentes aos desfechos reportados pelos pacientes relativos à condição articular e ao domínio psicológico. As medidas ultrassonográficas ocorrerão previamente aos testes funcionais para assegurar a qualidade da medida. Os desfechos relativos a arquitetura muscular e aos parâmetros funcionais serão aferidos na semana 0 e 12. Adicionalmente, os desfechos reportados pelos pacientes relativos à condição articular e psicossocial serão mensurados nas semanas 0, 6, 12 e em um período de *follow-up* (após 18 semanas). Além disso, o controle sobre a ingestão de medicação analgésica e anti-inflamatória será realizado em todos os momentos (semana 0, 6, 12 e 18).

3.4.4.1. Características clínicas e sociodemográficas

Uma avaliação detalhada do participante será realizada previamente a condução das medidas de desfechos de forma a caracterizar o perfil funcional e sociodemográfico dos sujeitos do estudo (Apêndice E). Uma anamnese será implementada contendo informações relevantes sobre a apresentação clínica, a caracterização sociodemográfica (idade, sexo, estatura e massa corporal, IMC, nível educacional e status de trabalho) e outras informações relevantes. Entre elas, serão incluídas questões relacionadas ao histórico familiar de OA de joelho, participação em lista de espera para cirurgia de artroplastia, referência de medo ao movimentar-se, e uso de medicamentos como anti-inflamatórios não esteroides.

3.4.4.2. Escala numérica de dor

A END possibilita a mensuração da percepção de dor do paciente por meio de um escore de 11 pontos que varia de “0” (ausência de dor) a “10” (dor máxima) (Anexo A). Os sujeitos serão questionados sobre o nível de dor nos últimos sete dias. A END trata-se de um desfecho reportado pelo paciente para avaliação e tomada de decisão clínica em pacientes com OA de joelho com boas propriedades psicométricas (ORNETTI *et al.*, 2011).

3.4.4.3. Knee Injury and Osteoarthritis Outcome Score

O KOOS é um questionário composto por 42 itens organizados em subescalas: dor, sintomas, atividades de vida diária, atividades esportivas e de lazer e qualidade de vida (Anexo B). O escore varia de 0 (problema extremo) a 100 (sem problemas) separadamente em cada subescala (COLLINS *et al.*, 2011). A versão brasileira do questionário KOOS foi recentemente validada consistindo em um instrumento com validade, confiabilidade e responsividade em pacientes com OA de joelho (ALMEIDA *et al.*, 2022).

3.4.4.4. Catastrofização da dor

A Escala de Pensamento Catastrófico sobre a Dor é um instrumento, validado e traduzido para o português, utilizado para classificar sujeitos com dor crônica como potenciais catastrofizadores (Anexo C) (SEHN *et al.*, 2012; SULLIVAN, BISHO e PIVIK, 1995). A catastrofização é uma reação mal adaptativa à dor e pode ser considerada um dos fatores que contribuem para a cronicidade de algumas síndromes dolorosas. A escala é composta por 13 itens envolvendo pensamentos, sentimentos e comportamentos catastróficos autorrelatados. Os itens são avaliados em uma escala Likert de 5 pontos, variando de 0 a 4, e a pontuação total é gerada pela soma das pontuações de todos os itens (0-52). Valores mais altos indicam pensamentos catastróficos sobre a dor.

3.4.4.5. Sintomas de depressão, ansiedade e estresse

A Escala de Depressão, Ansiedade e Estresse é um instrumento de autorrelato, validado e traduzido para o português, aplicado para mensurar os sintomas de depressão, ansiedade e estresse (Anexo D) (VIGNOLA e TUCCI, 2014). É composto por 21 itens os quais variam de 0 (não se aplica de maneira alguma) a 3 (aplica-se muito, ou na maior parte do tempo) divididos em subescalas de sete perguntas cada. O maior escore em cada subescala representa maior severidade dos sintomas de depressão, ansiedade e estresse.

3.4.4.6. Qualidade do sono

O questionário *The Pittsburgh Sleep Quality Index* (PSQI), validado para população brasileira, mensura a qualidade do sono através de perguntas relacionadas aos hábitos de sono no último mês (Anexo E) (BERTOLAZI et al., 2011). O instrumento é composto por 19 perguntas autoavaliadas e cinco direcionadas ao companheiro (a) de quarto. As últimas perguntas não serão consideradas por serem usadas para obtenção de informações clínicas. Deste modo, as 19 questões serão graduadas em uma pontuação de 0 a 3 e categorizadas em sete componentes: qualidade subjetiva do sono, latência do sono, duração do sono, eficiência habitual do sono, distúrbios do sono, uso de medicação para dormir e disfunção diurna. O somatório dos escores dos sete componentes resultarão em um escore global (0 a 21), sendo o maior valor indicativo de pior qualidade do sono.

3.4.4.7. Parâmetros funcionais

A caracterização do perfil funcional dos participantes será obtida através da implementação de testes funcionais recomendados pela OARSI para pacientes com OA de joelho, entre os quais destacam-se, os testes de sentar e levantar da cadeira em 30 segundos, o *Timed Up and Go*, o de caminhada rápida de 40 metros e o *Stair Climb* (DOBSON et al., 2013). Os testes funcionais descritos abaixo serão implementados em ordem aleatória.

Teste de Sentar e Levantar da Cadeira de 30 s

O teste de sentar e levantar da cadeira de 30 s consiste em uma medida da capacidade do sujeito de realizar a tarefa funcional de sentar e levantar da cadeira. A condução ocorrerá utilizando uma cadeira com altura de assento de aproximadamente 43 cm e um cronômetro. No início do teste, os participantes serão instruídos a sentar no centro da cadeira, a qual estará posicionada contra parede, com os membros superiores apoiados no tórax e os pés ligeiramente afastados e alinhados com o quadril. Inicialmente o participante fará os movimentos do teste para familiarização e orientado a sentar e levantar da cadeira o mais rápido possível dentro de 30 s. Assim, o resultado da medida consistirá no número de vezes que o participante executar a tarefa funcional de sentar e levantar da cadeira em 30 s em uma tentativa (Jones, Rikli e Beam, 1999).

Teste Timed Up and Go

O teste *Timed Up and Go* mensura a mobilidade funcional de pacientes em cenário ambulatorial. É necessário para realização do teste um cronômetro, uma cadeira com apoio de braços com altura de assento de aproximadamente 46 cm, e uma passarela de 3 m demarcada a partir da cadeira e com um ponto no final para marcar o retorno dos participantes (Dobson et al., 2013).

Os participantes a partir da posição sentada serão orientados a levantar, caminhar ao longo de 3 m em uma caminhada regular, e retornar ao assento até a posição inicial. O pesquisador responsável pela medida irá cronometrar o trajeto. O melhor resultado de duas tentativas será considerado como o valor final do teste com a medida expressa em segundos. Anteriormente a realização do teste uma familiarização será realizada.

Teste de caminhada rápida de 40 m

O teste de caminhada rápida de 40 m mensura a capacidade do sujeito de caminhar em curtas distâncias em velocidade rápida. É necessário para realização

do teste um cronômetro, a demarcação de 10 m no corredor com espaço adicional de 2 m no ponto inicial e final para o sujeito fazer a volta, e cones para sinalização (Dobson et al., 2013).

Os sujeitos serão orientados a caminhar o mais rápido possível sem correr na marca de 10 m, fazer a volta e retornar até finalizar os 40 m. Será realizada uma medida de familiarização, e a medida do tempo de caminhada consistirá somente no período de caminhada nos 10 m, excluindo as voltas. A medida será expressa em m/s dividindo os 40 m pelo tempo necessário para percorrer a zona do teste.

Teste Stair Climb

O Teste *Stair climb* mensura a capacidade do sujeito de subir e descer degraus. É necessário para realização do teste um cronômetro, um lance de escadas com corrimão com degraus de 20 cm de altura (Dobson et al., 2013).

Os sujeitos serão orientados a subir e descer um lance de escadas o mais rápido possível utilizando o calçado de uso habitual. Previamente a realização do teste definitivo será realizado um teste inicial para familiarização. A medida será expressa como o tempo em segundos para subir e descer um lance de escada.

3.4.4.8. Arquitetura muscular (espessura, qualidade muscular, comprimento do fascículo e ângulo de penação)

Imagens do quadríceps femoral serão geradas através de um equipamento de ultrassonografia no modo B (Ultrassom Versana Balance – *GE Healthcare*) com transdutor de matriz linear. Os parâmetros ultrassonográficos serão mantidos em todas as medidas, adotando-se uma profundidade da imagem entre 4 e 6 cm, com ganho geral de 58 dB e tempo de compensação do ganho na posição neutra (Girts et al., 2022). O membro inferior sintomático será considerado para realização da medida, e na osteoartrite bilateral, o lado mais sintomático será considerado para geração das imagens ultrassonográficas. O mesmo avaliador, com experiência em ultrassonografia musculoesquelética, realizará a geração das imagens.

Os voluntários serão orientados a repousar na posição supina por cinco minutos com os membros inferiores na posição neutra, evitando a ativação muscular e com joelhos em extensão (LOPEZ, PINTO e PINTO, 2019). O transdutor será

revestido com gel aquoso e posicionado perpendicularmente, aplicando a mínima pressão necessária, em cada ponto do quadríceps femoral para visualização da imagem ultrassonográfica. A captura do reto femoral e vasto intermédio ocorrerá pelo posicionamento do transdutor entre a espinha íliaca anterossuperior e a extremidade proximal da patela (ponto médio). Para visualizar o vasto lateral, o transdutor será posicionado a meio caminho entre o trocânter maior e o epicôndilo lateral do fêmur. E, para identificar o vasto medial, será considerada a medida de 30% distal entre o trocânter maior e o côndilo lateral do fêmur com a posição do transdutor a 5 cm medial ao ponto médio da coxa (TANIGUCHI et al., 2015).

As medidas musculares serão efetuadas posteriormente através do software *Image-J* (National Institutes of Health, USA, version 1.53). A medida de qualidade muscular, expressa pela ecogenicidade do quadríceps femoral, será mensurada utilizando de uma função específica no software na qual, através de uma escala de cinza, é graduada a intensidade do eco ou do brilho refletido pela estrutura muscular (PARIS e MOURTZAKIS, 2021b). Para o cálculo da média da ecogenicidade muscular será selecionada uma região de interesse em cada músculo priorizando a maior quantidade de tecido musculoesquelético possível, e evitando tecidos não contráteis. O valor da ecointensidade da região de interesse será expresso em unidade arbitrária, variando entre 0 (preto) e 255 (branco), no qual um maior valor é representativo de uma pior qualidade muscular e de deposição de tecido não contrátil dentro do músculo. Os dados coletados de ecogenicidade serão corrigidos conforme a espessura do tecido subcutâneo. A função *straight-line* será utilizada para mensurar a espessura do tecido subcutâneo de cada músculo. Assim, a ecogenicidade corrigida será calculada através da fórmula – $\text{ecogenicidade não corrigida} + (\text{espessura do tecido subcutâneo [cm]} \times 40.5278)$ (ORANCHUK et al., 2020). Os dados serão apresentados como a média dos valores de ecogenicidade dos músculos do quadríceps femoral e descritos separadamente (Figura 3).

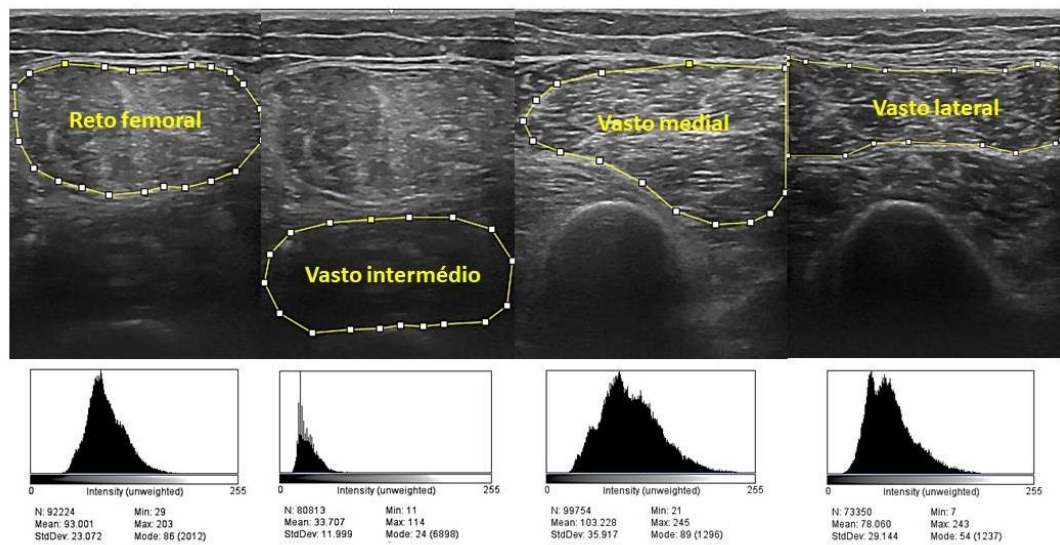


Figura 3. Medida da ecogenicidade muscular do quadríceps femoral *no software Image-J*.

A espessura muscular será mensurada inicialmente no equipamento por meio de um paquímetro elétrico demarcando a distância entre as fáscias musculares ou na interface fáscia e estrutura óssea, e posteriormente tal medida será reproduzida no software. A espessura muscular será medida em centímetros e apresentada como o somatório das medidas de cada músculo que compõe o quadríceps femoral, com os valores individuais também apresentados separadamente (Figura 4).

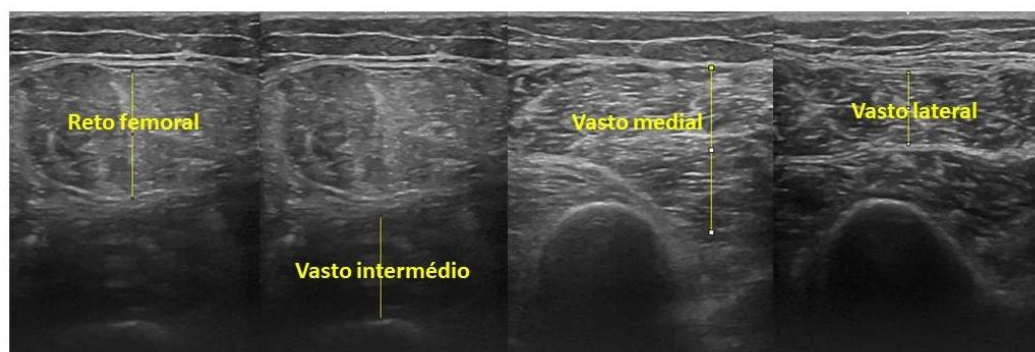


Figura 4. Medida da espessura muscular do quadríceps femoral *no software Image-J*.

As medidas do comprimento do fascículo e do ângulo de penação serão realizadas usando somente as imagens do vasto lateral em razão do alinhamento

dos fascículos (BLAZEVOICH et al., 2007). O ângulo de penação é definido como o ângulo formado entre a linha do fascículo muscular e a aponeurose profunda. E o comprimento do fascículo caracterizado pela distância do fascículo entre a aponeurose superficial e a profunda. Serão apresentadas as médias de três medidas para o ângulo de penação e o comprimento do fascículo.

3.4.4.9. Ingestão de medicação analgésica e anti-inflamatória

A quantidade de anti-inflamatórios e/ou analgésicos consumidos será registrada com base na última semana a partir das informações fornecidas pelo paciente.

3.5. Tamanho da amostra

O cálculo amostral inicial foi realizado no programa *GPower* versão 3.1.9, com base no desfecho primário dor aferido pela escala numérica de onze pontos. Os dados foram extraídos do estudo conduzido por Hinman et al. (2020), que analisou as respostas de orientações para realização de exercícios via telerreabilitação comparando-as com uma abordagem de tratamento usual, e observou um tamanho de efeito pequeno entre os grupos de intervenção em relação ao desfecho dor. A escolha deste estudo com esta magnitude de efeito justifica-se pela classificação do presente ensaio clínico randomizado como de não-inferioridade.

Inicialmente foi extraído o tamanho de efeito *Cohen's d* do desfecho dor, realizada a conversão para o *f*, adotado um nível de significância de 5% e poder de 80%, que resultou em um tamanho amostral de 64 sujeitos (Apêndice F). Ao considerar uma perda amostral prevista de 10% entre o *baseline* e o *follow-up*, conforme estudo de Bennell et al. (2017), serão necessários 68 participantes, 34 em cada grupo.

3.6. Randomização

3.6.1. Geração da sequência

A randomização será realizada após as medidas basais através do método de randomização estratificada, considerando a variável idade, para equilibrar a referida característica na linha de base. Será adotada uma razão de alocação de 1:1, e geração da sequência de randomização por um único pesquisador através de um site (<http://www.random.org/>).

3.6.2. Mecanismo de ocultação

O pesquisador responsável pelo pareamento e randomização dos participantes não estará envolvido nas etapas de recrutamento dos participantes e intervenção do estudo. O acesso a variável demográfica idade será exclusiva para o processo de randomização dos sujeitos nos grupos do estudo. Após randomização, a equipe responsável pela intervenção será comunicada sobre o grupo a qual cada paciente será designado.

3.6.3. Implementação

Após a assinatura do TCLE (Apêndice B) pelos participantes e a finalização das medidas basais a randomização será realizada. Os pacientes serão atribuídos ao grupo de exercícios remotos ou ao grupo de exercícios presenciais. Será equilibrado entre os grupos a característica sociodemográfica idade (nas categorias de participantes com idade de 45 a 54 anos ou com 55 a 80 anos). O fator sociodemográfico idade foi selecionado devido ao fato de impactar na apresentação sintomática de pacientes com OA de joelho e nos anos vividos com incapacidade (SAFIRI *et al.*, 2020; ZHOU *et al.*, 2023).

3.7. Análise estatística

As análises do estudo serão realizadas através do Statistical Package for Social Science (SPSS) versão 20.0. Os dados na linha de base serão apresentados utilizando a estatística descritiva. A diferença entre os grupos e o intervalo de confiança de 95% (IC 95%) após 6, 12 e 18 semanas de tratamento será calculado utilizando *Linear Mixed Models* considerando a interação dos grupos de tratamento *versus* tempo. Serão realizadas duas análises: a análise por intenção de tratar incluindo todos os participantes randomizados, e a análise por protocolo incluindo somente os participantes que aderiram a intervenção (aderência > 85%). Para análise por intenção de tratar o método de imputação múltipla será usado para imputar dados ausentes usando função específica no software SPSS. Os tamanhos de efeito (d de Cohen) entre os grupos serão calculados e classificados como pequenos (0,2 a 0,5), moderados (0,5 a 0,8) ou grandes (acima de 0,8). O nível de significância adotado neste estudo será de $\alpha = 0,05$.

3.8.Considerações éticas

A coleta de dados pela equipe do estudo iniciará somente após a apreciação e anuência da Escola Superior de Educação Física e Fisioterapia da Universidade Federal de Pelotas. Além disso, após o registro e aprovação do protocolo do estudo na plataforma *Clinical Trials*. O projeto de pesquisa foi descrito conforme as diretrizes e normas regulamentadoras de pesquisas envolvendo seres humanos - RESOLUÇÃO Nº 466, DE 12 DE DEZEMBRO DE 2012. Os dados coletados serão armazenados, em documento digital, no drive do pesquisador responsável, com os nomes dos participantes codificados (ID) permitindo assim facilitação no acesso das informações coletadas para futura análise de dados. Portanto, para manter a segurança dos participantes e para sanar qualquer dúvida sobre a pesquisa, as informações coletadas serão armazenadas durante 5 anos após o término da pesquisa.

5. ORÇAMENTO

Produto	Quantidade	Valor unitário	Valor total
Álcool em gel	3	R\$ 13,76	R\$ 41,28
Gel a base d'água	2	R\$ 59,90	R\$ 119,80
Algodão	2	R\$ 13,26	R\$ 26,52
Fita métrica	1	R\$ 29,49	R\$ 29,49
Cones para sinalização	2	R\$ 48,42	R\$ 96,84
Kit com faixas elásticas	21	R\$ 72,90	R\$ 2478,6
		Valor total	R\$ 2792,53

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Apêndices

Apêndice A – Termo de Anuência

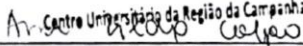


TERMO DE ANUÊNCIA

Declaro para os devidos fins que estou de acordo com a execução do projeto de pesquisa intitulado "Respostas de um programa de exercícios supervisionados nas modalidades remota e presencial em pessoas com osteoartrite de joelho: um ensaio clínico randomizado de não inferioridade". O estudo é o projeto tese de Maurício Tatsch Ximenes Carvalho, sob orientação da professora Cristine Lima Alberton, do Programa de Pós-graduação em Educação Física da Universidade Federal de Pelotas. Assumimos o compromisso de apoiar o desenvolvimento da referida pesquisa a ser realizada nessa instituição no Núcleo de Práticas em Saúde do Centro Universitário da Região da Campanha (URCAMP), no período de 01/11/2023 a 25/10/2024, após a devida aprovação no Sistema CEP/CONEP.

Bagé – Rio Grande do Sul, 02 de outubro de 2023.


 Mirtes Dalmaso (CPF: 1994610-34)
 Professora da URCAMP e Coordenadora do Núcleo de Práticas em Saúde do Hospital
 Universitário da URCAMP

Prof.ª. Dra. Ana Zilda Ceolin Colpo
 Curso de Fisioterapia
 Centro Universitário da Região da Campanha-URCAMP

 Ana Zilda Ceolin Colpo (CPF: 767359400-59)
 Professora da URCAMP e Coordenadora do Curso de Fisioterapia da URCAMP

Apêndice B – Termo de Consentimento Livre e esclarecido

TERMO DE CONSENTIMENTO LIVRE E ESCLARECIDO

Pesquisador responsável: Cristine Lima Alberton.

Instituição: Escola Superior de Educação Física e Fisioterapia

Endereço: Rua Luis de Camões, 625, Tres Vendas, Pelotas - RS, 96055-630.

Telefone: (53) 3273-2752.

Concordo em participar do estudo “Respostas de um programa exercícios supervisionados nas modalidades remota e presencial em pessoas com osteoartrite de joelho: um ensaio clínico randomizado de não inferioridade.” Estou ciente de que estou sendo convidado a participar voluntariamente do mesmo.

PROCEDIMENTOS: Fui informado (a) de que o objetivo é analisar as respostas de 12 semanas de um tratamento com exercícios remotos comparado ao presencial nos resultados que os pacientes relatam, na funcionalidade e na condição dos músculos da coxa de pessoas com osteoartrite de joelho. Estou ciente de que o tratamento consistirá em um programa de exercícios de fortalecimento muscular com a supervisão por videochamada ou presencial de um fisioterapeuta. O tratamento será realizado em dias não consecutivos, duas vezes na semana, nas primeiras duas semanas e depois, três vezes por semana, da semana três a semana 12. Após o período de tratamento, vídeos e um material descritivo dos exercícios serão disponibilizados para continuidade do tratamento por mais seis semanas sem a supervisão de um fisioterapeuta. Para avaliar se o tratamento é eficaz, serão feitas medições antes do tratamento, após seis, 12 e 18 semanas. A dor será medida através de uma pontuação. A visão do paciente sobre a saúde das suas articulações, bem como a condição emocional e qualidade do sono serão analisados por meio de questionários. A condição funcional será medida por meio de testes que envolvem tarefas cotidianas como levantar e sentar, caminhar, subir e descer e escadas. Os parâmetros neuromusculares serão medidos por meio de um equipamento de ultrassonografia para analisar os músculos da coxa (o tamanho e a qualidade). A quantidade de analgésicos e anti-inflamatórios em uso será contabilizada.

RISCOS E POSSÍVEIS REAÇÕES: Fui informado sobre os riscos relacionados com o tratamento e as medidas do estudo. O programa de exercícios envolve mudanças entre as posições sentado e em pé, assim há risco de queda durante o tratamento. Deste modo, tanto na abordagem de tratamento presencial ou por videochamada a equipe responsável pela intervenção será capacitada a proporcionar um ambiente seguro como, por exemplo, orientar o paciente a dispor de uma cadeira por perto para apoio durante os exercícios em pé. Como uma medida adicional para garantir a segurança, os participantes serão aconselhados a ter a presença de um familiar em casa durante os exercícios, sempre que possível. O pesquisador, a frente da intervenção, terá o contato do familiar caso necessite de ajuda para garantir a segurança para condução da

intervenção. No caso da impossibilidade da presença do familiar, destaca-se que os participantes serão previamente familiarizados com o exercício e quanto as medidas de segurança em ambiente domiciliar. Durante o estudo, os pesquisadores irão monitorar eventos adversos, os quais serão categorizados conforme gravidade (leve, moderado ou grave), previsibilidade (esperado ou inesperado) e possível associação com o exercício e o modo de supervisão (definitivamente associados, possivelmente associados ou não associados). Em caso de mal-estar ou queda do paciente os pesquisadores imediatamente acionarão o serviço de atendimento móvel de urgência (SAMU) e acompanharão o paciente, tanto no grupo presencial como por videochamada, até a transferência da responsabilidade de atendimento. Especialmente no grupo por videochamada, os pesquisadores capacitados quanto a estes episódios, irão manter contato com o paciente de forma a mantê-lo calmo e monitorando as manifestações clínicas até a chegada do serviço de atendimento. Durante as medidas com questionários os participantes podem relatar fadiga mental, constrangimento ou sentimento de desconforto, assim será assegurado um ambiente calmo e silencioso para a resposta dos questionários. Caso o paciente relate impossibilidade de continuar a responder os questionários devido a fadiga mental, o pesquisador irá oferecer uma nova data para a coleta de dados, ou o fracionamento da coleta em dias diferentes para diminuir o número de questões. No caso de risco de constrangimento e desconforto durante a coleta de dados, o pesquisador reforçará a confidencialidade das informações, esclarecendo que serão utilizadas exclusivamente para compreender os efeitos do protocolo de exercícios nas variáveis investigadas. Além disso, caso o paciente considere necessário, será feita uma pausa na coleta de dados. Persistindo o desconforto, será oferecida a opção de realizar a coleta de dados em outro momento ou será dispensado de responder sem prejuízos na sua participação no estudo. Há risco de queda e fadiga durante os testes funcionais, uma vez que envolve o esforço em tarefas de levantar e sentar, caminhar e subir e descer escadas. O ambiente da clínica será organizado para realização individualizada e sob supervisão atenta de um profissional capacitado. Nas medidas com o equipamento de ultrassom o paciente poderá relatar mal-estar por ficar alguns minutos deitado, mas o profissional realizará as medidas o mais rapidamente possível.

BENEFÍCIOS: O benefício em participar deste estudo consiste na melhora da compreensão dos efeitos de um programa de exercícios sob supervisão presencial ou por videochamada, assim ampliando os formatos de disponibilização do tratamento para pacientes com osteoartrite de joelho.

PARTICIPAÇÃO VOLUNTÁRIA: Conforme já explicado, minha participação neste estudo será voluntária e poderei interrompê-la a qualquer momento.

DESPESAS: Não vou precisar pagar por nenhum dos procedimentos, exceto o deslocamento até a instituição onde será realizada a intervenção; nem receberei compensações financeiras.

CONFIDENCIALIDADE: Fui informado que a minha identidade e meus dados coletados permanecerão confidenciais durante todas as etapas do estudo.

CONSENTIMENTO: Recebi explicações detalhadas sobre as etapas do estudo, todas registradas neste documento. Os investigadores do estudo responderam e responderão, em qualquer etapa do estudo, a todas as minhas perguntas, até que todas as minhas dúvidas sejam esclarecidas. Portanto, estou de acordo em participar do estudo. Este Formulário de Consentimento pré-informado será assinado por mim e arquivado na instituição responsável pela pesquisa.

Nome do participante/representante legal _____

Identidade: _____ ASSINATURA: _____

DATA: ____ / ____ / ____

DECLARAÇÃO DE RESPONSABILIDADE DO INVESTIGADOR: Expliquei a natureza, os objetivos, os riscos e os benefícios deste estudo. Coloquei-me à disposição para perguntas e as respondi de maneira completa. O participante compreendeu minha explicação e aceitou, sem imposições, assinar este consentimento. Comprometo-me em utilizar os dados e o material coletado para a publicação de relatórios e artigos científicos referentes a essa pesquisa. Em caso do participante ter alguma consideração ou dúvida sobre a ética da pesquisa, pode entrar em contato com o Comitê de Ética em Pesquisa da ESEF/UFPel – Rua Luís de Camões, 625 – CEP: 96055-630 - Pelotas/RS; Telefone: (53) 3273-2752.

ASSINATURA _____ DO _____ PESQUISADOR
RESPONSÁVEL _____

Apêndice C – Cartilha com os exercícios



Estudo *RISE-KOA*

Cartilha de Exercícios para os Joelhos

Por: Maurício Tatsch Ximenes Carvalho



Orientações

-  Reserve um momento do seu dia para fazer os exercícios;
-  Estabeleça uma rotina de no mínimo três vezes na semana;
-  Este é o tempo que você cuidará sozinho(a) do seu joelho;
-  Reserve uma cadeira e um travesseiro para fazer os exercícios;
-  Você conseguirá fazer sozinho os exercícios a seguir. Vamos em frente!

Programa de exercícios

Na rotina de autocuidado é importante que você realize ao menos 6 exercícios na seguinte ordem sugerida.

- ✓ Primeiro, marche no mesmo lugar por 1 minuto, conforme imagens abaixo.



- ✓ Enquanto você marcha no mesmo lugar, respire fundo, puxando o ar pelo nariz e soltando pela boca.

Programa de exercícios

Exercício 1 – músculos anteriores da coxa

Posição inicial



✓ Na posição sentada, coloque um travesseiro abaixo dos joelhos deixando-os levemente dobrados;

✓ Durante o exercício, aponte o pé bem pra cima e estique os seus joelhos por 20 segundos;

✓ Perceba a ativação dos músculos anteriores da coxa;

Posição final



✓ Mantenha respiração profunda durante o exercício;

✓ Repita de 5 a 8 vezes em cada perna por 20 segundos;

✓ Faça um intervalo de 1 minuto após repetir o exercício nas duas pernas.

Programa de exercícios

Exercício 2 – músculos anteriores da coxa

Posição inicial



- ✓ Na posição sentada, posicione seus quadris alinhados com o joelhos e os pés;
- ✓ Os pés precisam estar afastados na mesma distância um do outro;
- ✓ Os braços erguidos a frente do corpo;
- ✓ Agora, levante e sente da cadeira de 8 a 12 vezes e faça um intervalo de um minuto;

Posição final



- ✓ Perceba a ativação dos músculos da frente da coxa;
- ✓ Cuide para não fazer rápido os movimentos: 2 segundos para levantar e 2 segundos para sentar;
- ✓ Faça mais duas séries;
- ✓ Cuide da respiração: solte o ar quando levantar e puxe o ar quando sentar.

Programa de exercícios

Exercício 3 – músculos da parte interna da coxa

Posição inicial



✓ Na posição sentada, posicione um travesseiro entre os joelhos;

✓ Pressione os joelhos contra o travesseiro por 20 segundos de 5 a 8 repetições;

✓ Perceba a ativação dos músculos internos da coxa;

✓ Após fechar as repetições, faça um intervalo de 1 minuto;

✓ Faça mais duas séries;

✓ Mantenha respiração profunda durante o exercício.

Posição final



Programa de exercícios

Exercício 4 – músculos da parte externa da coxa

Posição inicial e final



- ✓ *Agora, de lado para parede dobre levemente o joelho apoiado no chão;*
- ✓ *E empurre a coxa encostada na parede ou na porta por aproximadamente 20 segundos;*
- ✓ *Perceba a ativação dos músculos da lateral da coxa;*
- ✓ *Caso não conseguir os 20 segundos, não se preocupe, faça em menos tempo;*
- ✓ *Repita de 5 a 8 vezes de cada lado;*
- ✓ *Mantenha respiração profunda durante o exercício.*

Programa de exercícios

Exercício 5 – músculos posteriores da coxa

Posição inicial



- ✓ *Agora, na posição deitada mantenha os quadris, joelhos e pés alinhados;*
- ✓ *Eleve o quadril o máximo que conseguir;*
- ✓ *Perceba a ativação dos músculos posteriores da coxa;*

Posição final



- ✓ *Repita de 8 a 12 vezes e faça um intervalo de um minuto;*
- ✓ *Cuide para não fazer rápido o movimento: 2 segundos para elevar e 2 segundos para retornar;*
- ✓ *Faça mais duas séries;*
- ✓ *Cuide da respiração: solte o ar quando elevar e puxe o ar quando retornar.*

Programa de exercícios

Exercício 6 – músculos posteriores da perna

Posição inicial



- ✓ Agora, na posição em pé com os pés afastados ao nível dos quadris;
- ✓ Eleve o corpo ficando na ponta dos pés;
- ✓ Perceba a ativação dos músculos posteriores da perna;
- ✓ Repita de 8 a 12 vezes e faça um intervalo de um minuto;

Posição final



- ✓ Faça mais duas séries;
- ✓ Cuide para não fazer rápido o movimento: 2 segundos para elevar e 2 segundos para retornar;
- ✓ Cuide da respiração: solte o ar quando elevar e puxe o ar quando retornar.

Programa de exercícios

- ✓ Ao finalizar, marche novamente no mesmo lugar por 1 minuto, conforme imagens abaixo.



- ✓ Enquanto você marcha no mesmo lugar, respire fundo, puxando o ar pelo nariz e soltando pela boca.

**Finalizamos,
obrigado pela sua
participação!**

**Você mesmo pode
cuidar dos seus
joelhos. Siga em
frente com os
exercícios!**

Equipe RISE-KOA

*RISE-KOA é a sigla internacional do estudo.
*Remote and In-person Supervised Exercise in Patients With Knee
Osteoarthritis (RISE-KOA)*

Apêndice D – Estratégia de educação em saúde para aumentar a aderência ao tratamento



**Osteoartrite de joelho e
exercício**

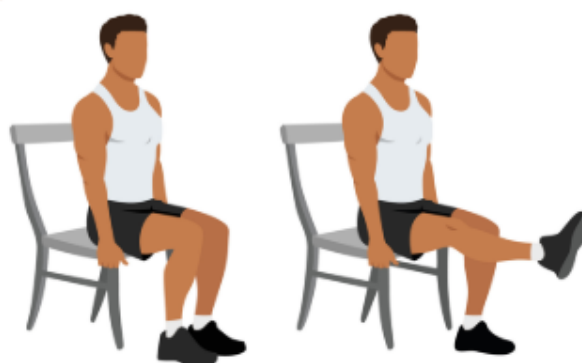


O que é a osteoartrite de joelho?

Doença articular **multifatorial** com as seguintes **manifestações:**

- ▶ Dor.
- ▶ Rigidez.
- ▶ Crepitação.
- ▶ Fraqueza muscular.
- ▶ Dificuldade em tarefas diárias.

Qual é o tratamento principal da osteoartrite?



Como viver melhor com a osteoartrite de joelho?

Através do exercício



O exercício é o tratamento principal, porque...

- ▶ Reduz a dor;
- ▶ Melhora a função do joelho;
- ▶ Promove benefícios de **longo prazo**;
- ▶ E não aumenta o risco de lesão no joelho.

Importância do exercício para toda a vida



Você pode sentir dor após o exercício?

Sim, mas existe diferença entre...

- ▶ Dor após o exercício;
- ▶ Dor da crise da osteoartrite do joelho.





PERGUNTA...

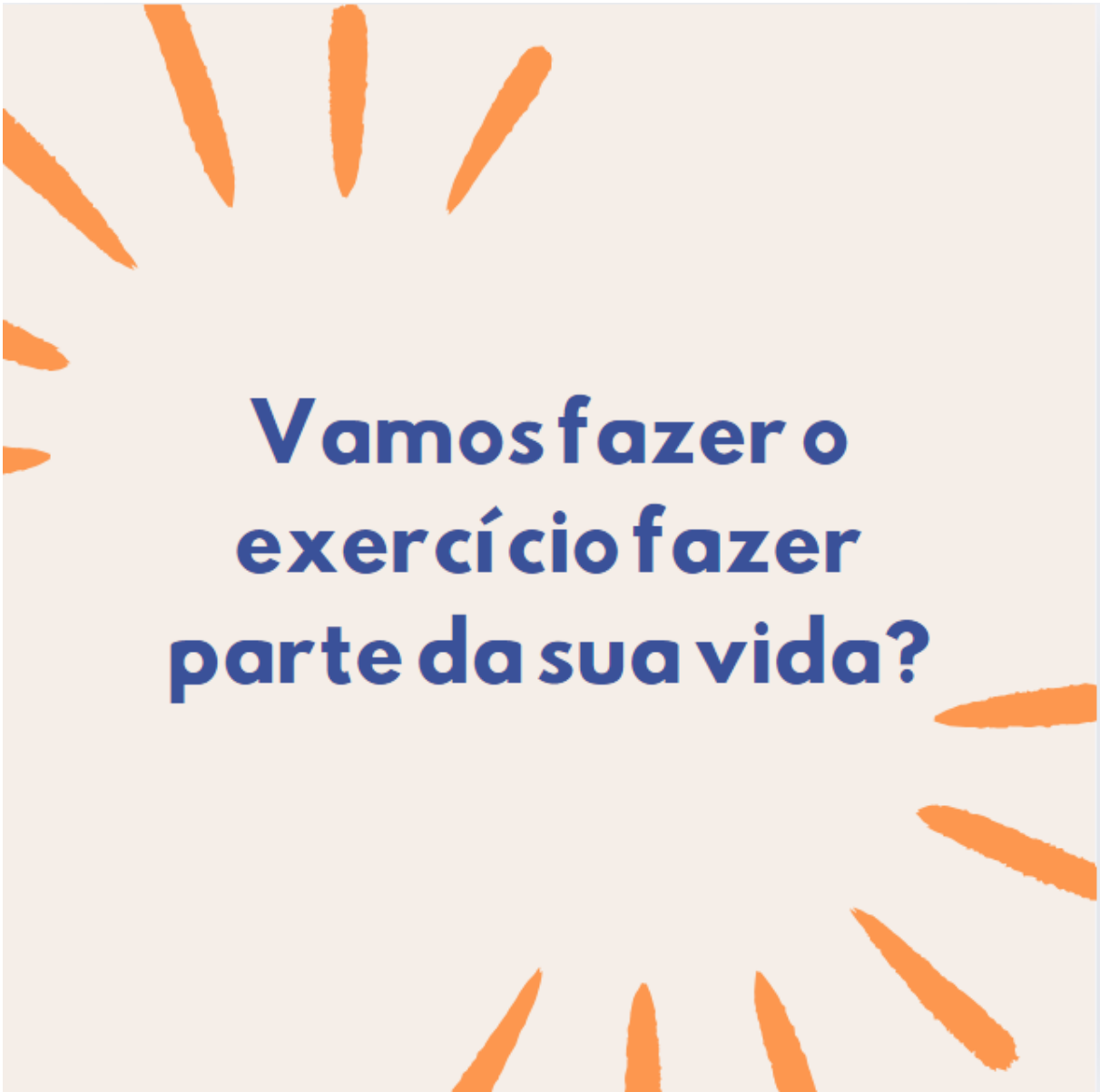
Você já teve medo de
se movimentar ou de
fazer exercício por
receio de sentir dor?





O EXERCÍCIO NA OA DE JOELHO...

- ▶ Encoraja você a realizar movimentos do dia a dia;
 - ▶ Não aumenta o risco de cirurgia no joelho;
 - ▶ Fortalece a musculatura das pernas;
 - ▶ Fortalece a articulação;
 - ▶ Diminui todos os sintomas articulares.
- 

A stylized graphic of a sunburst with orange rays emanating from a central point, set against a light beige background. The rays are thick and have a hand-drawn, textured appearance.

**Vamos fazer o
exercício fazer
parte da sua vida?**

Apêndice E – Fichas de avaliação**FICHA DE AVALIAÇÃO
(Anamnese)**

Data da avaliação: _____ Nome do avaliador: _____

Dados de identificação

Nome: _____
Sexo: () Masculino () Feminino
Raça: () Branca () Preta ou parda () Amarelo ou indígena
Data de nascimento: _____
Idade: _____
Estado civil: _____
Telefone: _____
Telefone de contato de um familiar: _____
Endereço: _____

Dados sociodemográficos

Nível de escolaridade: _____
Ocupação: _____

- ☐ Atualmente empregado
☐ Incapacidade para o trabalho por motivos de saúde
☐ Aposentado (não por motivos de saúde)
☐ Desempregado

Qual faixa de renda familiar melhor representa a sua situação financeira atual?

- ☐ Menos de R\$1.000
☐ R\$1.000 - R\$2.500
☐ R\$2.501 - R\$5.000
☐ R\$5.001 - R\$7.500
☐ Mais de R\$7.500

História da condição atual

OA de joelho

☐ Unilateral / ☐ Esquerdo ☐ Direito

☐ Bilateral.

Joelho mais sintomático

☐ Esquerdo

☐ Direito

Grau da OA de joelho

☐ II

☐ III

Duração dos sintomas

☐ < 2 anos

☐ 2 – 10 anos

☐ > 10 anos

História familiar de OA?

☐ sim ☐ não

Em lista de espera para cirurgia de artroplastia?

☐ sim ☐ não

Medo de realizar movimento?

☐ sim ☐ não

Consome medicamentos?

☐ sim ☐ não

Especificar (fármacos e dose): _____

☐ uso contínuo

☐ uso temporário

☐ auto-medicação

☐ receita médica

☐ indicação farmacêutica

☐ indicação de familiares ou amigos

Tratamento com injeção intra-articular?

☐ sim ☐ não

Tratamento fisioterapêutico prévio?

☐ sim ☐ não

Especificar abordagens de tratamento _____

Exame físico

Pressão arterial: _____ X _____

Massa: _____

Estatura: _____

IMC: _____

***Anexar exame de imagem à ficha de avaliação.**

Medidas com a ultrassonografia – RISE-KOA

Nome do paciente _____

Data da avaliação: ____/____/____

Medida de referência - espessura muscular do quadríceps femoral

Músculos	Medida 1	Medida 2	Medida 3
RF + VI			
VL - transversal			
VL - longitudinal			
VM			

Membro inferior avaliado () esquerdo () direito

Medida 1: ____cm

Medida 2: ____cm

Medida 3: ____cm

Teste Funcionais – RISE-KOA

Nome do paciente _____

Data da avaliação: ____/____/____

1. Sinais vitais

Pré-avaliação		Pós-avaliação	
Frequência cardíaca (bpm)		Frequência cardíaca (bpm)	
SpO ₂ (%)		SpO ₂ (%)	
Pressão Arterial (mmHg)		Pressão arterial (mmHg)	
Nível de dor (0 – 10)		Nível de dor (0 – 10)	

2. Teste de Sentar e Levantar da Cadeira de 30 s

*Observações

- 2.1. Materiais e ambiente: cadeira com altura de assento de aproximadamente 43 cm apoiada na parede e um cronômetro;
- 2.2. Execução: realizar o teste duas vezes apenas, uma para familiarização e a outra como a medida efetiva.
- 2.3. Importante: não contar em voz alta o número de repetições para não influenciar o paciente.
- 2.4. É permitido adaptações como apoiar a mãos nos membros inferiores ou usar de dispositivo auxiliar para locomoção.

Número de repetições	
Familiarização	
Teste	

Necessitou de dispositivo auxiliar? ☐ Sim ☐ Não.

Especificar: _____

Observações:

Quando o paciente referir dor articular durante o teste, questionar o grau (0-10):

_____.

3. Teste *Timed Up and Go*

1. Materiais e ambiente: cadeira com apoio de braços com altura de assento de aproximadamente 46 cm, cronômetro e uma passarela de 3 m demarcada a partir da cadeira e com um ponto no final para marcar o retorno dos participantes.
2. Execução: Os participantes a partir da posição sentada serão orientados a levantar, caminhar ao longo de 3 m em uma caminhada regular, e retornar

ao assento até a posição inicial. Realizar o teste três vezes, uma para familiarização e as demais como medidas do teste.

3. Importante: não ficar ao lado do paciente para não ditar o passo, mas estar próximo para o caso de desequilíbrio.
4. É permitido adaptações como utilizar um dispositivo auxiliar para marcha.

Tempo em segundos	
Familiarização	
Teste 1	
Teste 2	

Necessitou de dispositivo auxiliar? ☐ Sim ☐ Não.

Especificar: _____

Observações:

Quando o paciente referir dor articular durante o teste, questionar o grau (0-10):
_____.

4. Teste de caminhada rápida de 40 m

1. Materiais e ambiente: cronômetro, a demarcação de 10 m no corredor com espaço adicional de 2 m no ponto inicial e final para o sujeito fazer a volta, e cones para sinalização.
2. Execução: caminhar o mais rápido possível sem correr na marca de 10 m, fazer a volta e retornar até finalizar os 40 m. Realizar o teste duas vezes, uma para familiarização e a outra como a medida definitiva.
3. Importante: não ficar ao lado do paciente para não ditar o passo, mas estar próximo para o caso de desequilíbrio.
4. É permitido adaptações como utilizar um dispositivo auxiliar para marcha.

	Tempo (s)	V(m/s)
Familiarização		
Teste 1		

Necessitou de dispositivo auxiliar? ☐ Sim ☐ Não.

Especificar: _____

Observações:

Quando o paciente referir dor articular durante o teste, questionar o grau (0-10):
_____.

5. Teste *Stair Climb*

1. Materiais e ambiente: um cronômetro, um lance de escadas com corrimão com degraus de 20 cm de altura.

2. Execução: subir e descer um lance de escadas (nove degraus) o mais rápido possível utilizando o calçado de uso habitual. Realizar o teste duas vezes, uma para familiarização e a outra como a medida definitiva.
3. Importante: não ficar ao lado do paciente para não ditar o passo, mas estar próximo para o caso de desequilíbrio.
4. É permitido adaptações como utilizar um dispositivo auxiliar para marcha.

	Tempo (s)
Familiarização	
Teste 1	

Necessitou de dispositivo auxiliar? ☐ Sim ☐ Não.

Especificar: _____

Observações:

Quando o paciente referir dor articular durante o teste, questionar o grau (0-10):

_____.

Apêndice F – Cálculo amostral

1º cálculo do tamanho da amostra apresentado na qualificação

<i>Input parameters</i>		<i>Output parameters</i>	
<i>Effect size f</i>	0.1627	<i>Noncentrality parameter λ</i>	10.1649754
<i>α err prob</i>	0.05	<i>Critical F</i>	3.0692864
<i>Power ($1-\beta$ err prob)</i>	0.80	<i>Numerator df</i>	2.0000000
<i>Number of groups</i>	2	<i>Denominator df</i>	124
<i>Number of measurements</i>	3	<i>Total sample size</i>	64
<i>Corr among rep measures</i>	0.5	<i>Actual power</i>	0.8121853
<i>Nonsphericity correction ϵ</i>	1		

2º cálculo do tamanho da amostra após definição do limite de não-inferioridade no desfecho primário nível de dor

Significance level (alpha)	5% ▼
Power (1-beta)	80% ▼
Standard deviation of outcome	2
Non-inferiority limit, d	1.6
Calculate sample size	
Sample size required per group	20
Total sample size required	40

You could say:

If there is truly no difference between the standard and experimental treatment, then 40 patients are required to be 80% sure that the lower limit of a one-sided 95% confidence interval (or equivalently a 90% two-sided confidence interval) will be above the non-inferiority limit of -1.6.

Anexos

Anexo A – Escala Numérica de dor



Anexo B - Knee injury and Osteoarthritis Outcome Score (KOOS)

Knee injury and Osteoarthritis Outcome Score (KOOS), Brazilian Portuguese version LK1.1, updated June 2017

QUESTIONÁRIO KOOS SOBRE O JOELHO

Data de hoje: ____/____/____ Data de nascimento: ____/____/____

Nome: _____

INSTRUÇÕES: Este questionário perguntará sua opinião sobre o seu joelho. Estas informações nos fornecerão dados sobre como você se sente em relação ao seu joelho e até que ponto você consegue realizar suas atividades habituais.

Responda a cada pergunta assinalando o quadrado apropriado, apenas um quadrado deve ser escolhido para cada pergunta. Caso não tenha certeza sobre qual resposta escolher, por favor, escolha a que achar mais apropriada.

Sintomas

Estas perguntas devem ser respondidas de acordo com os sintomas do seu joelho durante a **última semana**.

S1. Você tem inchaço no joelho?

Nunca	Raramente	Às vezes	Frequentemente	Sempre
☐	☐	☐	☐	☐

S2. Você sente um rangido, estalidos ou ouve qualquer outro tipo de barulho quando movimenta seu joelho?

Nunca	Raramente	Às vezes	Frequentemente	Sempre
☐	☐	☐	☐	☐

S3. Seu joelho trava ou prende quando se movimenta?

Nunca	Raramente	Às vezes	Frequentemente	Sempre
☐	☐	☐	☐	☐

S4. Você consegue esticar seu joelho completamente?

Sempre	Frequentemente	Às vezes	Raramente	Nunca
☐	☐	☐	☐	☐

S5. Você consegue dobrar seu joelho completamente?

Sempre	Frequentemente	Às vezes	Raramente	Nunca
☐	☐	☐	☐	☐

Rigidez

As próximas perguntas dizem respeito à quantidade de rigidez no joelho que você sentiu **durante a última semana**. Rigidez é uma sensação de dificuldade ou lentidão para movimentar seu joelho.

S6. Qual a intensidade da rigidez do seu joelho de manhã ao acordar?

Nenhuma	Leve	Moderada	Severa	Extrema
☐	☐	☐	☐	☐

S7. Qual a intensidade da rigidez do seu joelho após sentar, deitar ou descansar no **final do dia**?

Nenhuma	Leve	Moderada	Severa	Extrema
☐	☐	☐	☐	☐

Dor

P1. Com que frequência você sente dor no joelho?

Nunca	Uma vez por mês	Uma vez por semana	Todos os dias	Sempre
☐	☐	☐	☐	☐

Qual a intensidade de dor no joelho que você sentiu durante a **última semana** para realizar as seguintes atividades?

P2. Girar ou torcer-se sobre o joelho machucado

Nenhuma	Leve	Moderada	Severa	Extrema
☐	☐	☐	☐	☐

P3. Esticar completamente o joelho

Nenhuma	Leve	Moderada	Severa	Extrema
☐	☐	☐	☐	☐

P4. Dobrar completamente o joelho

Nenhuma	Leve	Moderada	Severa	Extrema
☐	☐	☐	☐	☐

P5. Andar sobre uma superfície plana

Nenhuma	Leve	Moderada	Severa	Extrema
☐	☐	☐	☐	☐

P6. Subir ou descer escadas

Nenhuma	Leve	Moderada	Severa	Extrema
☐	☐	☐	☐	☐

P7. Na cama durante a noite

Nenhuma	Leve	Moderada	Severa	Extrema
☐	☐	☐	☐	☐

P8. Sentar-se ou deitar-se

Nenhuma	Leve	Moderada	Severa	Extrema
☐	☐	☐	☐	☐

P9. Ficar em pé

Nenhuma	Leve	Moderada	Severa	Extrema
☐	☐	☐	☐	☐

Atividades diárias

As perguntas a seguir são sobre sua função física, ou seja, nos referimos à capacidade de se movimentar e cuidar de si mesmo. Por favor, para cada uma das seguintes atividades indique o grau de dificuldade que você teve na **última semana** por causa do seu joelho.

A1. Descer escadas

Nenhuma	Leve	Moderada	Severa	Extrema
☐	☐	☐	☐	☐

A2. Subir escadas

Nenhuma	Leve	Moderada	Severa	Extrema
☐	☐	☐	☐	☐

Para cada uma das seguintes atividades indique o grau de dificuldade que você teve na **última semana** por causa do seu joelho.

A3. Levantar-se de uma posição sentada

Nenhuma	Leve	Moderada	Severa	Extrema
☐	☐	☐	☐	☐

A4. Ficar em pé

Nenhuma	Leve	Moderada	Severa	Extrema
☐	☐	☐	☐	☐

A5. Agachar/abaixar para pegar um objeto

Nenhuma	Leve	Moderada	Severa	Extrema
☐	☐	☐	☐	☐

A6. Andar sobre uma superfície plana

Nenhuma	Leve	Moderada	Severa	Extrema
☐	☐	☐	☐	☐

A7. Entrar ou sair do carro/ônibus

Nenhuma	Leve	Moderada	Severa	Extrema
☐	☐	☐	☐	☐

A8. Fazer compras

Nenhuma	Leve	Moderada	Severa	Extrema
☐	☐	☐	☐	☐

A9. Vestir as meias ou meias-calças

Nenhuma	Leve	Moderada	Severa	Extrema
☐	☐	☐	☐	☐

A10. Levantar-se da cama

Nenhuma	Leve	Moderada	Severa	Extrema
☐	☐	☐	☐	☐

A11. Tirar as meias ou meias-calças

Nenhuma	Leve	Moderada	Severa	Extrema
☐	☐	☐	☐	☐

A12. Deitado na cama (virar-se, manter a posição do joelho)

Nenhuma	Leve	Moderada	Severa	Extrema
☐	☐	☐	☐	☐

A13. Entrar e sair do banho

Nenhuma	Leve	Moderada	Severa	Extrema
☐	☐	☐	☐	☐

A14. Sentar-se

Nenhuma	Leve	Moderada	Severa	Extrema
☐	☐	☐	☐	☐

A15. Sentar e levantar do vaso sanitário

Nenhuma	Leve	Moderada	Severa	Extrema
☐	☐	☐	☐	☐

Para cada uma das seguintes atividades, indique, por favor, o grau de dificuldade que você teve na **última semana** por causa do seu joelho.

A16. Tarefas domésticas pesadas (mover caixas pesadas, esfregar o chão, etc)

Nenhuma	Leve	Moderada	Severa	Extrema
☐	☐	☐	☐	☐

A17. Tarefas domésticas leves (cozinhar, tirar o pó, etc)

Nenhuma	Leve	Moderada	Severa	Extrema
☐	☐	☐	☐	☐

Atividades esportivas e de lazer

As próximas perguntas são sobre suas funções físicas quando realizadas com níveis mais altos de dificuldade. As perguntas devem ser respondidas de acordo com o grau de dificuldade que você teve durante a **última semana** por causa do seu joelho.

SP1. Ficar de cócoras

Nenhuma	Leve	Moderada	Severa	Extrema
☐	☐	☐	☐	☐

SP2. Correr

Nenhuma	Leve	Moderada	Severa	Extrema
☐	☐	☐	☐	☐

SP3. Pular

Nenhuma	Leve	Moderada	Severa	Extrema
☐	☐	☐	☐	☐

SP4. Girar ou torcer-se sobre o joelho machucado

Nenhuma	Leve	Moderada	Severa	Extrema
☐	☐	☐	☐	☐

SP5. Ajoelhar-se

Nenhuma	Leve	Moderada	Severa	Extrema
☐	☐	☐	☐	☐

Qualidade de vida

Q1. Com que frequência você percebe o problema do seu joelho?

Nunca	Uma vez por mês	Uma vez por semana	Todo dia	Constantemente
☐	☐	☐	☐	☐

Q2. Você modificou seu estilo de vida para evitar atividades que poderiam piorar o seu joelho?

Não	Um pouco	Moderadamente	Bastante	Totalmente
☐	☐	☐	☐	☐

Q3. Até que ponto a falta de confiança no seu joelho te incomoda?

Nada	Um pouco	Moderadamente	Bastante	Extremamente
☐	☐	☐	☐	☐

Q4. Em geral, o seu joelho lhe causa muitos problemas?

Nenhum	Poucos	Alguns	Bastantes	Extremos
☐	☐	☐	☐	☐

Muito obrigado por responder todas as perguntas do questionário.

Anexo C – Escala de Pensamentos Catastróficos

Nome: _____ Data: ____/____/____

Escala de Pensamentos Catastróficos sobre a Dor

Na maior parte do tempo, nós dizemos coisas. Por exemplo: nos encorajamos a fazer coisas, nos culpamos quando cometemos um erro ou nos recompensamos por algo que fizemos com sucesso. Quando estamos com dor, frequentemente também nos dizemos coisas que são diferentes das coisas que nós dizemos quando estamos nos sentindo bem. Abaixo, listamos 13 declarações que descrevem diferentes pensamentos e sentimentos que podem lhe parecer na cabeça quando sente dor. Indique o grau destes pensamentos e sentimentos quando está com dor, circule o número que melhor descreve a sua situação utilizando esta escala: 0 = quase nunca até 5 = quase sempre.

	Mínima	Leve	Moderada	Intensa	Muito Intensa
	0	1	2	3	4
1. A preocupação durante todo o tempo com a duração da dor é	☐	☐	☐	☐	☐
2. O sentimento de não poder prosseguir (continuar) é	☐	☐	☐	☐	☐
3. O sentimento que a dor é terrível e que não vai melhorar é	☐	☐	☐	☐	☐
4. O sentimento que a dor é horrível e que você não vai resistir é	☐	☐	☐	☐	☐
5. O pensamento de não poder estar mais com alguém é	☐	☐	☐	☐	☐
6. O medo que a dor pode se tornar ainda pior é	☐	☐	☐	☐	☐
7. O pensamento sobre outros episódios de dor é	☐	☐	☐	☐	☐
8. O desejo profundo que a dor desapareça é	☐	☐	☐	☐	☐
9. O sentimento de não conseguir tirar a dor do pensamento é	☐	☐	☐	☐	☐
10. o pensamento que ainda poderá doer mais é	☐	☐	☐	☐	☐
11. O pensamento que a dor é grave porque ela não quer parar é	☐	☐	☐	☐	☐
12. O pensamento de que não há nada para fazer para diminuir a intensidade da dor é	☐	☐	☐	☐	☐
13. A preocupação que alguma coisa ruim pode acontecer por causa da dor é	☐	☐	☐	☐	☐

PONTUAÇÃO TOTAL DO QUESTIONÁRIO: _____

Anexo D - Escala de Depressão, Ansiedade e Estresse

DEPRESSION, ANXIETY, AND STRESS SCALE (DASS – 21) Versão traduzida e validada para o português do Brasil

Autores: Vignola, R.C.B. & Tucci, A.M.

Data da avaliação: ____/____/____. Avaliador: _____.

NOME DO PARTICIPANTE (INICIAIS):	ID:	DATA DE NASCIMENTO: / /

Instruções

Por favor, leia cuidadosamente cada uma das afirmações abaixo e circule o número apropriado 0,1,2 ou 3 que indique o quanto ela se aplicou a você durante a última semana, conforme a indicação a seguir:

- 0 Não se aplicou de maneira alguma
- 1 Aplicou-se em algum grau, ou por pouco de tempo
- 2 Aplicou-se em um grau considerável, ou por uma boa parte do tempo
- 3 Aplicou-se muito, ou na maioria do tempo

		Não se aplicou de maneira alguma	Aplicou-se em algum grau, ou por pouco de tempo	Aplicou-se em um grau considerável, ou por uma boa parte do tempo	Aplicou-se muito, ou na maioria do tempo
01	Achei difícil me acalmar	0	1	2	3
02	Senti minha boca seca	0	1	2	3
03	Não consegui vivenciar nenhum sentimento positivo	0	1	2	3
04	Tive dificuldade em respirar em alguns momentos (ex. respiração ofegante, falta de ar, sem ter feito nenhum esforço físico)	0	1	2	3
05	Achei difícil ter iniciativa para fazer as coisas	0	1	2	3
06	Tive a tendência de reagir de forma exagerada às situações	0	1	2	3
07	Senti tremores (ex. nas mãos)	0	1	2	3
08	Senti que estava sempre nervoso	0	1	2	3
09	Preocupe-me com situações em que eu pudesse entrar em pânico e parecesse ridículo (a)	0	1	2	3
10	Senti que não tinha nada a desejar	0	1	2	3
11	Senti-me agitado	0	1	2	3
12	Achei difícil relaxar	0	1	2	3
13	Senti-me depressivo (a) e sem ânimo	0	1	2	3
14	Fui intolerante com as coisas que me impediam de continuar o que eu estava fazendo	0	1	2	3
15	Senti que ia entrar em pânico	0	1	2	3
16	Não consegui me entusiasmar com nada	0	1	2	3
17	Senti que não tinha valor como pessoa	0	1	2	3
18	Senti que estava um pouco emotivo/sensível demais	0	1	2	3
19	Sabia que meu coração estava alterado mesmo não tendo feito nenhum esforço físico (ex. aumento da frequência cardíaca, disritmia cardíaca)	0	1	2	3
20	Senti medo sem motivo	0	1	2	3
21	Senti que a vida não tinha sentido	0	1	2	3

Anexo E - Índice de qualidade de sono de Pittsburgh (PSQI-BR)**Índice de qualidade de sono de Pittsburgh (PSQI-BR)**

Nome: _____

Idade: _____ Data: _____

Instruções:

As seguintes perguntas são relativas aos seus hábitos de sono durante o **último mês somente**. Suas respostas devem indicar a lembrança mais exata da **maioria** dos dias e noites do último mês. Por favor, responda a todas as perguntas.

1. Durante o último mês, quando você geralmente foi para a cama à noite?

Hora usual de deitar _____

2. Durante o último mês, quanto tempo (em minutos) você geralmente levou para dormir à noite?

Número de minutos _____

3. Durante o último mês, quando você geralmente levantou de manhã?

Hora usual de levantar _____

4. Durante o último mês, quantas horas de sono você teve por noite? (Este pode ser diferente do número de horas que você ficou na cama).

Horas de sono por noite _____

Para cada uma das questões restantes, marque a **melhor (uma)** resposta. Por favor, responda a todas as questões.

5. Durante o último mês, com que frequência você **teve dificuldade de dormir** porque você...

Não conseguiu adormecer em até 30 minutos

- a) Nenhuma no último mês
- b) Menos de 1 vez/ semana
- c) 1 ou 2 vezes/ semana
- d) 3 ou mais vezes/ semana

Acordou no meio da noite ou de manhã cedo

- a) Nenhuma no último mês
- b) Menos de 1 vez/ semana
- c) 1 ou 2 vezes/ semana
- d) 3 ou mais vezes/ semana

Precisou levantar para ir ao banheiro

- a) Nenhuma no último mês
- b) Menos de 1 vez/ semana
- c) 1 ou 2 vezes/ semana
- d) 3 ou mais vezes/ semana

Não conseguiu respirar confortavelmente

- a) Nenhuma no último mês
- b) Menos de 1 vez/ semana
- c) 1 ou 2 vezes/ semana
- d) 3 ou mais vezes/ semana

Tossiu ou roncou forte

- a) Nenhuma no último mês
- b) Menos de 1 vez/ semana
- c) 1 ou 2 vezes/ semana
- d) 3 ou mais vezes/ semana

Sentiu muito frio

- a) Nenhuma no último mês
- b) Menos de 1 vez/ semana
- c) 1 ou 2 vezes/ semana
- d) 3 ou mais vezes/ semana

Sentiu muito calor

- a) Nenhuma no último mês
- b) Menos de 1 vez/ semana
- c) 1 ou 2 vezes/ semana

d) 3 ou mais vezes/ semana

Teve sonhos ruins

- a) Nenhuma no último mês
- b) Menos de 1 vez/ semana
- c) 1 ou 2 vezes/ semana
- d) 3 ou mais vezes/ semana

Teve dor

- a) Nenhuma no último mês
- b) Menos de 1 vez/ semana
- c) 1 ou 2 vezes/ semana
- d) 3 ou mais vezes/ semana

Outra(s) razão(ões), por favor descreva _____

Com que frequência, durante o último mês, você teve dificuldade para dormir devido a essa razão?

- a) Nenhuma no último mês
- b) Menos de 1 vez/ semana
- c) 1 ou 2 vezes/ semana
- d) 3 ou mais vezes/ semana

6. Durante o último mês, como você classificaria a qualidade do seu sono de uma maneira geral?

- a) Muito boa
- b) Boa
- c) Ruim
- d) Muito ruim

7. Durante o último mês, com que frequência você tomou medicamento (prescrito ou “por conta própria”) para lhe ajudar a dormir?

- a) Nenhuma no último mês
- b) Menos de 1 vez/ semana
- c) 1 ou 2 vezes/ semana

d) 3 ou mais vezes/ semana

8. No último mês, com que frequência você teve dificuldade de ficar acordado enquanto dirigia, comia ou participava de uma atividade social (festa, reunião de amigos, trabalho, estudo)?

- a) Nenhuma no último mês
- b) Menos de 1 vez/ semana
- c) 1 ou 2 vezes/ semana
- d) 3 ou mais vezes/ semana

9. Durante o último mês, quão problemático foi para você manter o entusiasmo (ânimo) para fazer as coisas (suas atividades habituais)?

- a) Nenhuma dificuldade
- b) Um problema leve
- c) Um problema razoável
- d) Um grande problema

10. Você tem um(a) parceiro [esposo(a)] ou colega de quarto?

- a) Não
- b) Parceiro ou colega, mas em outro quarto
- c) Parceiro no mesmo quarto, mas não na mesma cama
- d) Parceiro na mesma cama

Se você tem um parceiro ou colega de quarto, pergunte a ele/ela com que frequência, no último mês, você teve...

Ronco forte

- a) Nenhuma no último mês
- b) Menos de 1 vez/ semana
- c) 1 ou 2 vezes/ semana
- d) 3 ou mais vezes/ semana

Longas paradas na respiração enquanto dormia

- a) Nenhuma no último mês
- b) Menos de 1 vez/ semana

- c) 1 ou 2 vezes/ semana
- d) 3 ou mais vezes/ semana

Contrações ou puxões nas pernas enquanto você dormia

- a) Nenhuma no último mês
- b) Menos de 1 vez/ semana
- c) 1 ou 2 vezes/ semana
- d) 3 ou mais vezes/ semana

Episódios de desorientação ou confusão durante o sono

- a) Nenhuma no último mês
- b) Menos de 1 vez/ semana
- c) 1 ou 2 vezes/ semana
- d) 3 ou mais vezes/ semana

Outras alterações (inquietações) enquanto você dorme; por favor, descreva

-
- a) Nenhuma no último mês
 - b) Menos de 1 vez/ semana
 - c) 1 ou 2 vezes/ semana
 - d) 3 ou mais vezes/ semana

RELATÓRIO DO TRABALHO DE CAMPO

O objetivo do presente relatório do trabalho de campo é descrever a trajetória de produção dos quatro produtos da tese, considerando o meu ingresso no doutorado no Programa de Pós-graduação em Educação Física em setembro de 2020.

O projeto de pesquisa da tese de doutorado, intitulado “Respostas de um programa de exercícios supervisionados remotamente e presencialmente em desfechos reportados pelos pacientes, parâmetros neuromusculares e funcionais de sujeitos com OA de joelho: ensaio clínico randomizado”, foi qualificado em 1º de setembro de 2023. No entanto, antes da elaboração desse projeto, a proposta inicial de estudo para o doutorado diferia da atual. A ideia original era conduzir um ensaio clínico para investigar os efeitos da estimulação elétrica neuromuscular combinada ao exercício em desfechos reportados pelos pacientes e na arquitetura muscular de pessoas com OA de joelho. Essa proposta foi estruturada em reuniões de orientação, mas a previsão de dificuldades para conduzir um estudo totalmente presencial no contexto da transição da pandemia de Covid-19 motivou a reformulação do projeto.

Mesmo diante dessa mudança, propus a realização de uma revisão sistemática com meta-análise, alinhada ao projeto inicial. O plano da revisão foi registrado na plataforma internacional PROSPERO (número do registro CRD42021291755) em 12 de dezembro de 2021. A pesquisa nas bases de dados ocorreu em abril de 2022, seguida pela triagem dos estudos, extração dos dados e escrita do artigo. O estudo resultante, intitulado “*Effectiveness of neuromuscular electrical stimulation training combined with exercise on patient-reported outcomes measures in people with knee osteoarthritis: A systematic review and meta-analysis*”, foi apresentado em 2023, na modalidade oral, na 9ª Semana Integrada de Inovação, Ensino, Pesquisa e Extensão, realizado na Universidade Federal de Pelotas (UFPEL), sendo destaque da sessão. Além disso, o trabalho foi aceito para publicação no mesmo ano no periódico *Physiotherapy Research International*. Considerando sua relevância para minha trajetória acadêmica dentro do grupo de pesquisa e o fato de ser a mesma população do ensaio clínico conduzido, e envolver as respostas terapêuticas de exercícios, esse manuscrito foi incluído como o primeiro artigo da tese.

Paralelamente, durante a pandemia, participei ativamente da coleta de dados em estudos remotos conduzidos por colegas do grupo de pesquisa LabNeuro. Atuei como membro da equipe de coleta nos seguintes ensaios clínicos randomizados: 1. “Efeitos de um programa de exercício físico supervisionado remotamente em indivíduos com diabetes tipo 2” e 2. “Programa de telereabilitação baseado em exercícios para policiais e bombeiros com dor lombar crônica inespecífica”. Essa experiência com reabilitação remota foi determinante para minha motivação em desenvolver um projeto de pesquisa nessa área, culminando na qualificação do estudo que integra minha tese.

No primeiro estudo, participei desde a etapa de cadastro na plataforma brasil, seguido pela elaboração do texto para a plataforma de registro de ensaios clínicos ClinicalTrials.gov e posteriormente a redação do estudo de protocolo. O que resultou na publicação do artigo, intitulado, *“Cardiometabolic, functional, and psychosocial effects of a remotely supervised home-based exercise program in individuals with type 2 diabetes (RED study): study protocol for a randomized clinical trial”* no periódico *Trials*. No segundo estudo, fui responsável pelas coletas dos desfechos reportados pelos pacientes em todo o período de coleta de dados. O artigo, intitulado, *“Effectiveness of an app-delivered, self-management exercise program in public safety workers with chronic low back pain: a randomized controlled trial”* está em revisão no periódico *“Brazilian Journal of Physical Therapy”*.

Após a finalização da coleta de dados dos estudos mencionados acima, na sequência qualifiquei o meu projeto de tese, seguido do cadastro na plataforma Brasil para apreciação ética ao Comitê de Ética em Pesquisa da Escola Superior de Educação Física e Fisioterapia da UFPEL, com aprovação em 10 de outubro de 2023 (Anexo I). Sequencialmente, registrei o estudo na plataforma ClinicalTrials.Gov em 16 de outubro de 2023 (Anexo II). Definimos o acrônimo RISE-KOA para identificação internacional do estudo, por extenso, **R**emote and **I**n-person **S**upervised **E**xercise in Patients with **K**nee Osteo**a**rthritis (RISE-KOA). Em 12 de abril de 2024 o artigo de protocolo (*Remote and In-person Supervised Exercise in Patients with Knee Osteoarthritis (RISE-KOA): study protocol for a non-inferiority randomized controlled trial*), que contempla todo o racional para condução do estudo, assim como o detalhamento dos métodos, foi submetido ao periódico *Trials*.

Entre outubro e novembro de 2023 recrutei estudantes do curso de fisioterapia do Centro Universitário da Região da Campanha (URCAMP), campus Bagé para participarem da equipe do projeto. A referida instituição é o meu local de trabalho desde 2019 e o local para condução do estudo. Os estudantes foram selecionados com base no interesse em pesquisa e disponibilidade para envolvimento com a carga horária de atividades do projeto. Escolhida a equipe, realizei uma capacitação teórica e prática para melhor condução das coletas de dados. A equipe foi integralizada com sete alunos de graduação e dois estudantes de doutorado.

A capacitação foi estruturada em duas etapas. Na primeira o projeto de pesquisa foi apresentado enfatizando inicialmente a definição, dados epidemiológicos, e a fisiopatologia da osteoartrite de joelho, e na sequência a abordagem de tratamento focada em exercícios. Após a capacitação teórica, a próxima etapa foi prática orientando a equipe quanto a condução da avaliação por desfechos reportados, e a realização das medidas de performance funcional. Aqueles responsáveis pela intervenção foram capacitados tanto em formato presencial como remoto. Cada membro da equipe recebeu orientações para realizar uma única função, um grupo responsável pela mensuração dos desfechos e outro pela condução da intervenção.

Em dezembro de 2023 foi iniciado o recrutamento dos primeiros participantes do estudo. O recrutamento estendeu-se até outubro de 2024 em fluxo contínuo. Fui responsável pelo recrutamento dos participantes ao longo do estudo. Foram conduzidas três vias de divulgação do estudo: postagens em rede social (*Instagram*) (figura 1 e 2), captação de participantes a partir da lista de espera para atendimento fisioterapêutico da Clínica Escola de Fisioterapia do Hospital Universitário da URCAMP e da Prefeitura Municipal de Bagé, divulgação por meio de notícia em jornal local (jornal minuano) (figura 3) e por fim divulgação de vídeo no instagram da URCAMP mostrando a rotina do estudo no Hospital Universitário. Um aspecto importante a ser destacado é o fato desse estudo ser o primeiro estudo clínico implementado no Hospital Universitário da URCAMP.



Figura 1. Primeira postagem de divulgação do estudo no Instagram pessoal em 13 de dezembro de 2023.

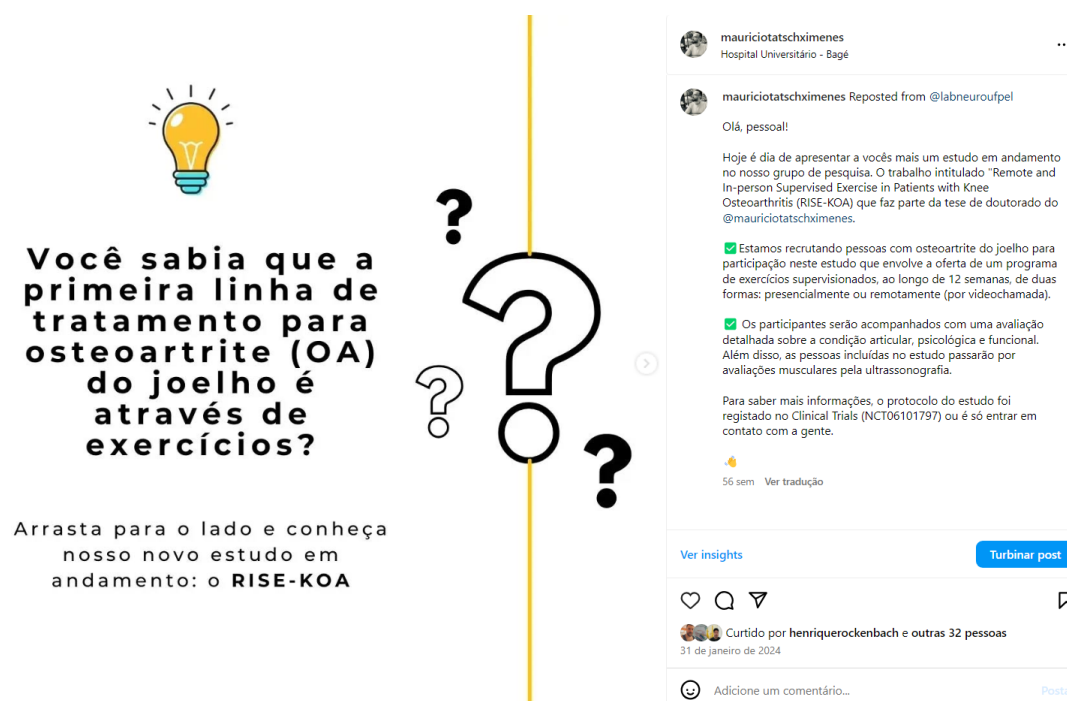


Figura 2. Segunda postagem de divulgação do estudo no Instagram pessoal em 31 de janeiro de 2024.

14 BAGÉ, 27, 28 E 29 DE JULHO DE 2024

mi Saúde

Pesquisa avalia reabilitação de pacientes com Osteoartrite do joelho

FOTO: CHRISTIAN RIBEIRO/SCON

O primeiro estudo clínico voltado para o tratamento fisioterapêutico de pessoas com Osteoartrite (artrose) do joelho, na cidade de Bagé, está em andamento no Núcleo de Práticas em Saúde da Urcamp. O projeto é parte do doutorado do professor Maurício Tatsch Ximenes Carvalho, que ministra aulas no curso de Fisioterapia e cursa seu doutorado na Universidade Federal de Pelotas, sob orientação da professora doutora Cristine Lima Alberton.

O trabalho busca investigar se um programa supervisionado de exercícios remotos (via videochamada) é tão eficaz quanto um programa de exercícios presenciais (na clínica de fisioterapia), para pacientes com patologia de osteoartrite do joelho. Para isso, estão sendo selecionadas pessoas acima de 45 anos, com acesso à internet, marcha independente (sem necessidade de muleta), e diagnóstico clínico e radiográfico da condição. As pessoas interessadas no estudo são encaminhadas para uma triagem presencial e, em seguida, aqueles que atendem aos critérios passam por uma avaliação detalhada.

A primeira etapa da avaliação consiste em uma consulta por videochamada, para analisar as características da dor, a presença de sintomas articulares, o bem-estar psicológico e a qualidade do sono. A avaliação também é realizada no setor de Radiologia, através de Ultrassonografia, para verificação da condição muscular. Além disso, testes funcionais são realizados no Núcleo de Práticas em Saúde da Urcamp, tudo com o auxílio de acadêmicos do curso de Fisioterapia da Urcamp.

A acadêmica Fernanda Silveira da Sena foi uma das selecionadas para participar do estudo e já pensa em seguir a carreira como pesquisadora. "Desde que iniciei, já comecei nos testes funcionais. Fui me entrosando e hoje eu faço, inclusive, a intervenção, que é estar integrada ao tratamento e reabilitação do paciente", explica.

Os participantes são reavaliados após seis semanas de tratamento e, novamente, ao final de 12 semanas. Após o término do tratamento supervisionado, eles são incentivados a continuar o programa de exercícios através de um material digital, sendo reavaliados após 18 semanas. "Essas pessoas recebem o tratamento de forma remota, com supervisão através de videochamadas ou recebem o tratamento aqui na clínica do HU (Hospital Universitário da Urcamp). Os alunos se envolvem muito neste trabalho, pois o atendimento prestado à comunidade neste projeto, tanto no remoto ou presencial, é conduzido por estudantes de Fisioterapia, assim como as etapas de avaliação e reavaliação. Isso acrescenta muito na formação", revela o professor.

A análise

O estudo clínico visa ampliar o acesso das pessoas à Fisioterapia, oferecendo uma alternativa ao tratamento presencial. A técnica em Enfermagem Ana Delpino, já cansada pelas constantes dores no joelho, aderiu ao tratamento depois de ver pelas redes sociais o recrutamento para a pesquisa. Ela conta que o processo de cura já chega a 98%. "Fui super acolhida e o tratamento remoto é muito bom. Tu consegues agendar o horário que fica melhor, juntamente do acompanhamento com o fisioterapeuta. E eu aprendi os exercícios, que me fizeram movimentar melhor os meus joelhos. Já posso fazer minha caminhada e hoje sinto muito mais firmeza", revela.

É o mesmo caso da aposentada Céles Helena da Silva Ramir. Ela foi ao HU fazer uma revisão e diz que teve as dores estancadas depois de concluir o tratamento. "Foi muito proveitoso. Quando comecei eu tinha dores, principalmente para levantar, agora levanto, agacho tranquilamente, então, estou muito satisfeita. Valeu a pena ter participado dessa pesquisa, fiquei muito agradecida pela oportunidade", avalia.

Pessoas interessadas em participar do estudo podem entrar em contato com o Núcleo de Práticas em Saúde do Hospital Universitário, pelo telefone (53) 3242-7433 ou pelo número (55) 99678-2793 para agendar a triagem.

Estudo é desenvolvido no Núcleo de Práticas da Saúde da Urcamp, em projeto de doutorado do professor Maurício Tatsch Ximenes Carvalho

Novidade em Bagé-RS
Cadeira EMSELLA

Agende sua consulta conosco

A solução inovadora contra a incontinência urinária.

Uma parceria de:

LEONARDO FERNANDES
D.M. in Rio

Dr. Leonardo Fernandes
Urologista
(51) 99163-3352

Dr. Rodrigo Gal -
Urologista
(51) 99166-2726

Figura 3. Divulgação do estudo para comunidade de Bagé-RS em matéria no Jornal Minuano (link para acesso a matéria: <https://www.jornalminuano.com.br/noticia/2024/07/28/pesquisa-avalia-reabilitacao-de-pacientes-com-osteoartrite-do-joelho>).

O primeiro contato com os participantes foi via celular de forma a identificar se o participante interessado estava dentro dos critérios para a etapa da triagem presencial. Os critérios iniciais consistiam em: pessoas com história de dor e redução da função do joelho, idade ≥ 45 anos e dor por mais de 3 meses. Na sequência, em uma triagem presencial, seguindo um formulário estruturado,

era identificado se o participante estava apto para ser incluído no estudo, conforme critérios de inclusão e exclusão. O checklist da triagem contemplou a coleta de dados de identificação, informações sobre a história da condição atual, e os tópicos de verificação da conformidade do participante com os critérios de inclusão e exclusão do estudo.

No total 96 participantes foram encaminhados para triagem, destes, três desistiram de participar, quatro não compareceram a triagem presencial, e 38 não atenderam aos critérios de inclusão ou foram excluídos. Dos 38 participantes, 11 participantes utilizavam dispositivos auxiliares para marcha, oito não tinham diagnóstico definitivo de OA de joelho, oito não tinham acesso à internet, cinco apresentaram $IMC \geq 35 \text{ kg/m}^2$, três praticavam atividade física regular, um participante apresentava OA avançada, um doença neurológica com repercussão motora em membros inferiores e outro participante com diagnóstico de artrite reumatoide.

O processo de triagem do estudo iniciou-se com uma amostra prevista de 68 participantes, 34 em cada grupo. Esse cálculo foi apresentado na qualificação do projeto de pesquisa. No entanto, durante o andamento do estudo, recalculamos o tamanho da amostra com base em uma análise de ensaios clínicos randomizados que utilizaram a margem de não inferioridade nos desfechos primários. O novo cálculo considerou dados de um estudo anterior, adotando um nível de significância (α) de 0,05, poder estatístico de 0,80, desvio padrão de 2 para o nível de dor e uma margem de não inferioridade de -1,6 pontos (20% menor que a diferença mínima clinicamente relevante de 2 pontos na Escala Numérica de Dor). Com esses parâmetros, o tamanho mínimo necessário da amostra foi estimado em 40 participantes. Para compensar uma perda esperada de aproximadamente 20% entre a linha de base e o acompanhamento, determinamos a necessidade de 48 participantes, distribuídos igualmente entre os grupos (24 por grupo).

Um componente importante da triagem foi a verificação da evidência radiográfica de osteoartrite de joelho. Nesse sentido, os participantes que não possuíam um exame com a classificação radiográfica, ou em caso de a radiografia ter sido realizada em período maior que 12 meses, um novo exame era solicitado no setor de radiologia do Hospital Universitário da URCAMP. Desse modo, os participantes já saíam da clínica de fisioterapia com o

encaminhamento para realização do exame radiográfico. Além de uma etapa fundamental para definição do grau da OA do joelho, os participantes na sequência ficavam com o laudo do exame.

Antes da inclusão no estudo, os participantes receberam informações detalhadas sobre toda a sua trajetória ao longo do tratamento, incluindo explicação sobre os procedimentos do estudo (avaliação e tratamento), riscos e possíveis reações, os benefícios do tratamento, aspectos sobre a participação voluntária, assim como o estudo não gerar nenhuma despesa para o paciente e a confidencialidade das informações coletadas. O participante somente iniciou as avaliações pré-tratamento após a assinatura do Termo de Consentimento Livre e Esclarecido (TCLE).

Após assinatura do TCLE eram agendados dois dias de avaliação, o primeiro presencial para coleta de informações sociodemográficas e clínicas, seguido da avaliação ultrassonográfica e da mensuração da performance funcional (Figura 4 e 5). As informações sociodemográficas clínicas e a mensuração da performance funcional foi conduzida na Clínica Escola de Fisioterapia do Hospital Universitário da URCAMP. E a avaliação ultrassonográfica foi conduzida no setor de radiologia do hospital. O segundo dia foi destinado a condução da avaliação por meio de desfechos reportados pelos pacientes utilizando uma videochamada para comunicação (Figura 6). Cada avaliação presencial teve duração de aproximadamente 40 minutos, enquanto a avaliação remota 20 minutos. As fichas de avaliação utilizadas durante a coleta de dados estão incluídas nos anexos A a E e no apêndice E do projeto de pesquisa. Após o período de avaliações, um único pesquisador realizou a randomização dos participantes. O grupo para o qual o participante foi randomizado foi enviado exclusivamente para o membro da equipe responsável pela intervenção via WhatsApp. Na sequência era marcada uma sessão de atendimento fisioterapêutico presencial para todos os participantes independente do grupo de alocação para familiarização com o protocolo de exercícios.



Figura 4. Mensuração da performance funcional. Em A, teste de performance funcional - *Stair Climb*. Em B, teste de performance funcional – Caminhada Rápida de 40 metros.



Figura 5. Geração de imagens ultrassonográficas do quadríceps femoral.

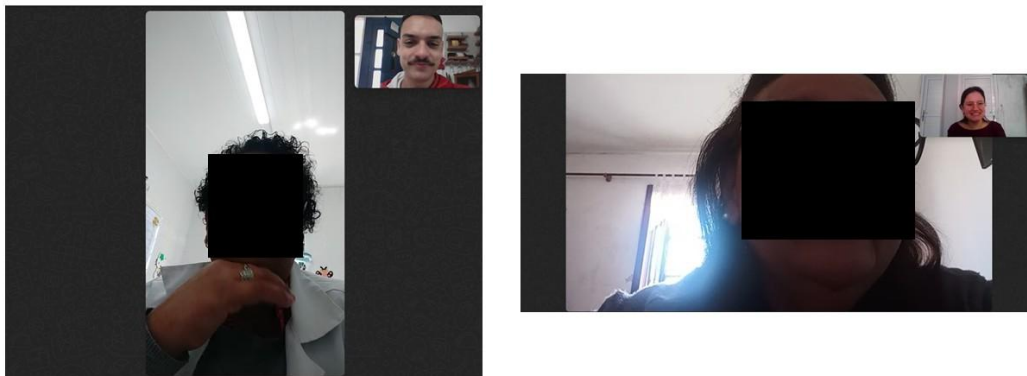


Figura 6. Avaliação dos desfechos reportados por videochamada

No dia da familiarização com os exercícios, o mesmo membro da equipe responsável pela familiarização foi o mesmo que conduziu todas as sessões de exercícios supervisionados. Neste momento, cada exercício foi ensinado aos participantes de forma que os mesmos aprendessem a correta execução. Para os participantes do grupo de exercícios supervisionados presencialmente esta sessão presencial foi destinada somente para familiarizar com os exercícios e, enquanto para o grupo de exercícios supervisionados remotamente a sessão presencial foi para familiarizar os participantes com os exercícios e com o uso de videochamadas, assim como para entrega das faixas elásticas. Após repassados todos os exercícios, era feita uma simulação da sessão por videochamada. O fisioterapeuta direcionava-se para outra sala e fazia a ligação para o participante e um exercício era selecionado para simulação do atendimento remoto. Orientações a respeito de cuidados no domicílio para condução das videochamadas com segurança incluíram manter uma cadeira e uma vassoura por perto para realização dos movimentos em pé para prevenção de quedas, evitar realizar movimento perto de tapetes que possam escorregar. Além disso, conforme o grau de dificuldade dos participantes de realizar os exercícios, quando possível, era solicitado que um familiar permanecesse por perto durante as primeiras sessões até que o participante conseguisse realizar

de forma independente. Finalizada a familiarização, na semana seguinte os participantes iniciavam o tratamento.

Cada participante passava por um período de intervenção de 12 semanas remotamente ou presencial (Figura 7 e 8). Os primeiros participantes randomizados iniciaram o tratamento em janeiro de 2024, enquanto os últimos participantes incluídos no estudo iniciaram o tratamento em outubro de 2024. De forma geral, todos os participantes do estudo realizaram o programa de exercício conforme protocolo pré-definido. No entanto, em alguns casos foi necessária adaptação de exercícios até a realização com qualidade. O exercício *Wall push*, por exemplo, foi adaptado na maioria dos participantes nas primeiras 4 semanas. Orientações foram fornecidas para realização do exercício com menor número de séries e repetições, pois os pacientes relatavam desconforto ao realizá-lo. Em alguns participantes, não foi possível avançar para o nível 2 do exercício de sentar e levantar da cadeira, uma vez que neste nível havia uma maior exigência de sobrecarga articular. Além disso, naqueles pacientes com relato de dor articular (>4 na escala numérica de dor), os exercícios eram orientados em menor amplitude de movimento ou sem o uso de faixas elásticas até o paciente estar realizar o exercício com qualidade.



Figura 7. Exercícios supervisionados remotamente do estudo RISE-KOA. Em A, exercício de extensão de joelhos. Em B, agachamento na parede.



Figura 8. Exercícios supervisionados presencialmente do estudo RISE-KOA. Em A, exercício de extensão de joelhos. Em B, exercício de abdução contra a parede (*wall push*).

A equipe responsável pela intervenção manteve atualizado uma planilha para demarcar a presença dos participantes nas sessões de tratamento, reportar a ocorrência de efeitos adversos do tratamento baseado em exercícios, assim como a necessidade de adaptações no protocolo conforme as necessidades individuais de cada participante. Em situações nas quais a equipe tinha dúvidas sobre como proceder com a abordagem de tratamento, especialmente em situações nas quais o paciente se apresentava com aumento no nível de dor, a equipe fazia contato com o pesquisador responsável pela condução do estudo, sem identificar o participante, para em consenso solucionar as questões. O pesquisador que liderou a coordenação das coletas de dados, também realizou o recrutamento e a geração das imagens ultrassonográficas. Reuniões com a equipe de trabalho foram constantes ao longo de todo o processo de coleta de dados e condução da intervenção de forma a manter as práticas alinhadas com o desenho do estudo definido no projeto de pesquisa.

O trabalho com dados preliminares do estudo, intitulado, “*Exercício remoto e presencial para pacientes com osteoartrite do joelho: dados preliminares de dor do estudo RISE-KOA*” foi apresentado, na modalidade oral, no 43º Encontro Nacional de Educação Física e 4º Encontro de Fisioterapia realizado na Escola Superior de Educação Física e Fisioterapia da UFPEL. E posteriormente publicados nos anais do evento.

Em janeiro de 2025 ocorreram as últimas avaliações presenciais dos últimos participantes recrutados para o estudo RISE-KOA. A previsão é que as últimas avaliações do *follow-up* ocorram em março de 2025. No arquivo final da tese constam os dados coletados na semana 0, 6 e 12. Os dados do follow-up serão incluídos futuramente no artigo principal da tese com os resultados do ensaio clínico. Optamos por neste momento da tese apresentar somente os dados relacionados aos efeitos durante a intervenção (após 6 semanas de tratamento) e imediatamente após 12 semanas.

Concomitante ao recrutamento dos últimos participantes no estudo, propus a condução de uma revisão sistemática abordando o uso da ultrassonografia musculoesquelética para avaliação do quadríceps femoral de pacientes com OA do joelho. A motivação para condução deste estudo se deve ao fato de que umas das variáveis de interesse no estudo clínico foi a avaliação da arquitetura e qualidade muscular do quadríceps femoral. Paralelamente a isto, analisando a literatura disponível, observou-se um crescente número de estudos sobre o uso da ultrassonografia para avaliação muscular de pacientes com OA de joelho. Além disso, não identificamos na literatura disponível uma revisão sistemática que sumarizou os protocolos de ultrassonografia, descrito os principais desfechos de avaliação muscular e analisado correlação da arquitetura e qualidade muscular com desfechos reportados pelos pacientes e parâmetros funcionais. Desse modo, em 22 de outubro de 2023 foi publicado o plano de revisão sistemática na plataforma PROSPERO - *Assessing quadriceps architecture in patients with knee osteoarthritis: implications for clinical practice - a systematic review of observational studies* (CRD42023471617). A pesquisa nas bases de dados ocorreu em novembro de 2023 e posteriormente uma nova busca em agosto de 2024, seguida pela triagem dos estudos, extração dos dados, avaliação da qualidade metodológica e escrita do artigo. O artigo final foi submetido em 11 de novembro de 2024 ao periódico *Annals of Physical and*

Rehabilitation Medicine, intitulado, *Ultrasonographic Assessment of Quadriceps Muscle Architecture and Quality in People with Knee Osteoarthritis: A Systematic Review*.

Nesse relatório foi descrita a trajetória para produção dos quatro produtos da tese, os quais representam o meu caminho no doutorado e no grupo de pesquisa LabNeuro. O primeiro produto, a revisão sistemática com metanálise abordando o efeito da combinação do exercício com a estimulação elétrica neuromuscular no tratamento da OA de joelho (*Effectiveness of neuromuscular electrical stimulation training combined with exercise on patient-reported outcomes measures in people with knee osteoarthritis: A systematic review and meta-analysis*); o segundo, o estudo de protocolo do ensaio clínico randomizado RISE-KOA (*Remote and In-person Supervised Exercise in Patients with Knee Osteoarthritis (RISE-KOA): study protocol for a non-inferiority randomized controlled trial*); o terceiro, o estudo de revisão sistemática com a temática da ultrassonografia (*Ultrasonographic Assessment of Quadriceps Muscle Architecture and Quality in People with Knee Osteoarthritis: A Systematic Review*), e o quarto, o artigo final do ensaio clínico randomizado RISE-KOA (*Remote and In-person Supervised Exercise in Patients With Knee Osteoarthritis (RISE-KOA study): a non-inferiority randomized clinical trial*).

Por fim, destaco a relevância de ter conduzido o meu estudo de doutorado em uma cidade de interior, na qual não é comum a condução de ensaios clínicos randomizados. Sendo este o primeiro conduzido no Hospital Universitário, da URCAMP, localizado na cidade de Bagé. Assim, 51 participantes foram beneficiados recebendo o tratamento baseado em exercícios recomendado pelas diretrizes internacionais para pacientes com OA de joelho. Foi gratificante receber tantos feedbacks de participantes do estudo que ficaram impressionados com os efeitos dos exercícios para redução da dor e para melhora do desempenho funcional. Espera-se que com a publicação futura do ensaio clínico os achados fortaleçam a condução de exercícios remotos por videochamadas especialmente para países em desenvolvimento. Desse modo, contribuindo para aumentar o corpo de conhecimento na área de telerreabilitação especialmente ao considerar a entrega de serviços de saúde em contextos de desigualdes sociais.

ARTIGO 1

Submetido ao periódico *Physiotherapy Research International* (fator de impacto 1.5), conforme a diretriz para autores (Anexo III), em 26 de maio de 2023 e aceito para publicação em 23 de outubro de 2023

Effectiveness of neuromuscular electrical stimulation training combined with exercise on patient-reported outcomes measures in people with knee osteoarthritis: a systematic review and meta-analysis

Maurício Tatsch Ximenes Carvalho, Victor Hugo Guesses Pinheiro, Cristine Lima Alberton

Abstract

Objective: This study examined the effectiveness of neuromuscular electrical stimulation (NMES) added to the exercise or superimposed to voluntary contractions on patient-reported outcomes measures (PROMs) in people with knee osteoarthritis.

Methods: This systematic review was described according to PRISMA guidelines. Randomized controlled trials (RCTs) were obtained from a systematic literature search in five electronic databases (PubMed, PEDro, LILACS, EMBASE, and SPORTDiscus) in April 2022. We described the effects of intervention according to each PROMs (scores for Pain; Self-reported functional ability; Symptoms (hear clicking, swelling, catching, restricted range of motion, and stiffness); Daily living function; Sports function; Quality of life) and used a random-effect model to examine the impact of NMES plus exercise on pain compared to exercise in people with knee osteoarthritis.

Results: Six RCTs (n=367) were included. In the qualitative synthesis, the systematic literature analysis shows improvement in pain after NMES plus exercise compared to exercise alone in three studies. The other three studies revealed no difference between groups in pain, although similar improvement after treatments. In the meta-analysis, NMES at a specific joint angle combined with exercise was not superior to exercise alone in pain management (SMD = -0.33, 95% CI = -1.05 to 0.39, p = 0.37). There was no additional effect of NMES to exercise on self-reported functional ability, stiffness, and physical function compared to exercise alone. In only one study, symptoms, activities of daily living, sports function, and quality of life were improved after whole-body electrostimulation combined with exercise.

Conclusion: This review found insufficient evidence for the effectiveness of NMES combined with exercise in treating knee osteoarthritis, considering PROMs. While pain relief was observed in some studies, more high-quality clinical trials are needed to support the use of NMES added to the exercise in clinical practice. Electrical stimulation in a whole-body configuration combined with exercise shows promise as an alternative treatment option.

Keywords

Orthopedic patients; Physical Therapy Modalities; Electric Stimulation Therapy; Voluntary exercise; Pain.

Introduction

Knee osteoarthritis (OA) is a common multifactorial joint disease that is a leading cause of disability and significantly affects both older adults and women (Cross et al., 2014; Cui et al. 2020). People with knee OA experience pain and limited physical function (Hall et al., 2022). In this regard, patient-reported outcome measures (PROMs), including pain and function, are an essential assessment component to understanding the functional implications of knee OA from the patient's perspective (Davis et al., 2022).

Exercise is a non-pharmacological therapy in knee OA recommended as the first line of treatment by several clinical guidelines (Overton et al., 2022). Aerobic and strength training, including neuromuscular or aquatic exercise programs, are effective ways of treatment for improving knee pain and functional capacity (Duan et al., 2022; Holm et al., 2021; Kuş et al., 2022; Luan et al., 2021). Exercise also reduces inflammation and improves muscle strength and structure (Marriott et al., 2021). However, some barriers are recognized to people engagement in exercise programs that involve a complex interaction between physical, personal, psychological, and socio-environmental factors (Kanavaki et al., 2017).

Therefore, neuromuscular electrical stimulation (NMES) is a promising approach to treating quadriceps muscle degeneration, providing benefits such as reduced knee pain and improved joint stiffness and mobility in knee OA people (Sax et al., 2022). NMES is the most effective electrical stimulation treatment in knee OA management, and its efficiency is higher when combined with a strength exercise program (Novak et al., 2020). In a systematic review, the authors concluded, with very low-certainty evidence, that NMES combined with exercise, compared to an active control group, increased isometric muscle strength of quadriceps femoris muscle in knee OA people (Bispo et al., 2021). However, these authors also included studies that compared NMES vs. exercise, not necessarily analyzing only the effects of NMES plus exercise. In addition, their primary outcomes were strength and functional measurements; they did not focus on the PROMs. Prior reviews investigated NMES effectiveness on knee OA people, but their systematic search only focuses on studies with protocols

involving conventional muscle application at specific articular angles; in this sense, our study investigated conventional modality and other such as whole-body configuration and NMES superimposed muscle contractions (Bispo et al., 2021; Novak et al., 2020). A systematic review addressing the different application possibilities of NMES will increase the body of knowledge and provide alternatives for treating people with knee OA.

A recent systematic review highlighted the promising effects of combining NMES with voluntary contractions in healthy people and orthopedic patients (Borzuola et al., 2022). However, there still needs to be consensus in the literature on using NMES combined with exercise in people with knee OA. Therefore, the present review aimed to investigate the effectiveness of NMES training combined with exercise on PROMs in people with knee OA. For this purpose, this review includes randomized, parallel-group trials focusing on the effectiveness of a combined intervention, NMES added to the exercise, or superimposed voluntary contractions compared to exercise alone.

Methods

A systematic review was conducted following Cochrane Handbook for Systematic Reviews of Interventions and reported in agreement with Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) guidelines (Higgins et al., 2022; Page et al., 2021). A priori methodological review protocol was registered in PROSPERO International Prospective Register of Systematic Reviews; registration number CRD42021291755.

Eligibility Criteria

The inclusion criteria were: (1) participants: symptomatic knee OA or radiographic (tibiofemoral OA) with the symptomatic condition, regardless of the stage of the disease; (2) intervention: NMES program combined with exercise or superimposed onto voluntary contraction with more than four weeks duration to elucidate this intervention's long-term effects; (3) comparators: exercise control group (knee and lower extremity muscle-strengthening exercises, balance

training, or low-load resistance training using the isokinetic dynamometer); (4) outcome measures: pain, self-reported functional ability, symptoms (hear clicking, swelling, catching, restricted range of motion, and stiffness), daily living function, sports function; quality of life. When a study includes more than one PROMs, such as pain for Numerical Rating Scale (NRS) and pain of Knee Injury and Osteoarthritis Outcome Score (KOOS), both data are extracted. (5) study design: randomized controlled trials. Studies were limited to Portuguese, English, and Spanish languages published in peer-reviewed journals. Exclusion criteria included studies with animals, simulators, and those conducted after total knee replacement surgery.

Information sources and search strategy

A systematic literature search was conducted in five electronic databases by two independent investigators (MTXC and VHGP) for indexed full-text publications (i.e., PubMed, PEDro, LILACS, EMBASE, and SPORTDiscus) in April 2022. A search strategy used MeSH terms, such as "Osteoarthritis, Knee" and "Electric Stimulation Therapy." Search terms were combined using Boolean operators AND or OR. The complete search strategy for each database is presented in the supplementary material (Supplementary Table 1).

Selection and Data Collection Process

Articles were retrieved and exported to the Mendeley Desktop 1.13.3 software. Two independent investigators (MTXC and VHGP) reviewed the search results and removed duplicates by automatic Mendeley toll. Titles and abstracts of all articles identified by the search strategy were screened to identify potentially eligible studies by two independent investigators (MTXC and VHGP). Additionally, the reference lists from retrieved articles were manually checked to ensure that all relevant papers were included. Disagreements were resolved by personal discussion between the reviewers to agree or consult with a third independent reviewer.

Study Risk of Bias Assessment

Two investigators (MTXC and VHGP) independently examined the risk of bias in each included study using the revised RoB 2. The instrument assesses the risk of bias arising from five categories in randomized trials: randomization process, deviations from the intended interventions, missing outcome data, measurement of the outcome, and selection of the reported result. Each domain is judged as low, with some concerns, or a high risk of bias, resulting in an overall bias judgment. Disagreements between reviewers were solved by consensus, and a third reviewer (CLA) was consulted as necessary.

Data extraction and synthesis

Full-text articles were stored electronically and systematically reviewed, including a year of publication, participant characteristics, NMES protocols, and exercise programs. We performed a data synthesis considering the following PROMs: Visual Analogue Scale (VAS) or NRS; The Western Ontario and McMaster Universities Osteoarthritis (WOMAC) Index (containing three subscales: pain, stiffness, and function, or total sum score); KOSS (containing five subscales: pain, symptoms, daily living function, sports function, and quality of life).

Qualitative synthesis was described according to the following topics: characteristics of participants, outcomes, interventions, risk of bias in studies, and results of individual studies. In addition, considering several NMES protocols, we describe the results following three categories of intervention: NMES at specific articular angle, NMES superimposed to voluntary contractions, and a whole-body configuration. Data from each study was summarized in tables, including characteristics of participants and interventions and main findings.

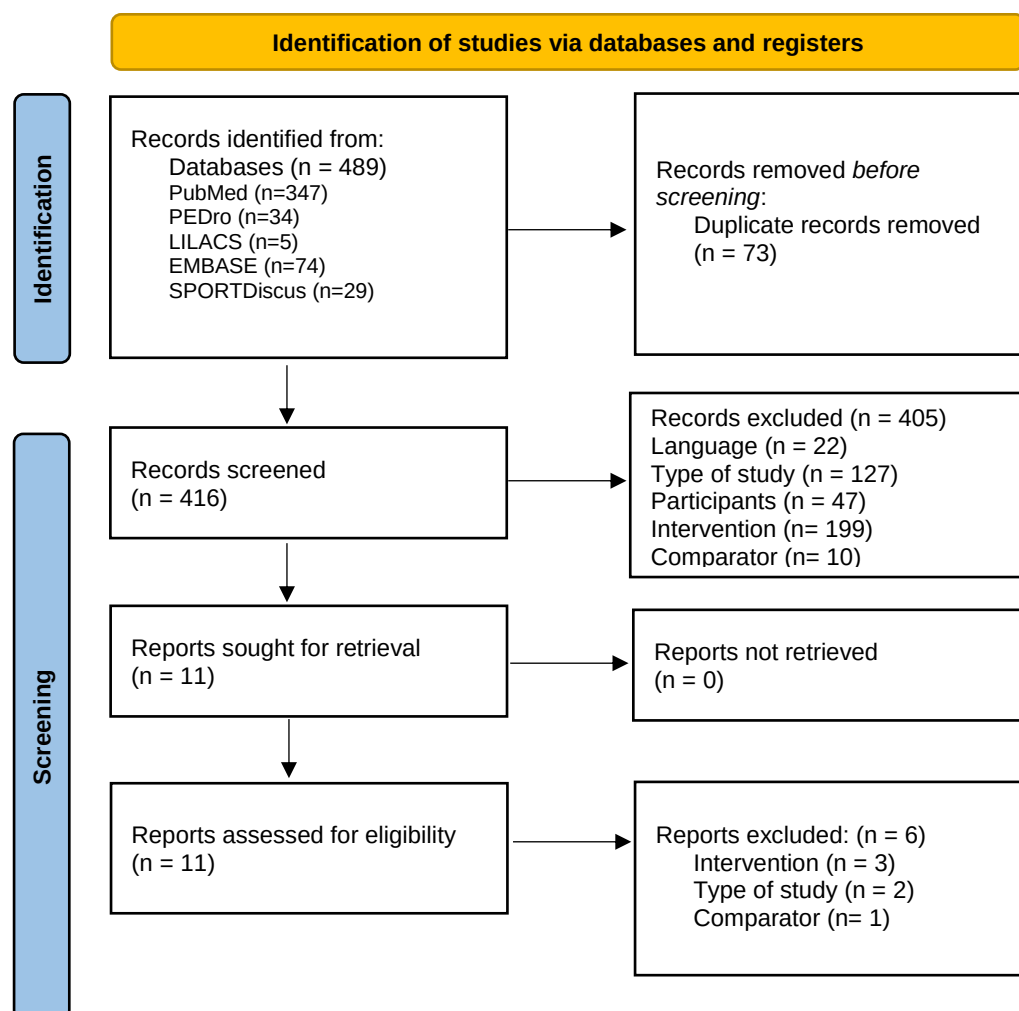
R software (version 4.2.2) and the “meta” package were used for data analyses. The standardized mean difference (SMD) and 95% confidence intervals (95%CI) were determined for continuous data, and a random-effects model with inverse variance was applied for the calculation. Data on a moment post-intervention of each study was used to compare differences between

groups. We assess the statistical heterogeneity using the Cochran Q test and estimated by the I^2 statistic. Studies were judged as having a high heterogeneity when I^2 values were greater than 50%. A p-value less than 0.05 indicated a statistically significant difference.

Results

Study Selection

The search retrieved 489 records from electronic databases. After removing 73 duplicates, 416 titles and abstracts were read, of which 405 were not eligible. Out of 11 articles read, six were excluded for one of the following reasons: (1) Intervention; (2) Type of study; (3) Comparator. Of 11 eligible articles, five articles were included in this systematic review, including one additional study identified by hand searching in the reference list of the eligible studies. A flow diagram of the review process is in Fig. 1.



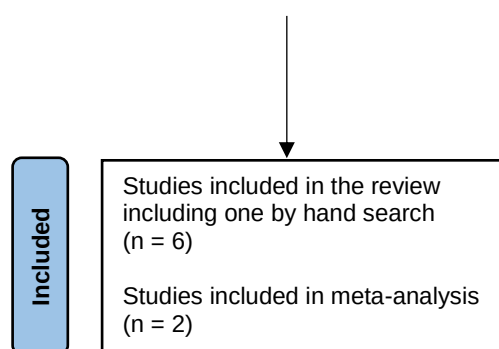


Fig. 1 Literature search flow chart

Participants

Six articles in the systematic review examined PROMs in 367 people with knee OA (Table 1). Four studies included people with a grade II or higher, determined by Kellgren and Lawrence (Elboim-Gabyzon et al., 2013; Imoto et al., 2013; Laufer et al., 2014; Rosemffet et al., 2004). One study selected people with early-stage conditions (I or II by Kellgren and Lawrence), and another recruited symptomatic subjects regardless of stage condition, however, with consideration of risk factors for knee osteoarthritis symptoms. These risk factors include a body mass index of 25 kg/m² or greater, a history of knee joint injury or surgery, or experiencing knee symptoms such as pain or stiffness for most of the previous 30 days (Park et al., 2021; Rabe et al., 2018). The age of participants ranged from 60 to 68.9 years. Four studies included males and females, and two females only (Elboim-Gabyzon et al., 2013; Imoto et al., 2013; Laufer et al., 2014; Rosemffet et al., 2004).

Table 1. Characteristics of the included studies.

Study	Country	Sample	Intervention	Outcomes		
				Pain	Self-reported functional ability	Symptoms, daily living function, sports function, and quality of life

Rosemff et al., (2004)	Argentina	Knee OA people and (Kellgren and Lawrence radiographic score ≥ 2). N: 26 Sex: Male and female. Age: 60 years (57.7–69.5).	NMES and exercise vs. exercise	Visual Analogue Scale	-	-
Elboim-Gabyzon et al., (2012)	Israel	Knee OA people and (Kellgren and Lawrence radiographic score ≥ 2) N: 50 Sex: Male and Female. Age: 68.9 $\pm$ 7,7	NMES and exercise vs. exercise	Visual Analogue Scale	WOMAC (total score)	-
Imoto et al., (2013)	Brazil	Knee OA people and (Kellgren and Lawrence radiographic score ≥ 2) N: 87 Sex: Male and Female. Age: 61,1 $\pm$ 6,8	NMES and exercise vs. exercise	Numerical Rating Scale WOMAC (pain)	WOMAC (function) WOMAC (stiffness)	-
Laufer et al., (2014)	Israel	Knee OA woman (Kellgren and Lawrence radiographic score ≥ 2) N: 50 Sex: Male and Female Age: 68,9 $\pm$ 7,7	NMES and exercise vs. exercise	Visual Analogue Scale	WOMAC (total score)	-
Rabe et al., (2018)	United States	Symptomatic knee OA (Risk factors for knee osteoarthritis symptoms) N: 35 Sex: Female Age: 66,6 $\pm$ 8,9	Hybrid training system (combination of NMES and volitional contractions) vs. exercise	KOOS (pain)	-	-

Park et al., (2021)	South Korea	Knee OA people (Kellgren and Lawrence radiographic score 1 or 2). N: 75 Sex: Female Age: 66,9±4,0	Isometric exercise and electromyostimulation vs. isometric exercise group alone vs. control group	KOOS (pain)	-	KOSS (Symptoms, daily living function, sports function, and quality of life)

NMES=Neuromuscular Electrical Stimulation; WOMAC= Western Ontario and McMaster Universities Arthritis Index; KOOS= Knee Injury and Osteoarthritis Score.

Outcomes

Three studies assessed pain intensity using the VAS, and one used NRS (Elboim-Gabyzon et al., 2013; Imoto et al., 2013; Laufer et al., 2014; Rosemffet et al., 2004). Self-reported functional ability was evaluated in three studies; two used the WOMAC Index (total sum score), while the other one used WOMAC by subscales analyzed separately (Elboim-Gabyzon et al., 2013; Imoto et al., 2013; Laufer et al., 2014). Only one study reported patient-reported symptoms (hear clicking, swelling, catching, restricted range of motion, and stiffness), daily living function, sports function, and quality of life using the KOSS by subscales (Park et al., 2021).

Interventions

In the studies conducted on knee OA people with grade II or higher, NMES protocols were performed in addition to the exercise program compared with exercise alone (Elboim-Gabyzon et al., 2013; Imoto et al., 2013; Laufer et al., 2014; Rosemffet et al., 2004). Of them, two studies described a specific joint angle of NMES sessions (with the knee and hip flexed to 90 degrees), while the others did not specify it (Elboim-Gabyzon et al., 2013; Imoto et al., 2013). Another study, conducted with symptomatic people independent of stage condition, applied a hybrid training (NMES combined with voluntary contractions) compared with low-load resistance training (Rabe et al., 2018). Hybrid training consists of a joint movement sensor that detects voluntary movement and stimulates with

NMES the antagonistic muscle. Moreover, in the latter study, conducted on knee OA people in early-stage conditions, isometric exercises were realized when wearing a suit with electrostimulation compared with isometric exercise alone (Park et al., 2021).

The combined intervention was carried out with a weekly frequency of 2-3 times/week and a total intervention time of 6-12 weeks. The exercise intensity control was reported in four studies. The exercise load ranged from 40 to 75% of 1RM, except for one study in which the load corresponded to 50–60% of the 10-repetition maximum (RM) (Elboim-Gabyzon et al., 2013; Imoto et al., 2013; Rabe et al., 2018). In addition, one study controlled exercise intensity using ratings of perceived exertion (ranging from 10 to 15) (Park et al., 2021). Two studies did not describe exercise intensity (Laufer et al., 2014; Rosemffet et al. 2004). Progression of the exercise programs was reported by three authors, according to details presented in Table 2 (Elboim-Gabyzon et al., 2013; Park et al., 2021; Rabe et al., 2018).

Risk of bias in studies

The results of the risk of bias assessment from individual studies and the overall risk of bias are seen in Figures 2 and 3. Based on the RoB 2 tool overall risk of bias was high, with five of the six assessed studies judged as a general risk of bias of 'high risk' and only one graded as 'some concerns'. The main methodological problem that resulted in a high risk of bias was the lack of blinding of the outcome assessors, or outcome assessment has been influenced by knowledge of the intervention received. On the other hand, the absence of a study protocol or registration on a clinical trial platform influenced the risk of bias.

	Risk of bias domains					Overall
	D1	D2	D3	D4	D5	
Rosemffet et al. (2004)	-	-	+	X	-	X
Elboim-Gabyzon, Rozen, Laufer (2012)	+	-	+	X	-	X
Imoto et al. (2013)	+	+	+	+	-	-
Laufer, Shtraker, Elboim Gabyzon (2014)	+	-	+	X	-	X
Rabe et al. (2018)	+	X	+	+	-	X
Park et al. (2021)	-	-	+	X	-	X

Domains:
D1: Bias arising from the randomization process.
D2: Bias due to deviations from intended intervention.
D3: Bias due to missing outcome data.
D4: Bias in measurement of the outcome.
D5: Bias in selection of the reported result.

Judgement
X High
- Some concerns
+ Low

Figure 2. Risk of bias from individual studies.

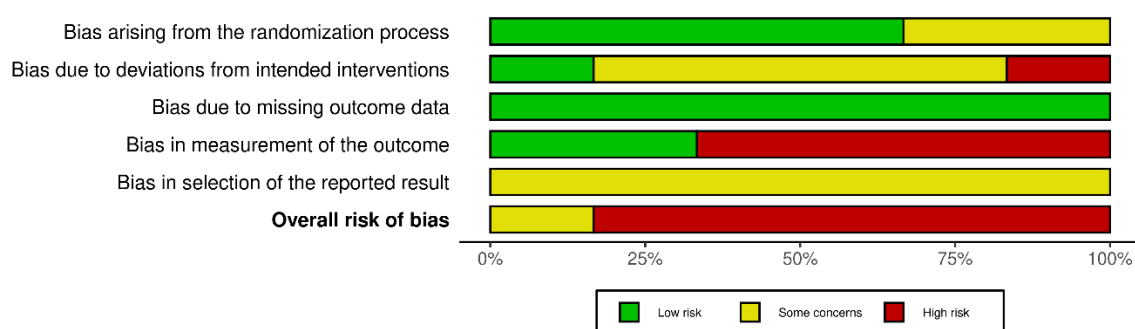


Figure 3. Overall risk of bias.

Results of individual studies

The effect of NMES plus exercise on pain was examined through a random-effect model by pooling data from two trials (137 participants). No significant effect of NMES at a specific joint angle combined with exercise on pain was detected (SMD, -0.33; 95% CI, - 1.05 to 0.39; $I^2=76\%$; $p=0.37$) (Fig 4). Our meta-analysis of the pain outcome was based on only two studies for the following reasons. One study lacked sufficient data to be included, while the other study incorporated data from a previous study by adding follow-up findings (Laufer et al., 2014; Rosemffet et al., 2004). The remaining two studies used

different NMES modalities (hybrid training system and whole-body configuration) (Park et al., 2021; Rabe et al., 2018).

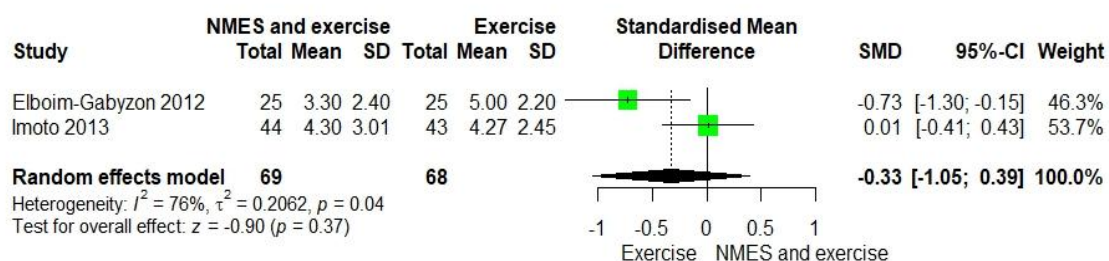


Figure 4. Effect of NMES and exercise on pain.

Two studies evaluated the effectiveness of NMES on the quadriceps femoris muscle in the involved leg in addition to an exercise program (Elboim-Gabyzon et al., 2013; Laufer et al., 2014). The authors reported a significant difference in the NMES group, indicating a greater decrease in pain (VAS) than in the control group (Elboim-Gabyzon et al., 2013). The result was maintained for 12 weeks after the training program (Laufer et al., 2014). There was no substantial change in self-reported functional ability according to the total sum score of WOMAC between the groups (Elboim-Gabyzon et al., 2013; Laufer et al., 2014).

In a pilot study, NMES combined with exercise resulted in no difference in pain intensity, according to VAS (Rosemffet et al., 2004). Similarly, in another study, NMES combined with exercise was applied on the quadriceps femoris. However, the authors evaluated pain according to NRS and WOMAC with pain, stiffness, and physical function subscales. There was no difference in change from baseline to 8 weeks between the two groups in all self-reported outcomes (Imoto et al., 2013).

Only one study evaluated the effectiveness of a low-load exercise program, using a hybrid training system with a combination of NMES and volitional contractions on quadriceps femoris and hamstring compared with a low-load exercise program alone. The authors used only KOOS Pain Subscale and found no differences between the groups from baseline to 12 weeks (Rabe et al., 2018). A study by Park and co-authors evaluated the effectiveness of isometric exercises wearing a suit with electrostimulation compared with isometric exercise

alone on KOSS subscales (Park et al., 2021). Scores for pain, symptoms, activities of daily living sports function, and quality of life in the isometric exercise group alone were lower than those in the electrostimulation group.

We could not perform a meta-analysis on other PROMs due to insufficient data. WOMAC data were presented in different ways in the studies, some showing the total score and others the scores of the subscales of pain, stiffness, and function (Elboim-Gabyzon et al., 2013; Imoto et al., 2013; Laufer et al., 2014; Rosemffet et al., 2004). The KOSS questionnaire was described with all subscales; in the other, only one subscale (Park et al., 2021; Rabe et al., 2018). Intervention characteristics and their effects on PROMs are described in Table 2.

Table 2. Characteristics of interventions and main findings.

Author, year	Intervention	Main findings
Rosemffet et al., (2004)	<u>NMES and exercise group vs. exercise group alone (8 weeks)</u> <i>NMES three times per week over 30 minutes.</i> - NMES device: not reported; - NMES in sitting position; - Stimulation electrodes position: quadriceps femoris (authors did not describe electrode size); - Wave form: monophasic with an amplitude of 0.2 mls;g; - Frequency: 25-Hz; - Pulse duration: not reported. - TON and TOFF: 5s; - Intensity: according to the people's tolerance. <i>Exercise program twice week, over 1 hour and 15 minutes.</i> - Warm-up (10 minutes); - Brisk walk (10 minutes); - Bicycle with progressive resistance (10 minutes); - Isotonic and isometric exercises (30 minutes);	No difference between groups regarding pain. Both interventions reduced pain equally.

	- Stretching (15 minutes), with special emphasis on the lower limbs.	
Elboim-Gabyzon et al., (2012)	<u>NMES and exercise group vs. exercise group alone (6 weeks)</u> <i>NMES twice week over 10 minutes</i> - NMES device: Enraf Nonius Myomed 932; - NMES in sitting position (hips and knees flexed at 90°); - Stimulation electrodes position: Two electrodes (17 x 7.5 cm) on quadriceps femoris. - Wave form: biphasic; - Frequency: 75 Hz; - Pulse duration: 200 µs; - TON: 10s; - TOFF: 50s; - Intensity: according to the people's tolerance (max 100mA). <i>Exercise program twice week over 45 minutes</i> - Range of motion exercises; - Knee and lower extremity muscle-strengthening exercises; - Functional activities; - Balance training; - Exercises had five levels of difficulty according with the number of repetitions, resistance (e.g. weights for knee extension resistance), time and external support. - Training load: 50-75% of the 1RM.	NMES intervention shows greater decrease in pain compared to exercise group. A significant decrease in pain intensity was demonstrated following both treatments. Both interventions improved Self-reported functional ability equally with no differences between groups.
Imoto et al., (2013)	<u>NMES and exercise group vs. exercise group alone (8 weeks)</u> <i>NMES twice week over 20 minutes</i> - NMES device: Globus ACTIVA 600 Pro; - NMES in sitting position (hips and knees flexed at 90°); - Stimulation electrodes position: Two electrodes (7.5 x 13 cm) on quadriceps femoris.	No difference between groups regarding outcomes. Both interventions decrease pain and improve stiffness and function equally.

- Wave form: pulsed, biphasic, asymmetrical, and rectangular waveform.
- Frequency: 50 Hz;
- Pulse duration: 250 μ s;
- TON: 10s;
- TOFF: 50s;
- Intensity: maximum tolerated by each people.

Exercise program twice week over 40 minutes

- Warm-up on a stationary bicycle ergometer;
- Stretching of hamstrings muscles with the aid of an elastic band;
- Knee extension exercises;
- Training load: 50-60% of the 10RM.

Laufer (2014)	et al.,	<u>NMES and exercise group vs. exercise group alone (12 treatments)</u>	NMES intervention shows greater decrease in pain compared to exercise group. A significant decrease in pain intensity was demonstrated following both treatments.
		<i>NMES twice week</i>	
		- NMES device: Enraf Nonius Myomed 932; - Stimulation electrodes position: quadriceps femoris (authors did not describe electrode size); - Intensity: maximum tolerated by each patient; - The authors did not describe a detailed NMES protocol.	Both interventions improved self-reported functional ability equally with no differences between groups.
		<i>Exercise program twice week</i>	
		- The authors did not describe exercise protocol.	No differences between the posttest and the follow-up assessments for pain and self-reported functional ability.
			The differences for pain, and self-reported

functional ability between the pretest and follow-up assessment indicate these variables maintained improvements 12 weeks after completion of the program.

Rabe et al., (2018) Hybrid training system (combination of NMES and volitional contractions) vs. low load resistance exercise (12-weeks). No difference between groups regarding pain. Both interventions reduced pain equally.

NMES twice week

- NMES device: HIZA TRAINER, EU-JLM50S, Panasonic Corporation, Osaka, Japan.
- NMES in a seated position with feet not touching the floor.
- Stimulation electrodes position: anterior thigh over the vastus medialis, vastus lateralis, rectus femoris (15 x 6 cm), and medial and lateral hamstrings on the posterior thigh (12 x 6 cm).
- Wave form: standard Russian current.
- Frequency: 40 Hz;
- Pulse duration: 200 μ s;
- TON: 3-seconds (knee extension); 3-seconds (knee flexion) – 5 sets of 10 repetitions.
- TOFF: 30s;
- Intensity: maximum tolerated by each people with progression.

Exercise program twice week

- 5 sets of 10 repetitions of 3-second isokinetic extension and flexion contractions;
- 30-seconds of rest period.

- Intensity: 40% of the isotonic 1RM on each leg using the isokinetic dynamometer.

Park et al., (2021)

Isometric exercise and electromyostimulation group vs. isometric exercise group alone (8 weeks)

Isometric exercise and electromyostimulation group three times a week over 30 min

- NMES device: Miracle, Seoul, South Korea.
- Isometric exercise wearing a whole-body suit with electrical stimulation during 20 minutes.
- Full body stretch before and after the exercise intervention during 5 minutes.
- Eight types of isometric movements were performed during the impulse phase (abdomen crunches, bridge, leg raises, side planks, back extension, front planks, front lunges, and squats).
- Stimulation electrodes position: upper legs, both upper arms, buttocks, abdomen, chest, lower back, upper back, and latissimus dorsi.
- Wave form: rectangular.
- Frequency: 85 Hz.
- Pulse duration: 350 μ s.
- TON: 6s.
- TOFF: 4s.
- Intensity:
 - 60% of 1MT from baseline to week 2;
 - 70% of 1MT from week 3 to week 5;
 - 80% of 1MT from week 6 to week 8.

Isometric exercise group three times a week over 30 minutes

Electromyostimulation combined with isometric exercise shows greater improvement in pain, symptoms, and activities of daily living compared to exercise alone.

Both interventions improved pain, symptoms, activities of daily living, sports and recreation and knee-related quality of life.

- Isometric exercise wearing a whole-body suit without electrical stimulation during 20 minutes.
- Full body stretch before and after the exercise intervention during 5 minutes.
- Eight types of isometric movements was performed (abdomen crunches, bridge, leg raises, side planks, back extension, front planks, front lunges, and squats).
- 6-s contraction with a 4-s break.
- Intensity:
 - 10-11/ RPE from baseline to week 2;
 - 12-13/ RPE from week 3 to week 5;
 - 14-15/ RPE from week 6 to week 8.

NMES= Neuromuscular Electrical Stimulation; TON and OFF= Time ON and OFF; 1RM=One-repetition Maximum; 10RM= Ten-repetition Maximum; 1MT= Maximal tolerance; RPE= Rating of perceived exertion.

Results of individual studies based on each outcome

NMES at specific articular angle

Rosemffet et al., (2004) evaluated the effectiveness of exercise combined with NMES compared to a group with NMES alone in the following patient-reported outcomes: pain measured by VAS and self-reported functional ability with WOMAC score in people with knee OA. However, the authors mentioned the WOMAC score in this study with incomplete data. In this sense, we extracted only data about VAS. The results of this study indicate no differences between groups regarding pain. Both interventions reduced pain equally.

Elboim-Gabyzon et al., (2012) and Laufer et al., (2014) examined the effectiveness of applying NMES to the quadriceps femoris muscle to enhance exercise programs for knee OA people. The studies focused on the patient's pain levels (measured by VAS) and self-reported functional ability (measured by WOMAC). NMES combined with exercise resulted in a greater pain reduction than the exercise group. However, both interventions improved the patients' self-reported functional abilities, with no significant differences between the groups.

Laufer et al. (2014) conducted a follow-up study using the same data, which showed no differences in pain and self-reported functional ability between the post-test and follow-up assessments. The improvement in pain and self-reported functional ability from the pretest to the follow-up assessment suggests that these variables were maintained 12 weeks after program completion.

Imoto et al., (2013) conducted a study to evaluate the effectiveness of NMES alone and in combination with exercise in alleviating pain (measured by NRS) and enhancing physical function (measured by each WOMAC subscale) in people with knee OA. The study results revealed no significant difference between the two interventions regarding outcomes. Both interventions were equally effective in reducing pain and improving stiffness and function.

NMES superimposed to voluntary contractions

Rabe et al., (2018) assessed the effectiveness of a low-load exercise program using a hybrid training system that combines NMES and voluntary contractions in people with knee OA. The study compared this program to an active control group regarding its ability to alleviate knee pain (measured by KOOS subscale). The authors found no difference in pain reduction between the two groups, as both interventions were equally effective in reducing pain levels.

NMES in a whole-body configuration

Park et al., (2021) examined whether isometric exercise combined with whole body-electromyostimulation can improve arthritis pain and functional status (measured by KOOS subscale) in elderly women with early knee OA. The authors discovered that the combination of these interventions significantly improved all KOOS subscales, including pain, symptoms (such as clicking, swelling, catching, restricted range of motion, and stiffness), daily living function, sports function, and quality of life.

Discussion

The objective of this study was to explore the effectiveness of NMES additionally to exercise or superimposed voluntary contractions on PROMs compared to exercise alone in people with knee OA. In the qualitative synthesis, the systematic analysis of the literature on this specific topic shows in three studies improvement in pain after NMES combined with exercise compared to exercise alone. In contrast, the other three studies revealed no difference between groups in pain, although similar improvement after treatments. In the meta-analysis, NMES at a specific joint angle combined with exercise was not superior to exercise alone in pain management. It should be highlighted that this random-effect model was obtained by pooling data from only two trials, including 137 participants. There was no additional effect of NMES on self-reported functional ability, stiffness, and physical function. In only one study, symptoms (such as clicking, swelling, catching, restricted range of motion, and stiffness), daily living function, sports function, and quality of life were improved after whole-body electrostimulation combined with exercise.

Previous systematic reviews found that NMES significantly impacts pain, function, and quadriceps femoris muscle strength in knee osteoarthritis (Giggins, Fullen & Coughlan, 2012). However, studies included in this review compared NMES in combination with any other therapeutic intervention that differs from our review. We aimed to investigate NMES only combined with exercise. In this sense, another systematic review found that NMES associated with exercise, compared to an active control group, increased isometric muscle strength of quadriceps muscle in patients with knee osteoarthritis, with very low-certainty evidence (Bispo et al., 2021). Our review focused only on NMES combined with exercise, including other NMES alternatives such as superimposed on voluntary contractions and in a whole-body configuration. In addition, we focus on the effectiveness of combined intervention on PROMs. Another systematic review focuses on providing guidelines for treatment parameters regarding NMES by investigating its efficacy in improving muscle strength and decreasing pain in patients with knee OA (Novak et al., 2020). Our review differs from them for the following reasons: (1) the review protocol was not previously registered on the International Prospective Register of Systematic Reviews (PROSPERO); (2) the

search strategy was not reported with sufficient details for replication; and (3) authors analyzed the risk of bias based on 2005 Oxford standard. In this sense, our review added methodological rigor to this topic compared to the earlier study.

Exercise programs are the primary treatment for knee OA people recommended by the Osteoarthritis Research Society International and appear safe and effective in pain management (Bannuru et al., 2019). In this context, no consensus exists on better exercise and its combination with NMES. A previous meta-analysis showed that combining strengthening exercises with flexibility and aerobic exercises training was the optimal program for people with knee OA (Guo et al., 2022). Studies included in this review used different exercise approaches, including protocols with stretching of hamstrings muscles, knee and lower extremity muscle-strengthening, range of motion, functional activities, balance training, isometric exercises, and superimposed voluntary contractions. In addition, exercise which comprise a core treatment, can be combined with other therapeutic approaches, such as manual therapy and knee brace (Nigam, Satpute & Hall, 2021; Yokoyama et al., 2023).

Included studies were characterized by variability in pain outcome measures. NRS, VAS, WOMAC subscale, and KOSS subscale were used to detect pain changes after treatment. Meta-analysis of two trials indicated no additional effect of NMES to exercise on pain. On the other hand, according to the qualitative synthesis of three trials included in this review, NMES may confer additional effects to exercise or be equally effective concerning pain. One of the authors speculated mechanisms that explain pain relief after NMES, assigning pain relief to intensive sensory input provided by electrically induced contractions (Laufer et al., 2014). Additionally, another study's findings suggested that NMES-superimposed isometric contractions provided a better neuromuscular stimulus since contractions facilitate spinal excitability through a combination of greater motor neuronal and corticospinal excitability (Borzuola et al., 2020). Of the three trials that showed between groups difference in pain, two used NMES only in the quadriceps femoris, and another whole-body electrical stimulation. Considering that knee extensor muscle weakness is associated with incident symptomatic knee OA, NMES on the lower limb or whole body may be an alternative treatment for symptom control (Culvenor et al., 2017).

Self-reported functional ability improved equally exercise group. Several factors may have explained these findings, such as methodological characteristics, including variability in measuring the PROMs. Two studies did not describe subscales of WOMAC, only the total score. Thus, the presentation of the WOMAC subscales (pain, stiffness, and function) is recommended to facilitate the interpretation of the study's findings regarding each domain, including the functional implications of NMES combined with exercise (Copsey et al., 2019). Regarding the subscales of WOMAC, only one study investigated the combined intervention, and no significant differences were found in the pain, stiffness, and function subscales. The authors attribute the study's findings to the fact that the people did not present significant clinical functional and muscular alterations (Imoto et al., 2013).

An essential aspect of the NMES protocol through intervention was muscle length. Two studies applied electrical stimulation in a sitting position with a specific joint angle (hips and knees flexed at 90°) (Elboim-Gabyzon et al., 2013; Imoto et al., 2013). Electrically evoked submaximal isometric contractions at long muscle lengths provide significant muscle damage (Fouré & Gondin, 2021). Thus, NMES with short muscle length seems to be a promising strategy for minimizing muscle damage and better muscle adaptations to electrical stimulation (Fouré et al., 2020). We suggested that this aspect could explain why NMES did not improve physical function in the included studies that described electrical stimulation protocol with long muscle length (hips and knees flexed at 90°).

Park et al., (2021) reported that isometric exercise combined with whole-body electrical stimulation for knee OA people with grade I or II showed better results in pain, symptoms, and activities of daily living. The authors suggested the best results to the higher intensity of exercise when electrical stimulation is combined with exercise. Mechanisms of electrical stimulation with exercise responses in patients with knee OA remain unclear. A previous study suggested that combined therapy should augment the stimuli through greater synchronous recruitment of muscle fibers, thus, promoting a potential accumulation of physiologic effects (Matos et al., 2022). Therefore, to fully explain the impact on muscle and function, a deeper understanding of the neurophysiological adaptations to NMES plus exercise was necessary (Borzuola et al., 2022).

Traditional parameters of NMES can enhance muscle size and function and induce neural adaptations. Nevertheless, to achieve the maximum efficiency of NMES, this modality can be improved by adjusting specific protocols (e.g., parameters, stimulation site, current distribution) (Blazevich et al., 2021). Analysis of all the included articles revealed large variability of NMES parameters, the most common parameters used in knee OA people, according to this review, are: stimulation frequencies ranging from 25 to 85Hz, pulse duration from 200 to 350 μ s, session time ranging from 10-30 min, with a weekly frequency of 2-3 times/week, and a total intervention time of 6-12 weeks. One study did not describe all the stimulation parameters (Laufer et al., 2014). The current intensity was monitored according to the people's tolerance, and in only one study, a maximal rating of perceived exertion scale was used (Park et al., 2021). In this review, NMES was applied only on the quadriceps femoris, two antagonistic muscles (quadriceps and hamstrings), or in a whole-body configuration. Other studies used similar parameters in orthopedic populations, such as people after knee arthroplasty surgery or anterior cruciate ligament reconstruction (Conley et al., 2021; Kim et al., 2010).

The results of this systematic review summarize NMES responses in addition to exercise on patient-reported outcomes. The risk of bias in the selected studies was analyzed using the ROB 2 tool. Previous systematic reviews have analyzed the repercussions of electrical stimulation in people with knee OA (Giggins et al., 2012; Novak et al., 2020; de Oliveira Melo et al., 2013). However, they have not analyzed the risk of bias. The only study that conducted such an assessment used the previous tool version (Bispo et al., 2021). Thus, one of this review's strengths is that it analyzed the risk of bias in studies based on outcomes deemed to be the most critical for decision-making, as recommended by Cochrane (Flemyng et al., 2023).

The findings of the present systematic review must be interpreted with caution since most of the studies were classified as having a "high risk of bias." Bias in the measurement of the outcome was the main factor that classified the studies as "high risk of bias." In some studies, there was insufficient information about blinding of outcome assessors. In addition, the evaluation of treatment on the outcome of each trial included in this review may have been influenced by knowledge of the intervention received, once the people self-reported the

outcomes. However, it is essential to mention that recommended core set of measures by OARSI Clinical Trials Recommendation includes the PROMs (Fitzgerald et al., 2015). Furthermore, most studies did not blind participants due to the nature of the intervention. Only one study was their blinding participants since all eligible people were instructed to wear their whole-body electrical stimulation suits and were blinded if electrical stimulation was provided. Despite the high risk of bias in the studies of the present review, it is essential to mention the potential impact of the findings by highlighting the need for new clinical trials to understand better the effectiveness of the combined intervention (NMES plus exercise) in patients with knee osteoarthritis in PROMs.

This study has some limitations. First, most included studies looked at intervention effects immediately after treatment and did not perform a follow-up. Therefore, it is impossible to infer the long-term responses of NMES. Second, the findings of this review come from only six randomized controlled trials. Third, insufficient data on pain and physical function precluded the meta-analysis with these results. Fourth, the variability of the NMES prevented the meta-analysis with all studies since some trials implemented the protocol in a specific joint angle, with a hybrid muscle contraction system, or in a whole-body configuration. Finally, we suggest conducting future clinical trials with robust methodological quality and observing long-term treatment responses. A detailed description of the randomization process, blinding of outcome assessors, and presentation of the intention-to-treat analysis are suggested in future trials. Future trials should consider testing interventions that include a promise combined isometric exercise and NMES in a whole-body configuration to deliver electrophysical modality in dynamic mode.

Implications for physiotherapy practice

NMES combined with exercise may be a therapeutic alternative to reduce pain in people with knee OA compared to exercise alone, with no effects on physical function. Several guidelines recommend therapeutic exercise as a treatment for knee OA. However, there is insufficient evidence to prescribe combined intervention (NMES plus exercise) in clinical practice to improve PROMs since only exercise improves outcomes. Furthermore, using electrical

stimulation in a whole-body configuration plus isometric exercises can be a promising future therapeutic alternative to improve PROMs.

Conclusion

This review found insufficient evidence for the effectiveness of NMES combined with exercise to improve PROMs in people with knee OA. Although there may be a decrease in pain in certain studies, future high-quality clinical trials are required to confirm the use of NMES in conjunction with exercise in clinical settings.

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ARTIGO 2

Submetido ao periódico *Annals of Physical and Rehabilitation Medicine* (fator de impacto 3.9), conforme a diretriz para autores (Anexo IV), em 4 de novembro de 2024, com retorno da revisão por pares em 29 de dezembro de 2024, e nova submissão em 25 de janeiro de 2025.

Ultrasonographic Assessment of Quadriceps Muscle Architecture and Quality in People with Knee Osteoarthritis: A Systematic Review

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Alberton

Abstract

Background: Knee osteoarthritis (OA) is a painful joint condition characterized by changes in quadriceps femoris muscle architecture and quality. While ultrasound is an emerging tool for evaluating muscle condition in this population, its usefulness and clinical implications remain unclear.

Objectives: Investigate the effects of knee OA on quadriceps muscle architecture, summarizing ultrasound protocols used in studies, and explore the associations between muscle characteristics with symptoms and physical function.

Materials and methods: This systematic review was described according to the Preferred Reporting Items for Systematic Reviews and Meta-Analyses guidelines. Searches across three electronic databases (PubMed, PEDro, and EMBASE) were performed by two independent investigators, according to strict inclusion and exclusion criteria.

Results: The findings highlight that ultrasound protocols often lack detailed descriptions, even if there is growing interest in how the quadriceps femoris muscle changes in knee osteoarthritis people, particularly in muscle thickness and echo intensity. Muscle changes include reduced muscle thickness in the vastus medialis and decreased muscle quality in both the vastus medialis and vastus intermedius. Additionally, quadriceps femoris muscle thickness is associated with condition-specific patient-reported outcomes and physical function in knee OA people, while there is a relationship between echo intensity and physical function.

Conclusions: In conclusion, the study highlights the need for standardized ultrasound protocols to capture changes in quadriceps muscle architecture and quality, as some of these changes correlated to patient-reported outcomes measures and physical function in knee OA people.

Trial registration: PROSPERO database (registration number: CRD42023471617). No funding.

Keywords: Osteoarthritis, Knee; Muscle degeneration; Ultrasound; Pain; Physical function; Physical medicine.

Introduction

Knee osteoarthritis (OA) is a multifactorial joint disease with a high global prevalence and is one of the leading causes of disability worldwide [1,2]. Weakness in the knee extensor muscle has clinical consequences in this joint disease, with increasing risks of symptomatic and radiographic manifestations of knee OA in both women and men [3]. However, other deficits in skeletal muscle, including changes in quadriceps femoris architecture and muscle quality, coexist with this weakness [4]. Quadriceps femoris architecture encompasses parameters such as muscle thickness, cross-sectional area, pennation angle, and fascicle length, and differences have been previously identified in muscle thickness, pennation angle, and fascicle length when comparing people with knee OA to healthy individuals [5,6]. Muscle quality, often assessed via echo intensity (ECHO) [7], reflects the physiological properties of skeletal muscle, including the amount of contractile tissue as well as the muscle's adipogenic and fibrotic status [8]. Notably, changes in muscle quantity and quality differ according to knee OA progression, with earlier changes noted in the vastus medialis (VM) [4].

A previous systematic review highlighted that individuals with knee OA have higher intermuscular and intramuscular fat levels in their thigh muscles compared to healthy controls, indicating a loss of muscle quality [9]. This study included data on fat infiltration within and between muscles; however, it was not designed to include data from studies considering the measurement of ECHO or studies examining muscle architecture outcomes. Another systematic review summarized the available evidence regarding differences in the entire quadriceps femoris architecture or any individual part using imaging techniques in patellofemoral pain pathology [10]. Findings indicate controversial results related to the role of quadriceps femoris degeneration in patellofemoral pain pathology. While some studies indicate no difference in quadriceps muscle architecture between patellofemoral pain people and healthy participants, other studies found a significant difference between symptomatic and asymptomatic limbs of

the patellofemoral pain people. In addition, none of the above-cited reviews investigated the relationship between quadriceps muscle architecture and patient-reported outcome measures (PROMs) or functional status in people with knee OA.

Ultrasound is a valuable tool for assessing the quantity and quality of the quadriceps muscle in several clinical populations with joint pain because it offers a pain-free method for skeletal muscle evaluation and advantages such as cost-effectiveness [11-13]. In a previous systematic review, authors searched studies that described US protocols to assess skeletal or diaphragm muscles considering a different clinical population, people who are critically ill. However, to our knowledge, no systematic review has summarized US protocols to assess the quadriceps femoris muscle in people with knee OA.

Therefore, summarizing the muscle ultrasound protocols for people with knee OA is relevant to help clinicians conduct a better muscle assessment in clinical settings [14]. In this sense, the present systematic review aims to 1) Analyze ultrasound protocols for measuring quadriceps architecture in knee OA people; 2) Summarize literature on differences in quadriceps architecture between individuals with and without knee OA; and 3) Investigate associations between quadriceps architecture and condition-specific PROMs or functional measurements in people with knee OA.

Materials and methods

The study was conducted in accordance with the Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) [15]. The complete PRISMA checklist is available in the supplementary material. The study protocol was prospectively registered with the International Prospective Register of Systematic Reviews (PROSPERO) under CRD42023471617.

Eligibility criteria

The inclusion criteria were as follows:

- (1) People/exposure: People diagnosed with primary knee OA, regardless of sex or whether it affects one knee (unilateral) or both knees (bilateral). The diagnosis of knee OA must be based on the American College of Rheumatology (ACR) guidelines, which consider clinical and radiographic characteristics according to Kellgren and Lawrence criteria (Grade I to IV);
- (2) Comparators: Healthy individuals served as the comparator group. In addition, studies without a comparator were included if they investigated associations between quadriceps architecture and quality with PROMs and/or functional measurements;
- (3) Outcomes:
 - Quadriceps femoris (rectus femoris (RF), vastus intermedius (VI), VM, and vastus lateralis (VL)) architecture: muscle thickness, cross-sectional area, pennation angle, and fascicle length;
 - Quadriceps muscle quality: Muscle quality indicates the amount of contractile tissue and intramuscular fat infiltration [8]. ECHO, as a biomarker of muscle quality, is measured according to the pixel intensity of the muscle image. A higher ECHO value indicates a decline in muscle quality.

- PROMs related to symptoms (variable among different studies): Numerical Rating Scale, Visual Analogue Scale, The Western Ontario and McMaster Universities Osteoarthritis (WOMAC) Index, The Knee Injury and Osteoarthritis Score, and The Knee Society's Knee Scoring System;
 - Functional measurements: Physical function tests, including (but not limited to) Timed Up and Go, Six-Minute Walk, 20-Meter Walking, Sit-to-Stand, and Stair Climbing Tests;
- (4) Study design: observational studies, such as cohort, cross-sectional, and case-control designs, published in peer-reviewed journals in Portuguese, English, and Spanish languages.

Studies were excluded based on the following criteria:

- (1) Study design: pre-clinical studies, abstracts, case reports, review articles, editorials, pre-prints, and articles without original data, randomized clinical trials;
- (2) Outcome measures: studies investigating associations with clinical parameters other than quadriceps architecture or quality, such as joint structures; studies using image techniques other than ultrasound (e.g., magnetic resonance imaging, computerized tomography, bioelectrical impedance analysis); studies with no appropriate outcome measures or validated ultrasound metrics;
- (3) Population: studies involving people with other rheumatologic diseases or clinical conditions such as lupus, rheumatoid arthritis, hip or hand OA only, knee OA with coexisting OA in another joint, and anterior cruciate ligament reconstruction.

Information sources and search strategy

A systematic literature search was conducted on November 5, 2023, in three electronic databases (PubMed, PEDro, and EMBASE) by two independent investigators (MTXC and VHGP). The search period ranged from the earliest manuscript available to November 5, 2023. The search terms included both text words and Medical Subject Heading (MeSH) terms, specifically “Ultrasonography” and “Osteoarthritis, Knee”. These terms were combined using Boolean operators (AND or OR). The complete search strategy for each database is available in the supplementary material (Supplementary Table S1). An additional search of the gray literature was performed in August 3, 2024 using Google Scholar, applying the same search terms used in the databases.

Selection and Data Collection Process

All retrieved references were imported into the Rayyan app for screening. Two independent investigators (MTXC and VHGP) reviewed the search results, and duplicates were removed using Rayyan’s automatic tool. Titles and abstracts of all articles identified by the search strategy were screened to identify potential eligibility. Before full screening, both investigators conducted a pilot review of 100 articles to ensure standardization. Additionally, reference lists of the retrieved articles were manually checked to ensure that all relevant studies were included. All abstracts that did not provide sufficient information regarding the inclusion and exclusion criteria were further assessed in the full-text form. Any disagreements were resolved through discussion between the reviewers to reach a consensus or by consulting a third independent reviewer (CLA).

Assessment of methodological quality

Two investigators (MTXC and VHGP) independently assessed the methodological quality of the included studies using the Newcastle Ottawa Quality Assessment Scale for Cohort Studies for observational cohort studies and an adapted version for cross-sectional studies [1]. Any disagreements were resolved through discussion between the reviewers to reach a consensus or by consulting a third independent reviewer (CLA).

Data extraction and synthesis

Relevant study characteristics and clinical outcome measures were extracted using a standardized form created by the authors in Excel. The standardized form included basic information from the qualified studies. The synthesized data from each study are summarized in tables focusing on the following topics:

(1) Data synthesis according to the study and people characteristics: lead author, year of publication, study location, study design (cross-sectional or cohort study), sample size, people characteristics (age, sex, body mass index, and knee OA grade and affected side), ultrasound outcomes (e.g., muscle thickness, cross-sectional area, pennation angle, fascicle length, and muscle quality via ECHO, and the ultrasound protocol (imaging parameters, people positioning, number of measurements).

(2) Data synthesis according to study design:

(2a) Case-control and cohort studies investigating differences in quadriceps architecture between people with knee OA and healthy controls were summarized in a table with the main findings, including measures of variability or effect size (mean and standard deviation and Cohen's *d* for group comparisons).

(2b) Cross-sectional studies investigating associations between quadriceps femoris architecture and PROMs and/or physical function measures in people with knee OA are summarized in a table, including the main findings, and effect estimates, such as relative risk, odds ratio, correlation coefficient (r), or coefficient of determination (r^2).

Results

Study selection

The database search initially retrieved a total number of 869 studies. After removing duplicates, 764 remained for screening (Fig. 1). The titles and abstracts of these 764 studies were reviewed for eligibility, leading to 28 potentially relevant studies being selected for full-text review. After assessing the full texts, eleven studies were excluded for the following reasons: three based on population criteria, seven due to study design, and one because of outcome measures. Of the 28 potentially relevant studies, 17 were included in this systematic review according to database search [4, 6, 16-30]. An additional study was identified through a search on grey literature [31]. Finally, 18 observational studies were included in the final review. The flowchart outlining the review process is shown in Figure 1.

People characteristics

The studies included in this review were published between 2008 and 2024, examining ultrasound outcomes in a total of 770 people with knee OA. Nine studies included people based on radiographic criteria defined by Kellgren and Lawrence classification [4, 6, 16-20, 23, 24], four studies used the symptomatic presentation as determined by the American Rheumatology Criteria [21, 25, 27, 31], and five studies applied both radiographic and clinical criteria [22, 26, 28-30]. Among the studies, nine included both male and female [6, 18, 19, 24, 26-28, 31], eight included only female [4, 17, 21, 22, 23,

25, 29, 30], and one study focused solely on male [16]. The age of people ranged from 45.3 to 74.3 years, with body mass index ranging from 22.1 to 33.0 kg/m². People characteristics are summarized in Table 1.

Ultrasound protocols

Ultrasound parameters

The equipment characteristics were reported in 18 studies included in this systematic review [4, 6, 16-31]. However, in most of these studies, image parameters for muscle ultrasound assessments — such as probe frequency [6, 18, 19, 23, 25-27, 31], mode [16-21, 24, 26-28], gain [6, 16-21, 23-28], dynamic range [6, 16-21, 23-28, 30] time gain compensation [6, 16-29, 31], depth [6, 16-20, 22-29] and focus [6, 16-20, 23-28, 31] — were not consistently detailed. Reported probe frequencies ranged from 4 to 14 MHz [4, 16, 17, 20-22, 24, 28-30] with B-mode as the primary ultrasound mode [4, 6, 22, 23, 29-31]. Gain settings varied between 50 and 58 dB [4, 22, 29-31], and the dynamic range was reported to range from 69 to 72 dB [4, 22, 29, 31]. Time gain compensation was generally described as being in a “neutral position” [4, 30], while depth settings ranged from 3 to 6 cm [4, 21, 30, 31]. Focus was generally set to the depth of the muscle of interest [4, 22, 29]. The software tools used for image analysis included OsiriX MD [23], Python scripts [21], MATLAB R2015b [20], Scion Image [16], and ImageJ [6, 17, 22, 29-31]. A summary of the ultrasound protocols is provided in Table 1.

People positioning

People positioning was reported in all 18 studies [4, 6, 16-31]. Most studies positioned people in the supine position for muscle assessment. However, three studies had people seated in an isokinetic dynamometer chair with knees flexed at angles of 90°, 60°, or 45° [17, 21, 23]. Only one of these studies specified that the hip angle was flexed at 85° [17].

Additionally, one study positioned people supine with knees supported by a bolster at a 30° angle [31].

Probe compression

Nine studies included in this systematic review reported probe compression details [16, 18-21, 25, 28, 30, 31]. In these studies, the probe was described as positioned with minimal compression, just enough to visualize the muscles under the skin.

Review findings

Quadriceps muscle architecture outcomes

Four studies evaluated all portions of the quadriceps femoris (RF, VI, VM, and VL) [4, 22, 28, 30]. Two studies focused on three portions: one assessed the RF, VL, and VI, while the other examined the RF, VM, and VL, respectively [16, 23]. Seven studies evaluated two portions of the quadriceps femoris: six assessed the muscle layer comprising the RF and VI [18, 19, 21, 24, 26, 27], while one examined the RF and VL [20]. Additionally, five studies each focused on a single portion of the quadriceps femoris, specifically the RF, VM, or VL [6, 17, 25, 29]. In most studies, the primary ultrasound outcome measure was muscle thickness (n=15) [4, 6, 16-22, 24-29], with several studies specifically assessing muscle layer thickness (n=6) [18, 19, 20, 24, 26, 27]. Other outcome measures included ECHO (n=8) [4, 16, 20-22, 29, 30, 31], cross-sectional area (n=2) [16, 23], pennation angle (n=2), and fascicle angle (n=2) [6, 17].

Quadriceps muscle architecture in knee OA and healthy people.

Eleven studies compared muscle ultrasound outcomes between people with knee OA and healthy individuals, as summarized in Table 2 [4, 6, 16, 17, 22-27, 30]. Among these, nine studies reported muscle thickness measurements [4, 6, 16, 17, 22, 24-27] four

assessed echo intensity [4, 16, 22, 30], two evaluated cross-sectional area [16, 23], and two examined pennation angle and fascicle length [6, 17].

Muscle thickness, pennation angle and fascicle length

Four of the five studies that assessed the RF muscle thickness found no significant difference between people with knee OA and healthy participants [4, 16, 22, 25]. Only one study reported greater RF muscle thickness in knee OA people compared to healthy individuals [24]. Three of the four studies that measured VI muscle thickness found no significant difference [16, 22, 24], while one reported reduced VI thickness in knee OA people [4].

Additionally, three studies evaluated the combined muscle layer thickness (RF+VI) [24, 26, 27]. Of these, two found similar muscle layer thickness between knee OA people and healthy participants [24, 26], while one study reported a decrease in muscle thickness in the OA group [27].

Three of the five studies assessing VL muscle thickness found similar muscle conditions between people with knee OA and healthy participants [4, 16, 22]. At the same time, the other two reported reduced VL muscle thickness in knee OA people [17, 19]. Lastly, two studies assessing VM muscle thickness found a decrease in muscle thickness in knee OA people compared to healthy participants [4, 22].

Only two studies assessed the pennation angle and fascicle length of the VL muscle [6,17]. In one study, the pennation angle was lower in people with knee OA compared to healthy participants [6], while in the other study, this outcome was similar between the groups [17]. Both studies assessing fascicle length reported shorter fascicles in people with knee OA compared to healthy participants [6,17].

Cross-sectional area

Two studies assessing the cross-sectional area of the quadriceps femoris muscle found no significant difference between knee OA people and healthy participants [16, 23].

Echo intensity

Three studies assessed the ECHO of the RF and VI in people with knee OA [4, 16, 22]. One study reported decreased RF muscle quality [16], while two found no difference compared to healthy participants [4, 22]. In contrast, all studies evaluating the VI reported reduced muscle quality [4, 16, 22]. Two studies assessing the VM showed a reduction in muscle quality [4, 22]. Finally, in three studies assessing VL, no significant difference in muscle quality was observed between knee OA people and healthy participants [4, 16, 22]. According to knee OA severity, one study found a higher VM echo intensity in the severe and mild OA people compared to healthy participants, while a higher VI ECHO in the severe OA people compared to healthy participants [4]. In contrast, there was no difference in RF and VL ECHO between groups (mild OA, severe OA, and healthy participants) [4]. In another study, RF, VL and VM ECHO did not differ according to knee OA severity [16].

Differences in Quadriceps Muscle Architecture Between People with Unilateral or Bilateral Symptomatic Knee Osteoarthritis

A single study [28] evaluated quadriceps muscle thickness, specifically the RF, VI, VL, and VM in people with symptomatic and radiographic knee OA affecting either one leg (unilateral) or both legs (bilateral). In addition, both groups (unilateral or bilateral knee OA) were classified according to pain severity, assessed with Visual Analogue Scale as the relatively serious leg and the contralateral leg as the relatively moderate leg. In the unilateral OA group, the thickness of the evaluated muscles was reduced in both the relatively serious leg and the relatively moderate leg, with the most pronounced decrease observed in the VM. In the bilateral OA group, the RF, VI, and VL muscles were thinner in the more severely affected leg than the relatively moderate leg, although no difference has been observed in VM muscle thickness.

Association between quadriceps architecture and patient-reported outcomes measures

Seven studies assessed the relationship between quadriceps muscle characteristics and PROMs [18, 19, 21, 23, 27, 29, 31]. Of them, three studies evaluated the relationship between quadriceps muscle layer thickness and pain intensity, as well as WOMAC pain, stiffness, or physical function scores, found a negative correlation between these outcomes [18, 19, 27]. In contrast, one study found no relationship between quadriceps muscle thickness (RF and VL) and pain intensity or self-reported function [21]. Another study found no relationship between muscle cross-sectional area of RF, VM and VL with pain during gait [23]. Additionally, two studies assessing VM muscle thickness and cross-sectional area found no significant relationship with pain or self-reported functional measure [23, 29].

Three studies investigated the relationship between echo intensity and PROMs [21, 29, 31]. Two found no correlation between RF echo intensity and pain intensity [21, 31], while one reported a relationship between RF echo intensity and movement-evoked pain [31]. One study reported no association between VL echo intensity and pain intensity [21], and another study verified that VM echo intensity was significantly associated with the progression of functional disabilities and symptoms [29].

Association between quadriceps architecture and functional measurements

Four studies assessed the relationship between quadriceps muscle thickness and functional measurements [18, 20, 21, 27]. Of them, three found a negative relationship between quadriceps muscle layer thickness and functional performance, including the Timed Up and Go test, 10-meter walking test, 50-meter walking test, and 10-step stair test [18, 20, 27]. One study, however, found no relationship between the thickness of the RF, and VL and the six-minute walk distance [21]. Two studies assessed the relationship between quadriceps muscle ECHO and functional measurements [20, 21]. Both found a significant relationship between quadriceps muscle ECHO and functional performance,

with functional measurements including a six-minute walking test and the Timed Up and Go test. Table 2 summarizes the details of each study.

Quality of studies

Seventeen studies investigating quadriceps femoris architecture and muscle quality outcomes were evaluated using the Newcastle Ottawa Quality Assessment Scale adapted for cross-sectional studies. The results were as follows: one study scored 0 points; four studies scored 3 points; four studies scored 4 points; three studies scored 5 points; two studies scored 6 points; and three studies scored 8 points. The methodological quality of these studies is detailed in Table 3. One study was classified as a cohort study; thus, it was evaluated using the Newcastle - Ottawa Quality Assessment Scale for Cohort Studies and received a score of 6 points.

Discussion

Muscle evaluation using ultrasound in people with knee OA has been studied since 2008. However, several important measurement parameters remain underexplored in the literature. Most studies focus on muscle thickness and ECHO, with fewer addressing muscle cross-sectional area, pennation angle, and fascicle angle. The impact of knee OA on the muscle thickness of the RF, VI, and VL muscles remains unclear. While most studies report similar muscle thicknesses between people with OA and healthy controls, some suggest an increased RF and reduced VI, and VL muscle thickness. In contrast, studies consistently show decreased muscle thickness in the VM of people with OA. Concerning the cross-sectional area, no significant differences between OA people and healthy individuals have been observed. In terms of muscle quality, the effects of OA on the RF are inconclusive, although a reduction in muscle quality has been consistently noted in the VI and VM, with no significant changes in the VL. Regarding the pennation angle, the impact of knee OA remains uncertain, while studies have shown a reduction

in the fascicle length in people with OA. Quadriceps femoris muscle layer thickness is negatively correlated with pain, functional condition, and joint stiffness. Both muscle thickness and quality have been associated with functional performance in knee OA people.

In a systematic review exploring ultrasound measurements for assessing skeletal and diaphragmatic muscles in people who are critically ill [14], the authors reported that many crucial ultrasound measurement parameters were not adequately described in the studies, including those mentioned in our review findings. Key ultrasound parameters — such as probe frequency, mode, gain, dynamic range, time gain compensation, depth, and focus — are essential for ensuring replicability and guiding clinicians during ultrasound evaluations of people with knee OA. Another systematic review's findings emphasized the need to standardize these parameters to advance and improve the use of ultrasound in clinical practice [31]. Although our review identifies potential pathways for defining equipment parameters for quadriceps femoris muscle measurements, the inconsistent reporting across studies hinders the establishment of a consensus on the most appropriate parameters.

Standardizing ultrasound equipment settings is essential for accurately assessing muscle quality. Key parameters such as gain, time gain compensation, dynamic range, and focus are known to influence pixel intensities [32]. In several studies included in this review, the authors failed to report these essential parameters for muscle quality measurements. This finding raises the question about whether all assessments were conducted with the necessary standardization. A previous study found that ECHO remains stable between depths of 4.0cm and 6.0 cm, and changes according to gain adjustment [33]. In other words, there is an acceptable margin of variation for depth and the need for specific and constant gain adjustment between muscle scans to reliable muscle quality assessment. Another parameter that needs special attention in muscle quality assessment is focus because a focus depth adjusted to the center of the muscle reflected intramuscular fat infiltration more accurately than that without adjustment [34].

Regarding ultrasound outcomes, quadriceps muscle thickness, a key measure of muscle architecture, was the primary parameter reported in studies involving people with knee OA. This parameter is clinically significant, as low skeletal muscle mass has been independently associated with radiographic manifestations of OA [35]. In particular, lower limb muscle mass has been linked to the occurrence and severity of knee OA in women [35]. However, despite the recognized impact of muscle mass on the disease pathophysiology, the findings from the studies included in our review suggest that the loss of muscle structure may not be uniform across the quadriceps femoris. Based on our review findings, the decline in muscle layer thickness, RF, VI, and VL remains uncertain when compared to healthy people. In this line, another quantitative muscle parameter, the cross-sectional area of the quadriceps femoris, showed no decline compared to healthy participants. These results are consistent with another systematic review focused on the hamstring, which found no significant decline in muscle morphology in people with knee OA [36]. Considering studies that employed magnetic resonance imaging for quadriceps muscle assessment, one found a significantly lower VM cross-sectional area in knee OA people with radiographic grade ≥ 2 compared to grade 1. At the same time, there was no difference in RF, VI, and VL morphology between OA grades [37]. In a second study, findings revealed no difference in VM cross-sectional area between healthy participants and knee OA people [38].

Therefore, based on our findings and available literature, we suggest that the most significant effects of knee OA may not solely involve the entire quadriceps muscle structure. Additionally, the decline in quadriceps muscle appears selective, with a more pronounced reduction, especially in the VM thickness and not the muscle cross-sectional area. In this context, it is important to emphasize the extensive literature investigating the implications of changes in the vastus medialis, a medial stabilizer of the femorotibial joint, in knee OA [39-42]. However, caution should be considered when generalizing the findings of this review concerning measures of muscle architecture, particularly regarding the selectivity of muscle thickness reduction. The studies differ in several key

aspects, such as some including only women or men, while others include people of both genders. Additionally, not all studies calculated sample sizes, and the severity of osteoarthritis also differed among the studies.

Another muscle architecture parameter investigated in this review was pennation angle and fascicle length. However, only two studies in this review reported these measures, specifically in the VL. The impact of knee OA on the pennation angle remains uncertain, though it may have possible repercussions on muscle length. In a systematic review investigating quadriceps femoris architecture in other clinical populations, such as people with patellofemoral pain, none of the included studies investigated the pennation angle or fascicle length of the VL [10]. The VL is an ideal muscle for conducting ultrasound examinations, given its tissue characteristics that allow for the clear visualization of fascicles and the pennation angle [43]. In this context, mentioning the recognized interplay between VL muscle thickness and pennation angle is relevant. Therefore, further studies focusing on these architectural measurements are necessary to determine whether there are indeed concomitant changes in the muscle thickness, pennation angle, and fascicle length in people with knee OA.

In people with knee OA, the quadriceps femoris does not show consistent changes in muscle quality across all muscles, as indicated by ECHO, similar to the variability seen in muscle structure. Specifically, our review indicates that the VM, and VI exhibit increased muscle ECHO, indicating poorer muscle quality. It is not surprising to observe a reduced muscle quality selectively in the VM, and VI as both muscles act as a potential functional muscular complex. The VM indirectly assists in knee extension by regulating and adjusting the length of the extensor apparatus throughout the entire range of motion. In contrast, the VI contributes directly by pulling the patella medially and maintaining its medial tracking during knee extension [44]. In other words, the reduced muscle quality seen in knee OA is likely not limited to the VM precisely because of the interconnected role between the VI and VM. In addition, mechanisms underlying the deterioration of the VM muscle in knee OA people include the presence of non-contractile

muscle tissue, which is predictive of worsening joint symptoms and is associated with reduced knee extensor muscle torque [45]. Furthermore, the deposition of intramuscular adipose tissue selectively in the VM, associated with no structural change (in the cross-sectional area of the muscle), predicts the change in muscle function [38]. Therefore, interventions aimed at enhancing the overall function of the quadriceps femoris are essential for improving the muscle quality of the vastus medialis and its overall function.

Measuring muscle quality using ultrasound has several limitations that need to be considered. Muscle ECHO can change according to probe tilt, ultrasound parameters, and people positioning [32-34, 46, 47]. Demographic aspects such as gender, race, and ethnicity can influence muscle quality measurements [8]. In this sense, protocols of ECHO measurements across studies included in this review were not uniform. This aspect highlights the need to carefully analyze the findings of studies considering the limitations of the muscle assessment method. In addition, there is no consensus on the need to correct ECHO for subcutaneous thickness; however, this aspect is relevant when analyzing the available literature [48]. Another essential aspect to consider is the method used to measure ECHO in the ImageJ software, as there are differences in the measurements obtained with the polygon and segmented line tools [49]. The majority of studies included in this review failed to describe these tools.

The association between quadriceps muscle thickness and pain, functional status, and joint stiffness supports the promising use of imaging biomarkers in clinical practice to assess better the impact of knee OA on muscle function and its clinical manifestations. Consistent with these findings, a nationwide cross-sectional study identified a correlation between lower muscle mass index and knee pain in people with radiographically mild knee OA [50]. However, while these findings suggest a relationship between muscle structure and symptom severity, it is important to note that the muscle condition in that study was determined using dual-energy X-ray absorptiometry. In this context, musculoskeletal ultrasound offers significant clinical advantages for people with

knee OA, particularly due to its cost-effectiveness, safety, and ability to efficiently capture both static and dynamic images [51].

Regarding muscle quality, alterations in muscle ECHO, which indicate decreased muscle quality, are frequently observed in people with knee OA and correlated with symptom severity and functional decline. These characteristics highlight the need to incorporate such assessments into clinical practice. ECHO, a marker of muscle quality, reflects the presence of non-contractile intramuscular content, such as fibrous tissue and intramuscular fat [52]. A systematic review and meta-analysis revealed that individuals with knee OA exhibit higher levels of fatty infiltration, mainly in intermuscular, than those without OA [53]. However, muscle ECHO is a measure that indicates intramuscular fat infiltration. Only one study included in this review [53,54] evaluated intramuscular fat infiltration using magnetic resonance imaging and found that people with radiographic knee OA have higher intramuscular fat infiltration in quadriceps femoris than healthy people. In addition, the authors found a negative association between muscle quality condition-specific PROMs and physical measures of function.

In this context, we propose that arthrogenic muscle inhibition may be a potential mechanism contributing to poor functional capacity [55]. However, the nature of the studies included in this review does not allow for conclusions about a causal relationship between muscle quality, symptoms, and functional capacity. Further research is necessary to establish a definitive cause-and-effect relationship between muscle quality, clinical manifestations, and functional outcomes.

The quality of the evaluated studies varied, with scores ranging from 0 to 8, and only three studies achieved the maximum score of 8 points. The first two aspects in the "selection" domain resulted in the lowest scores on the Newcastle - Ottawa Quality Assessment Scale. These results were related to the representativeness of the sample and the sample size calculation. In the "Outcome" domain, most studies also scored poorly on the second aspect, as the authors either did not sufficiently describe the statistical tests used or provided incomplete descriptions.

Limitations

This study has some limitations. First, the main limitation of the systematic review is that some findings are based on a small number of studies; therefore, it is necessary to take caution in interpreting these results. Second, muscle assessment variability precluded the comparison between studies, as some reported ultrasound measurements of the entire quadriceps femoris, while others focused on specific portions of the muscle. Third, since most studies did not include all parameters of muscle architecture, it is not possible to make definitive conclusions about the impact of knee OA on the entire muscle architecture. Lastly, the insufficient description of key parameters for muscle evaluation in most studies directly affects the quality of the data generated by the authors. The differences in ultrasound settings and the absence of muscle evaluation of each portion of the quadriceps femoris in some of the included studies affect the quality of comparisons, precluding a meta-analysis. Additionally, the variability in gender, sample size, and the muscles evaluated necessitates a cautious interpretation of the studies included in this review. Therefore, these factors should be taken into account when analyzing and applying the results to clinical practice.

In light of the available literature, we recommend conducting future observational studies with robust methodological quality, including a comprehensive description of ultrasound parameters. These studies should encompass all relevant outcomes of muscle architecture — such as muscle thickness, cross-sectional area, pennation angle, and fascicle length — alongside measures of muscle quality. More specifically, we suggest conducting a study that investigates the association of the individual ECHO of each portion of the quadriceps femoris, the average value of all portions of the quadriceps femoris, and objective functional measures, including abilities such as sit-to-stand, walking ability, and climbing and descending stairs. Future research should also include a detailed account of sample representativeness, sample size calculations,

appropriate statistical analyses, and all steps involved in the muscle ultrasound evaluation, including people positioning, ultrasound parameters, and probe positioning.

Conclusion

Muscle ultrasound protocols exhibited great variability, with many studies lacking detailed descriptions of key ultrasound parameters that could directly affect the quality, accuracy, and reliability of these measurements. Despite this, there is a growing interest in the literature regarding changes in quadriceps femoris muscle architecture in people with knee OA, particularly in terms of muscle thickness and ECHO. The evidence suggests that the muscle morphology changes of the quadriceps femoris are selective in these people, with a reduction in the muscle thickness of the VM and the muscle quality of both VM and VI. In addition, the muscle thickness of the quadriceps femoris is associated with condition-specific PROMs and functional performance of people with knee OA. Furthermore, the relationship between ECHO and functional measurements has been verified.

Author's contribution

MTXC and CLA conceived the study idea.

MTXC and CLA developed the search strategy and registered the systematic review protocol in PROSPERO (CRD42023471617).

MTXC and VHGP performed the reference screening.

MTXC and VHGP performed the methodological quality assessment.

MTXC was responsible for data extraction and wrote the entire manuscript with assistance from CLA, who also revised the document.

All authors read and approved the final manuscript.

Declaration of competing interest

The authors declare no conflicts of interest.

Funding

This study has no funding

Additional Materials

1. Complete PRISMA checklist.
2. Ccomplete search strategy for each database (Supplementary Table S1).

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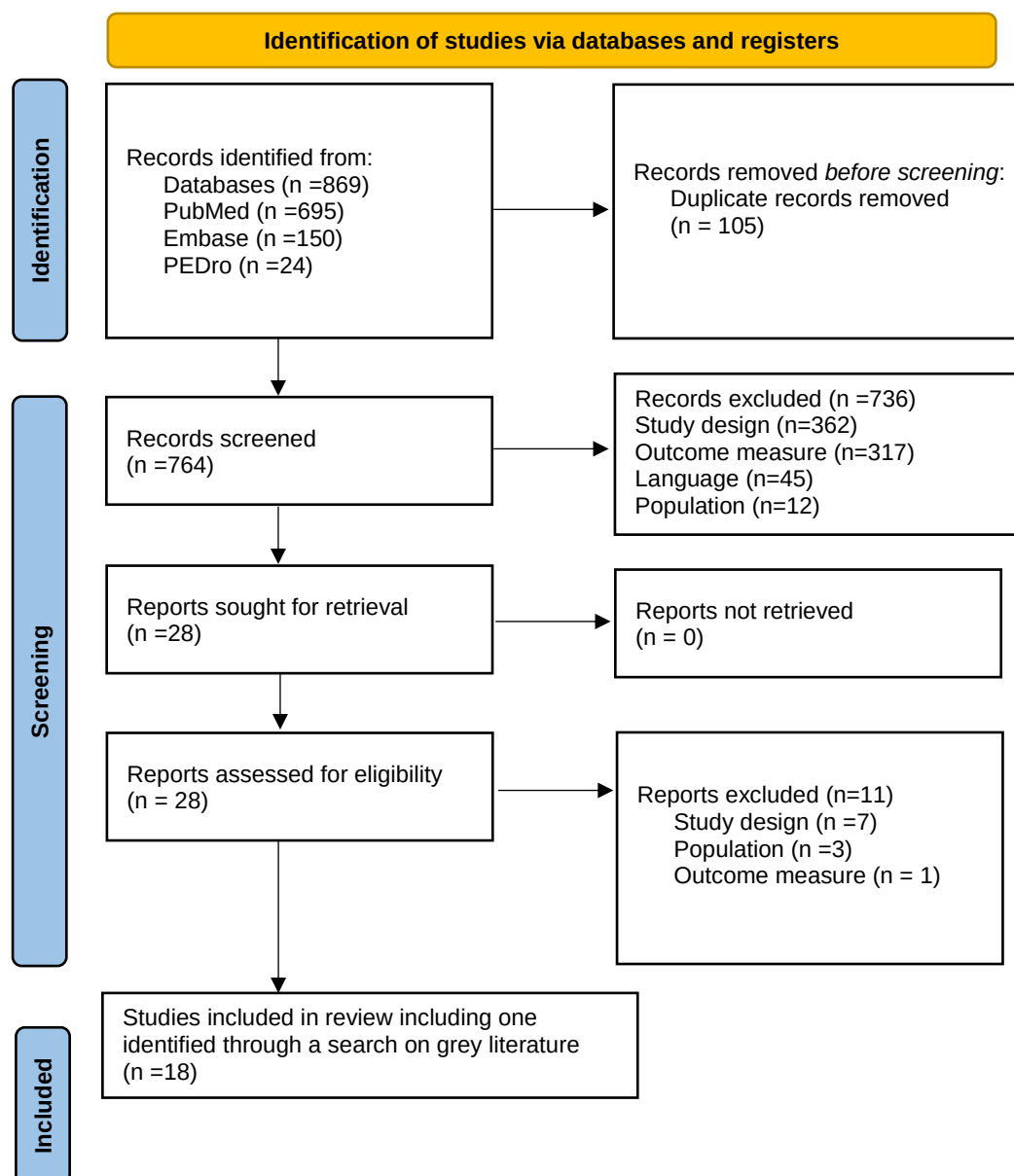
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Figures

Figure 1 - Literature search flow chart.



Tables

Tables

Table 1. Characteristics of the included studies.

Study	Country	Sample	Ultrasound outcomes	Ultrasound protocol			
				Equipment	Imaging parameters	People position	Probe position
Liikavainio et al., 2008 [16]	Finland	Knee OA people (K/L grade I to IV). N: 54 Sex: Male Age: 59.0 (5.3) years BMI: 29.7 (4.7) kg/m ²	Muscle thickness, and cross-sectional area of the RF, VL, and VI.	Not reported	Probe Frequency: 5Mhz. Wide probe: 5cm.	People laid in a supine position with the legs totally relaxed.	Measurement point: midway between the lateral joint space and the trochanter major.
		Healthy participants N: 53 Sex: Male Age: 59.2 (4.7) years BMI: 27.1 (3.1) kg/m ²	ECHO of the RF, VL, and VI.		Authors did not describe others imaging parameters. Software for image measurements: Scion Imageb software.		Compression: avoid tissue compression. Probe was then assumed to be at right angles to the femur.
Vaz et al., 2013 [17]	Brazil	Knee OA people (K/L grade II or III). N: 20 Sex: Female Age: 61 (8) years BMI: 30 (5) kg/m ²	Muscle thickness, fascicle length, and pennation angle of the VL.	Ultrasound device :SSD 4000, 51 Hz, ALOKA Inc., Japan.	Probe Frequency: 7.5Mhz. Wide probe: 6cm.	At rest with the people sitting on the chair of an isokinetic dynamometer with the hip and knee flexed at 85° and 90°, respectively.	Measurement point: midway between the lateral condyle of the femur and the

		Healthy participants N: 10 Sex: Female Age: 60 (7) years BMI: 27 (3) kg/m ²			Image parameters: not reported Software for image measurements: ImageJ software (National Institute of Health, Bethesda, MD).		greater trochanter. Compression: not reported. Probe was positioned in the approximate direction of the vastus lateralis muscle fibers.
Koca et al., 2014 [18]	Turkey	Knee OA people (K/L grade I to IV). N: 75 Sex: Male and Female Age: 57.9 (5.2) years BMI: 27.6 (2.2) kg/m ²	Muscle layer thickness of the quadriceps femoris (RF+VI).	Ultrasound device: Portable Siemens Acuson Antares (Siemens, Erlangen, Germany) equipped with linear transducer Siemens (Acuson Antares VFX 9- 4Mhz).	Probe Frequency: not reported. Wide probe: not reported. Authors did not describe others imaging parameters. Software for image measurements: not reported.	People laid in supine with their legs in full extension.	Measurement point: center of the line between the anterior superior iliac spine and the upper pole of the patella. Compression: not reported.
Taniguchi et al., 2015 [4]	Japan	Knee OA people (K/L grade ≥ 2). N: 21 Sex: Female Age (K/L grade=2): 62.3 (6.5) years Age (K/L grade=3 or 4): 66.8 (9.6) years	Muscle thickness and echo intensity of the RF, VI, VL, and VM.	Ultrasound device: (LOGIQ e, GE Healthcare UK, Chalfont, UK) with linear transducer.	Probe Frequency: 8 MHz. Wide probe: not reported. Mode: B-mode;	People in supine position.	Measurement point: RF and VI: Midway between anterior superior iliac spine and

		BMI (K/L grade=2): 22.1 (2.5) kg/m² BMI (K/L grade=3 or 4): 26.4 (4.3) kg/m² Healthy participants N: 23. Sex: Female Age: 60.7 (7.9) years BMI: 22.7 (3.4) kg/m²			Gain: 58-dB. Dynamic range: 69 Hz; Time gain compensation: at neutral position. Depth: 3.0–5.0cm (VL) 1.0–4cm (RF, VI, and VM). Focus: set to the depth of the muscle of interest. Software for image measurements: not reported.		proximal end of patella. VM: 5 cm medial of 20% distal between anterior superior iliac spine and proximal end of patella. VL: Midway between greater trochanter and lateral femoral tuberosity. Compression: not reported.
Gellhorn et al., 2018 [19]	USA	Knee OA people (K/L grade I to IV). N: 23 Sex: Male and Female Age: 63.8 (9.3) years BMI: 26.9 (3.7) kg/m²	Muscle layer thickness of the quadriceps femoris (RF+VI).	Ultrasound device: A Sonosite X-Porter (Bothell, WA) with a curvilinear transducer (5–2 MHz).	Probe frequency: not reported. Wide probe: not reported. Mode: not reported. Authors did not describe others imaging parameters.	People in supine position.	Measurement point: Midway between the greater trochanter and the lateral condyle of the femur. Compression: no pressure to the muscle.

Aly et al., 2019 [6]	Brazil	Knee OA people (K/L grade II and III). N: 40 Sex: Males and Female <i>Middle-aged group</i> N: 20 Age: 45.3 (2.7) years BMI: 26.8 (2.7) kg/m² <i>Older group</i> N: 20 Age: 74.3 (2.8) years BMI: 27.2 (2.9) kg/m²	Fascicle angle, muscle thickness, and fascicle length of the VL.	Ultrasound device: Acuson X300 PE, (Siemens) with a linear array transducer (4–11.4 MHz).	Probe frequency: not reported. Wide probe: not reported. Mode: B-mode. Authors did not describe others imaging parameters. Software for image measurements: ImageJ software (National Institutes of Health, USA).	People in supine position.	Measurement point: Midpoint between the greater trochanter and the lateral epicondyle of the femur. Compression: no pressure to the muscle.
		Healthy participants N:40 Sex: Males and Female <i>Middle-aged group</i> N: 20 Age:45.2 (3.7) years BMI: 26.0 (3.3) kg/m² <i>Older group</i>					

		N: 20 Age: 74.6 (3.1) years BMI: 25.4 (3.0) kg/m ²					
Núñez et al., 2019 [20]	Spain	Knee OA people (K/L grade II to IV). N: 61 Sex: Males and Female Age: 69.7 (7.2) years BMI: 33.0 (5.7) kg/m ²	Muscle layer thickness of the quadriceps femoris (RF + VI). ECHO of the RF.	Ultrasound device: ALOKA F 31 ultrasound scanner (Hitachi Medical Systems SLU) with a high frequency linear 9 MHz probe.	Probe frequency: 9 MHz. Wide probe: not reported. Mode: not reported. Authors did not describe image parameters. Software for image measurements: Matlab R2105b software (The MathWorks, Inc., Natick, Massachusetts, U.S.A)	People were placed in the supine position with the legs extended and relaxed.	Measurement point: midpoint between the iliac spine and the superior pole of the patella. Compression: avoid compression of the skin and tissues.

Chopp-Hurley et al., 2020 [21]	Canada	Knee OA people (according to American College of Rheumatology criteria). N: 31 Sex: Female Age: 61.3 (6.1) years BMI: 27.7 (6.0) kg/m ²	Muscle thickness and ECHO of the RF and VL.	Ultrasound device: A high frequency (12 MHz) linear array ultrasound transducer (Vivid Q BT0, GE Healthcare, Milwaukee, WI, USA).	Probe frequency: 11 MHz. Wide probe: not reported. Mode: not reported. Gain: not reported. Dynamic range: not reported. Time gain compensation: not reported. Depth: 6 cm. Focus: 4 focus points. Software for image measurements: Python script.	Images for each muscle were captured on the symptomatic leg with the participant seated in an isokinetic dynamometer (Biodex System 3, Shirley, MA, USA) and knee angle standardized to 60° of flexion.	Measurement point: RF: midpoint between the anterior superior iliac spine and the superior border of the patella. VL: midpoint between the greater trochanter and the lateral femoral condyle. Compression: not reported.

Taniguchi et al., 2021 [22]	Japan	Knee OA people (according to American College of Rheumatology criteria and K/L grade ≥ 2). N: 41 Sex: Female Age: 71.4 (6.0) years BMI: 24.2 (3.7) kg/m ²	Muscle thickness and ECHO of the RF, VI, VL and VM.	Ultrasound device: LOGIQ e; GE Healthcare UK Ltd., Chalfont, UK with an 8 MHz linear-array probe.	Probe frequency: 8MHz. Wide probe: not described. Mode: B-mode. Gain: 58-dB. Dynamic range: 69-dB. Time gain compensation: not reported. Depth: not reported. Focus: was set to the middle of the muscle of interest. Software for image measurements: ImageJ Software (ImageJ-WinJP; LISIT, Japan).	The participants rested for more than 3 min in the relaxed supine position.	Measurement point: RF and VI: Midway between anterior superior iliac spine and proximal end of patella. VM: 5 cm medial of 20% distal between anterior superior iliac spine and proximal end of patella. VL: Midway between greater trochanter and lateral femoral tuberosity. Compression: the pressure of the transducer was kept to a minimum.
		Healthy participants N: 27 Sex: Females Age: 75.6 (4.9) years BMI: 21.3 (2.1) kg/m ²					

Yagi et al., 2022 [23]	Japan	Knee OA people (K/L grade $\geq$ II) N: 22 Sex: Females Age: 69.5 (5.4) years BMI: 23.7 (3.8) kg/m ²	Muscle cross-sectional area of the RF, VM, and VL.	Ultrasound device: (Aixplorer version 12.2.0; SuperSonic Imagine, Aix-en-Provence, France with a 4- to 15-MHz linear transducer).	Probe frequency: not reported. Wide probe: not reported. Mode: B-mode. Authors did not describe others imaging parameters. Software for image measurements: Osirix MD (version 9.0; OsiriX, Geneva, Switzerland)	Participants seated on a dynamometer (Biodex System 4; Biodex Medical Systems, Inc.) with their bodies fixed. The dynamometer axis was aligned to their targeted knee axis. The knee was then fixed at 45° flexion.	Measurement point: RF: Midway between anterior superior iliac spine and proximal end of patella. VM: 5 cm medial of 20% distal between anterior superior iliac spine and proximal end of patella. VL: Midway between greater trochanter and lateral femoral tuberosity. Compression: not reported.
		Healthy participants N: 15 Sex: Females Age: 69.5 (5.4) years BMI: 23.7 (3.8) kg/m ²					

Takahashia et al., 2022 [24]	Japan	Knee OA people K/L grade $\geq$ II N: 20 Sex: Male and Female. Age: 69.5 (11.3) years BMI: 25.1 (2.8) kg/m ²	RF, VI, and quadriceps layer thickness (RF+VI).	Ultrasound device: 14-MHz linear array probe (Noblus, Hitachi, Tokyo, Japan).	Probe frequency: 14MHz. Wide probe: not reported. Mode: not reported. Authors did not describe others imaging parameters. Software for image measurements: not reported.	Not reported.	Measurement point: midpoint between the anterior inferior iliac spine and the proximal edge of the patella. Compression: not reported.
		Healthy participants N: 20 Sex: Male and Female Age: 71.2 (8.6) years BMI: 21.8 (1.7) kg/m ²					

Aslan and Genç (2023) [25]	Turkey	Knee OA people (according to the American College of Rheumatology criteria). N: 90 Sex: Females Age: 60.3 (4.7) years BMI: 32.8 (5.4) kg/m ²	Muscle thickness of the RF.	Ultrasound device: 5–12 MHz linear multifrequent transducer (Logic e portable; GE Healthcare, China).	Probe frequency: specific probe frequency was not reported. Wide probe: not reported. Authors did not describe others imaging parameters. Software for image measurements: not reported.	Supine position.	Measurement point: not reported. Compression: minimal pressure to avoid excessive compression of the muscles.
		Healthy participants N: 33 Sex: Females Age: 59.8 (5.2) years BMI: 29.2 (3.2) kg/m ²					
Razaq, Kara, Özçakar (2023) [26]	Pakistan	Knee OA people (clinical and radiographic criteria) N: 50 Sex: Male and Female Age: 58.2 (8.6) years BMI: 29.9 (4.1) kg/m ²	Muscle layer thickness (RF + VI).	Ultrasound device: 5-12 MHz linear probe (Esaote MyLab 20, Italy).	Probe frequency: not reported. Wide probe: not reported. Mode: not reported. Authors did not describe others imaging parameters.	Supine position	Measurement point: mid-thigh between the anterior superior iliac spine to the upper pole of the patella. Compression: not reported.

		Healthy participants N: 90 Sex: Male and Female Age: 56.1 (9.2) years BMI: 28.4 (4.8) kg/m ²			Software for image measurements: not reported.		
Bozan and Erhan (2023) [27]	Turkey	Knee OA people (according to the American College of Rheumatology criteria). N: 71 Sex: Male and female Age: 61.4 (7.7) years BMI: 30.4 (4.7) kg/m ²	Muscle layer thickness (RF+VI).	Ultrasound device: Esaote MyLab60 and a 6-18 MHz linear probe.	Probe frequency: not reported. Wide probe: not reported. Mode: not reported. Authors did not describe others imaging parameters. Software for image measurements: not reported.	Supine position	Measurement point: the midpoint of the line between the anterior superior iliac crest and the upper pole of the patella. Compression: not reported.
		Healthy participants N: 31 Sex: Male and Female Age: 32.8 (5.8) years BMI: 29.8 (3.6) kg/m ²					
Chen et al., 2023 [28]	China	Knee OA people (according to American College of Rheumatology criteria and K/L grade ≥ 2).	Muscle thickness of RF, VI, VL and VM.	Ultrasound device: Supersonic Imaging Aixplorer (French) color Doppler ultrasound	Probe frequency: 4–12 MHz. Wide probe: not reported.	Supine position	Measurement point: RF and VI: measured at

		N: 56 (30 - unilateral OA group (UG), and 26 – bilateral OA group (BG)) Sex: Male and Female Age: 68.1 (9.4) years (unilateral group). 65.1 (8.9) years (bilateral group). BMI: 24.3 (2.7) kg/m² (unilateral group). 25.0 (3.1) kg/m² (bilateral group)		diagnostic instrument using L15-4 linear array probe (frequency 4–12 MHz).	Mode: not reported. Authors did not describe others imaging parameters. Software for image measurements: not reported.		10 cm above the patellar area. VM: at 10 cm supratellar and 55° inside the long axis of the femur. VL: at 10 cm supratellar and 18° long axis of femur. Compression: avoid the compression of soft tissue.
Taniguchi et al., 2023 [29]	Japan	Knee OA people (according to American College of Rheumatology criteria and K/L grade ≥ 2). N: 33 Sex: Females Age: 71.6 (5.3) years BMI: 24.5 (4.4) kg/m²	Muscle thickness and ECHO of the VM.	Ultrasound device: LOGIQ e; GE Healthcare UK Ltd., Chalfont, UK with an 8 MHz linear-array probe.	Probe frequency: 8MHz; Wide probe: not reported. Mode: B-mode. Gain: 58dB. Dynamic range: 69dB. Time gain compensation: not reported.	Supine position	Measurement point: 30% distal between the greater trochanter and lateral femoral tuberosity. Compression: not reported.

					Depth: not reported.		
					Focus: the middle of the VM.		
					Software for image measurements: Image J (ImageJ-WinJP; LISIT, Japan).		
Karapinar et al., 2024 [30]	Turkey	Knee OA people (according to American College of Rheumatology criteria and K/L grade ≥ 2). N: 36 Sex: Females. Age: 51 years (50 - 59) BMI: 30.7 kg/m ² (27.1 – 39.0)	ECHO of the RF, VI, VL, and VM.	Ultrasound device: Philips Medical Systems EPIQ5 Release5.0.2, Amsterdam with a linear-array probe (8e12 MHz,code:eL18-4).	Probe frequency: 12MHz. Wide probe: not reported. Mode: B-mode. Gain: 58db. Dynamic range: not reported. Time gain compensation: at neutral position. Depth: 4cm. Focus: Focus number and area	Supine position	Measurement point: RF and VI: the midpoint of the line connecting the anterior superior iliac spine with the superior edge of the patella. VM and VL: The transducer positioned at 50% of the distance between the greater trochanter and the lateral condyle of femur.
		Healthy participants N: 36 Sex: Females. Age: 50 years (47 - 57)					

		BMI: 29.4 kg/m ² (25.8 - 38.9)			were increased to maximum and kept consistent across all participants to adjust for differences in muscle size. Software for image measurements: ImageJ.		Compression: minimum pressure required to obtain clear images.
Johnson et al., 2024 [31]	USA	Knee OA people (according to American College of Rheumatology criteria). N: 26 Sex: Males and females. Age: 67.0 (7.4) years BMI: 30.5 (6.7) kg/m ²	ECHO of the RF.	Ultrasound device: 2–10 MHz linear array transducer (Aixplorer Mach 30, Hologic Supersonic Imagine).	Probe frequency: not reported. Wide probe: not reported. Mode: B-mode. Gain: 50dB. Dynamic range: 72. Time gain compensation: not described. Depth: 3-5cm.	Supine position with knees supported by a bolster at a 30° angle.	Measurement point: RF: at 60% of the distance between the superior patella edge and the anterior superior iliac spine. Compression: minimal tissue compression.

					Focus: not reported. Software for image measurements: ImageJ software (National Institute of Health, version 1.54f).		

Age and BMI are reported in mean (SD) or median (IQR range). BMI: Body Mass Index; ECHO: Echo intensity; K/L: Kellgren and Lawrence Grading System for Osteoarthritis; OA: Osteoarthritis; RF: Rectus Femoris; Vastus lateralis; VI: Vastus intermedius; VM: Vastus medialis.

Table 2. Main findings of the included studies.

Author	Aim	Outcomes	Main Findings
<i>Quadriceps muscle architecture differences between people with knee OA and healthy participants</i>			
Liikavainio et al., 2008 [16]	Examine the properties of the quadriceps femoris muscle in men with KOA and to compare the results with these from age- and sex-matched, randomly selected healthy controls.	Ultrasound outcomes: Muscle thickness and, cross-sectional area of the RF, VL and VI. ECHO of the RF, VL and VI.	There were no significant differences between the groups in the absolute muscle thickness (in centimeters) and area (in cm ²). The RF and VI, but not the VL muscle compartments of the quadriceps femoris muscle, exhibited significantly more heterogeneity (decline in muscle quality) in the knee OA group compared with the control (RF= 176.0 (10.0) cm vs. 171.0 (11.0) cm; VI= 206.0 (12.0) cm vs. 198.0 (28.0) cm).
Vaz et al., 2013 [17]	Identify the associations of KOA with structural parameter (muscle architecture) of the knee	Ultrasound outcomes:	VL muscle thickness and fascicle length were smaller in OA people compared to healthy people (VL muscle thickness= 11.9 (2.5) mm vs.

	extensor muscles in elderly women.	Muscle thickness, fascicle length, and pennation angle of the VL.	14.1 (2.5) mm; VL fascicle length= 21 (6) % vs. 25 (5) %). While pennation angles were the same for the OA and control groups.
Taniguchi et al., 2015 [4]	Compare muscle quantity and quality in lower extremity muscles between individuals with and without KOA.	Ultrasound outcomes: Muscle thickness and ECHO of the RF, VI, VM, and VL.	VM muscle thickness in the severe and mild OA groups was significantly smaller than the muscle thickness in the healthy group (1.10 (0.38) cm vs. 1.50 (0.19) cm vs. 1.88 (0.43) cm). Muscle thickness of the VI in the severe OA group was significantly smaller than the muscle thickness in the mild OA and healthy groups (1.33 (0.25) cm vs. 1.45 (0.39) cm vs. 1.76 (0.40) cm). ECHO of the VM was significantly higher in the severe and mild OA groups than in the healthy group (99.3 (11.3) a.u vs. 100.3 (13.1) a.u vs. 82.5 (19.5) a.u). ECHO of VI, were significantly higher in the severe OA group than in the

			healthy group (79.1 (11.1) a.u vs. 72.8 (11.1) a.u vs. 66.2 (14.3) a.u). There was no significant difference in the muscle thickness and echo intensity of other muscles between the groups.
Aily et al., 2019 [6]	Investigate whether there are differences in muscle architecture in people of different ages and with and without the presence of KOA.	Ultrasound outcomes: Fascicle angle, muscle thickness, and fascicle length of the VL.	VL of healthy middle-aged people presented the highest FA when compared to the people with knee OA (middle aged or older) or healthy older participants (15.6 (3.4) deg vs. 12.2 (2.3) deg vs. 10.1 (1.7) deg vs 13.4 (1.8) deg). The middle-aged healthy group had the longest fascicles when compared to the people with knee OA (middle aged or older) or healthy older participants (0.15 (0.02) (FL/femur length) vs. 0.13 (0.03) (FL/femur length) vs. 0.12 (0.02) (FL/femur length) vs. 0.13 (0.02) (FL/femur length)).

			The older OA group presented the lowest MT when compared to the middle-aged knee OA people or healthy participants (middle aged or older) (1.0 (0.3) cm vs. 1.5 (0.3) cm vs. 1.7 (0.4) cm vs.1.3 (0.2) cm). The comparison between the middle-aged OA and older groups (with or without knee OA) showed no difference in FA between these groups. The comparison between the middle-aged OA, and older groups (with or without knee OA) showed no differences in FL between these groups. There were no differences in MT between the middle-aged healthy,

			middle-aged OA, and older healthy groups.
Taniguchi et al., 2021 [22]	Clarify the characteristics of quadriceps muscle degeneration by focusing on muscle quality changes in people with KOA.	Ultrasound outcomes: Muscle thickness and ECHO of the RF, VI, VM, and VL.	VM was significantly smaller in the knee OA group than in the healthy control group (1.61 (0.06) cm vs. 2.05 (0.08) cm). VI and VM ECHO in the knee OA group were significantly higher than those in the healthy control group (VI= 62.4 (2.2) cm vs. 52.9 (2.8) cm, and VM= 91.8 (2.1) cm vs. 69.5 (2.6) cm). There was no significant difference in the MT and ECHO of other muscles between the groups.
Yagi et al., 2022 [23]	Aimed to clarify the individual forces of each quadriceps head during low-load contractions and the associations between muscle	Ultrasound outcomes: Muscle cross-sectional area (RF, VM, and VL).	There were no significant differences between the groups (healthy participants and knee OA people) in VM, RF and VL cross-sectional area.

	force and cartilage thickness and symptoms in female KOA people.		
Takahashia et al., 2022 [24]	The purpose of this study was to evaluate the structural changes in the central aponeurosis and clarify the conditions associated with rectus femoris overstrain in individuals with KOA.	Ultrasound outcomes: RF, VI, and muscle layer thickness (RF + VI).	The RF thickness at rest was significantly higher in the knee OA group than in the elderly group, indicating hypertrophy of RF (17.0 (3.1) mm vs. 14.8 (2.5) mm) The VI thickness at rest was not significantly different between the two groups.
Aslan and Genç, 2023 [25]	Investigate the relation between OA and sarcopenia and to identify the most practical, easily accessible, and inexpensive method for investigating sarcopenia.	Ultrasound outcomes: RF muscle thickness.	No significant difference in bilateral rectus femoris muscle thickness between knee OA people and healthy participants.
Razaq, Kara, Özçakar, 2023[26]	Investigate the relationship between the type of body composition (i.e., obesity only, sarcopenia only, or	Ultrasound outcomes: Muscle layer thickness (RF + VI).	Anterior thigh muscle thickness were found to be similar between the groups (Knee OA vs. control group).

	sarcopenic obesity) and KOA.		
Bozan and Erhan, 2023 [27]	Investigate the quadriceps muscle thickness measured by US in knee osteoarthritis comparing the values with healthy young adults.	Ultrasound outcomes: Muscle layer thickness (RF + VI).	Right and left quadriceps muscle layer thickness was significantly reduced in people with knee OA compared to healthy participants (right= 23,7 (6,1) mm vs. 36,6 (3,5) mm; left = 23,7 (5,8) mm vs. 35,5 (3,4) mm).
Karapinar et al., 2024 [30]	Evaluate the intramuscular fat in muscles around the knee in middle-aged women with and without KOA, to compare the two groups.	Ultrasound outcomes: Echo intensity of the RF, VI, VM, and VL.	The echo intensity of the RF, VI, and VM was significantly higher in the knee OA than in the healthy group (RF= 39.19 (34.98 - 44.01) a.u vs. 31.24 (27.05 - 33.74) a.u; VI=45.64 (31.94 -54.08) a.u vs. 40.93 (26.75 - 42.61) a.u; VM= 70.94 (62.01 - 80.79) a.u vs. 61.52 (49.23 - 69.88) a.u. There was no significant difference in the ECHO of the VL between the groups.
Quadriceps muscle architecture differences between people with knee OA symptomatic in unilateral or bilateral legs			
Chen et al., 2023 [28]	Evaluate the muscle characteristics in people	Ultrasound outcomes:	In the unilateral OA group, the thickness of the evaluated muscles

	with unilateral or bilateral KOA	Muscle thickness of the RF, VI, VL, and VM.	was reduced in both the relatively serious leg and the relatively moderate leg, with the most pronounced decrease observed in the VM (RF= 0.99 (0.16) cm vs. 1.05 (0.21) cm; VI=1.03 (0.20) cm vs. 1.11 (0.26) cm; VL= 1.42 (0.14) cm vs. 1.48 (0.14) cm; VM= 3.52 (0.18cm) vs. 3.73 (0.21) cm). In the bilateral OA group, the RF, VI, and VI muscles were thinner in the more severely affected leg than the relatively moderate leg, (RF= 0.92 (0.14) cm vs. 0.97 (0.17) cm; VI= 0.92 (0.14) cm vs. 0.97 (0.14) cm; VL= 1.40 (0.16) cm vs. 1.44 (0.16) cm). There was no significant difference in VM thickness.
<i>Association between quadriceps architecture and condition-specific patient-reported outcomes or functional measurements</i>			
Koca et al., 2014 [18]	The relationship between quadriceps muscle thickness measured by US, clinical parameters, and	Ultrasound outcomes: Muscle layer thickness of the quadriceps femoris (RF+VI).	A statistically significant negative correlation was found between the quadriceps muscle layer thickness of the people with knee OA and VAS scores at rest and while active ($r = -0.285$; $r = -0.342$); the WOMAC

	radiological staging in knee osteoarthritis was investigated.	PROMs: Pain at rest – Visual analogue scale (0 – 10). Pain at movement - Visual analogue scale (0 – 10). Pain score: WOMAC pain. Stiffness: WOMAC stiffness. Physical function: WOMAC function. WOMAC total score. Functional Measurements: 50-meter walking test, and 10-step stair test.	scores (pain, stiffness, function, total) (respectively, $r=-0.473$; $r=-0.496$ $r=-0.357$ $r=-0.502$). There was also a statistically significant negative correlation in the 50-m walking test and the 10-step stair test (respectively, $r=-0.470$; $r=-0.418$).
Yagi et al., 2022 [22]	Aimed to clarify the individual forces of each quadriceps head during low-load contractions and the	Ultrasound outcomes:	There was no significant correlation between RF, VM and VL cross sectional area and pain during gait.

	associations between muscle force and cartilage thickness and symptoms in female KOA people.	Muscle cross-sectional area (RF, VM, and VL). PROMs: Pain during gait.	
Gellhorn et al., 2018 [19]	Investigate the relationship between ultrasound measured bulk knee and self-reported function in adults with KOA.	Ultrasound outcomes: Muscle layer thickness of the quadriceps femoris (RF + VI). PROMs: Pain score: WOMAC pain. Stiffness: WOMAC stiffness. Physical function: WOMAC function. WOMAC total score.	Muscle layer thickness of the symptomatic quadriceps femoris correlated negatively with pain, function and WOMAC total scores (respectively, $r=-0.48$; $r=-0.62$; $r=-0.60$). Muscle layer thickness of the asymptomatic quadriceps femoris correlated negatively with function, and WOMAC total scores (respectively, $r=-0.54$; $r=-0.53$).

			In multivariable regression, the unadjusted beta for symptomatic quadriceps thickness normalized to weight was - 67.2. In other words, for every 1 mm/kg increase in quadriceps thickness, the corresponding total WOMAC score decreased by 67.2.
Núñez et al., 2019 [20]	Evaluate the relationships between quadriceps muscle thickness and quality and subcutaneous fat thickness and function in older people with KOA on a waiting list for total knee replacement.	Ultrasound outcomes: Muscle layer thickness of the quadriceps femoris (rectus femoris and vastus intermedius). ECHO of rectus femoris. Functional Measurements: Timed Up and Go Test.	Quadriceps muscle thickness and percentage correlated negatively with the TUG scores (respectively, $r = -0.36$, $r = -0.29$), and a significant positive correlation between EI and the TUG scores ($r = 0.27$). In the multiple linear regression analysis, it was found that greater muscle ECHO was associated with worse function ($R^2 = 0.15$, IC-95% 0.30 to 0.26).
Chopp-Hurley et al., 2020 [21]	Determine whether rectus femoris and vastus lateralis muscle quality, as measured from ultrasound-derived ECHO, was related to clinical severity (pain,	Ultrasound outcomes: Muscle thickness and ECHO of rectus femoris and vastus lateralis.	ECHO was inversely related to mobility. Specifically, higher ECHO of the rectus femoris ($r = -0.52$), and vastus lateralis ($r = -0.74$) was

	self-reported function, and six-minute walk test (mobility) in women with KOA.	PROMs: Pain and self-reported function: KOOS questionnaire with five dimensions (pain, symptoms, activities of daily life function, sport and recreation function, and knee-related quality of life). Functional Measurements: Six-minute walk test.	related to a shorter six-minute walk distance. Rectus femoris and vastus lateralis thickness was not related to six-minute walk distance. Rectus femoris ECHO was not correlated to pain. Vastus lateralis ECHO was not correlated to pain. Muscle thickness of the rectus femoris and vastus lateralis was not related with any outcome (pain or self-reported function).
Taniguchi et al., 2023 [29]	Aimed to clarify the association between muscle degeneration at baseline and the worsening of functional disabilities and	Ultrasound outcomes:	The enhanced VM ECHO (crude OR [95% CI] 1.10 [1.01–1.20]) was identified as a potential predictor of progression of symptoms and functional disabilities.

	symptoms in people with KOA over a period of 3 years.	Muscle thickness and ECHO of vastus medialis. PROMs: Functional activities and symptoms: KSS score. • The functional activities category consisted of four components: walking and standing, routine activities, advanced activities, and discretionary activities; • The symptom category consisted of three components: the degree of knee pain during walking, the degree of knee pain when travelling up or down stairs, and knee stiffness.	In the multivariable analysis, enhanced VM ECHO was the only significant predictor of progression (adjusted OR [95% CI] 1.13 [1.03–1.25]). In the logistic regression subcategory analysis, the VM ECHO, but not the VM muscle thickness, at baseline was found to be significantly associated with the progression of functional disabilities (adjusted OR [95% CI] 1.24 [1.03–1.50]) and symptoms (adjusted OR [95% CI] 1.13 [1.01–1.25]) even after adjustment for baseline KSS scores.
Bozan and Erhan, 2023 [26]	Determine the relationship between quadriceps muscle thickness measured by US	Ultrasound outcomes: Muscle layer thickness (RF and VI).	There was a significant negative correlation between bilateral quadriceps muscle (RF+IV) thickness

	and clinical parameters in KOA.	PROMs: Pain at rest, night, movement and mean score: Visual analogue scale – 0 to 10. Pain score: WOMAC pain. Stiffness: WOMAC stiffness. Physical function: WOMAC function. WOMAC total score. Functional measurements: Timed Up and Go test and Ten Meter Walk test.	and VAS rest, night, movement, mean score. There was a significant negative correlation between bilateral quadriceps muscle (RF+VI) thickness and WOMAC pain, WOMAC stiffness, WOMAC physical function, WOMAC total scores. There was a significant negative correlation between bilateral quadriceps muscle (RF+VI) thickness and TUG test score, and 10-meter walking test scores. Authors did not report r values.
Johnson et al., 2024 [31]	Evaluate muscle quality in persons with KOA and	Ultrasound outcomes:	There was no significant association between ECHO of the rectus femoris

	associations with pain and physical impairment.	ECHO of the rectus femoris. PROMs: Graded chronic pain scale: • Pain intensity: over the past 6 months in their index knee on a 0 (“no pain”) to 10 (“pain as bad as could be”). • Pain interference: during daily activities, recreational/social/family activities, and ability to work on a 0 (“no interference”) to 10 (“unable to carry out activities”). Pain during isokinetic knee strength test (movement-evoked pain): • Using a 0 (“no pain”) to 100 (“worst pain imaginable”) numerical rating scale.	and pain intensity or pain interference. ECHO was significantly associated with movement-evoked pain after adjusting for knee extension strength, age, sex, and BMI ($b = 0.84$, IC 95% = 0.1–1.2).

Quadriceps femoris architecture outcomes are reported in mean (SD) vs mean (SD) or median (IQR range) vs. median (IQR range). ECHO: Echo intensity; KOA: Knee Osteoarthritis; KOOS: Knee Injury and Osteoarthritis Outcome Score; KSS: Knee Scoring System; PROMs: Patient-reported outcomes measures; RF: Rectus Femoris; VAS: Visual Analogue Scale; Vastus lateralis; VI: Vastus intermedius; VM: Vastus medialis; WOMAC: Western Ontario and McMaster Universities Osteoarthritis Index.

Table 3. Evaluation of the methodological quality of studies using the Newcastle Ottawa Quality Assessment Scale adapted for cross-sectional studies.

Reference	Selection				Comparability	Outcome		Total
	1	2	3	4	0	1	2	
Liikavainio et al., 2008 [16]	*	0	0	**	*	0	0	4
Vaz et al., 2013 [17]	*	0	0	**	*	**	0	6
Koca et al., 2014 [18]	0	0	0	**	0	**	0	4
Taniguchi et al., 2015 [4]	*	0	0	**	*	**	0	6
Gellhorn et al., 2018 [19]	0	0	0	**	**	0	0	4
Aily et al., 2019 [6]	*	*	0	**	*	**	*	8
Núñez et al., 2019 [20]	0	0	*	**	**	**	*	8
Chopp-Hurley et al., 2020 [21]	0	0	*	0	0	**	0	3
Taniguchi et al., 2021 [22]	0	0	*	**	*	**	*	8
Yagi et al., 2022 [23]	0	0	*	**	0	0	0	3
Takahashia et al., 2022 [24]	0	0	0	0	0	0	0	0
Aslan and Genç, 2023 [25]	0	0	*	**	**	0	0	5

Razaq, Kara, Özçakar, 2023 [26]	0	0	0	**	**	0	*	5
Bozan and Erhan, 2023 [27]	0	0	0	**	0	**	0	4
Chen et al., 2023 [28]	0	*	0	**	0	0	0	3
Karapinar et al., 2024 [30]	0	*	0	**	0	0	0	3
Johnson et al., 2024 [31]	0	*	*	0	**	0	*	5

Scores ranging from 0- 10; Maximum 5 stars to “selection”; Maximum 2 stars to “comparability”; Maximum 3 stars for “outcome”.
 0= does not score on the scale criterion. *=scores one star on the scale criteria **=scores two stars on the scale criteria.

Supplementary material

Supplementary Table S1 - The complete search strategy for each database.

	Ultrasonographic Assessment of Quadriceps Muscle Architecture and Quality in Patients with Knee Osteoarthritis: A Systematic Review of Observational Studies
	PUBMED
1	((((((((((Ultrasonography[MeSH Terms]) OR (Muscle ultrasound[Title/Abstract])) OR (Muscle quantity[Title/Abstract])) OR (Muscle quality[Title/Abstract])) OR (Muscle thickness[Title/Abstract])) OR (Cross-sectional area[Title/Abstract])) OR (Pennation Angle[Title/Abstract])) OR (Muscle echogenicity[Title/Abstract])) OR (Echo intensity[Title/Abstract])) OR (Muscle echo intensity[Title/Abstract]))
2	((((((((((Osteoarthritis, Knee[MeSH Terms]) OR (Osteoarthritis Knee[Title/Abstract])) OR (Knee Osteoarthritides[Title/Abstract])) OR (Knee Osteoarthritis[Title/Abstract])) OR (Osteoarthritides, Knee[Title/Abstract])) OR (Osteoarthritis Of Knee[Title/Abstract])) OR (Knee, Osteoarthritis Of[Title/Abstract])) OR (Knees, Osteoarthritis Of[Title/Abstract])) OR (Osteoarthritis Of Knees[Title/Abstract]))
3	#1 AND #2 ((((((((((((Ultrasonography[MeSH Terms]) OR (Muscle ultrasound[Title/Abstract])) OR (Muscle quantity[Title/Abstract])) OR (Muscle quality[Title/Abstract])) OR (Muscle thickness[Title/Abstract])) OR (Cross-sectional area[Title/Abstract])) OR (Pennation Angle[Title/Abstract])) OR (Muscle echogenicity[Title/Abstract])) OR (Echo

	intensity[Title/Abstract])) OR (Muscle echo intensity[Title/Abstract])) AND (((((((((Osteoarthritis, Knee[MeSH Terms]) OR (Osteoarthritis Knee[Title/Abstract])) OR (Knee Osteoarthritis[Title/Abstract])) OR (Knee Osteoarthritis[Title/Abstract])) OR (Osteoarthritis, Knee[Title/Abstract])) OR (Osteoarthritis Of Knee[Title/Abstract])) OR (Knee, Osteoarthritis Of[Title/Abstract])) OR (Knees, Osteoarthritis Of[Title/Abstract])) OR (Osteoarthritis Of Knees[Title/Abstract]))
	PEDRO
	Osteoarthritis, Knee* Muscle Ultrasound*
	EMBASE
	('muscle ultrasound':ab,ti OR 'muscle quantity':ab,ti OR 'muscle quality':ab,ti OR 'muscle thickness':ab,ti OR 'cross sectional area':ab,ti OR 'pennation angle':ab,ti OR 'muscle echo intensity':ab,ti) AND ('knee osteoarthritis':ab,ti OR 'knee arthritis':ab,ti)

Prisma Checklist

Section and Topic	Item #	Checklist item	Location where item is reported
TITLE			
Title	1	Identify the report as a systematic review.	p.2
ABSTRACT			
Abstract	2	See the PRISMA 2020 for Abstracts checklist.	p.2
INTRODUCTION			
Rationale	3	Describe the rationale for the review in the context of existing knowledge.	p.3-4
Objectives	4	Provide an explicit statement of the objective(s) or question(s) the review addresses.	p.4
METHODS			
Eligibility criteria	5	Specify the inclusion and exclusion criteria for the review and how studies were grouped for the syntheses.	p.5-6
Information sources	6	Specify all databases, registers, websites, organisations, reference lists and other sources searched or consulted to identify studies. Specify the date when each source was last searched or consulted.	p.7
Search strategy	7	Present the full search strategies for all databases, registers and websites, including any filters and limits used.	p.7, and in the supplementary material
Selection process	8	Specify the methods used to decide whether a study met the inclusion criteria of the review, including how many reviewers screened each record and each report retrieved, whether they worked independently, and if applicable, details of automation tools used in the process.	p.7
Data collection process	9	Specify the methods used to collect data from reports, including how many reviewers collected data from each report, whether they worked independently, any processes for obtaining or confirming data from study investigators, and if applicable, details of automation tools used in the process.	p.7-8
Data items	10a	List and define all outcomes for which data were sought. Specify whether all results that were compatible with each outcome domain in each study were sought (e.g. for all measures, time points, analyses), and if not, the methods used to decide which results to collect.	p.5-6
	10b	List and define all other variables for which data were sought (e.g. participant and intervention characteristics, funding sources). Describe any assumptions made about any missing or unclear information.	p.5-6
Study risk of bias assessment	11	Specify the methods used to assess risk of bias in the included studies, including details of the tool(s) used, how many reviewers assessed each study and whether they worked independently, and if applicable, details of automation tools used in the process.	p.8
Effect measures	12	Specify for each outcome the effect measure(s) (e.g. risk ratio, mean difference) used in the synthesis or presentation of results.	p.9

Section and Topic	Item #	Checklist item	Location where item is reported
Synthesis methods	13a	Describe the processes used to decide which studies were eligible for each synthesis (e.g. tabulating the study intervention characteristics and comparing against the planned groups for each synthesis (item #5)).	p-8-9
	13b	Describe any methods required to prepare the data for presentation or synthesis, such as handling of missing summary statistics, or data conversions.	p-8-9
	13c	Describe any methods used to tabulate or visually display results of individual studies and syntheses.	p-8-9
	13d	Describe any methods used to synthesize results and provide a rationale for the choice(s). If meta-analysis was performed, describe the model(s), method(s) to identify the presence and extent of statistical heterogeneity, and software package(s) used.	Not applicable
	13e	Describe any methods used to explore possible causes of heterogeneity among study results (e.g. subgroup analysis, meta-regression).	Not applicable
	13f	Describe any sensitivity analyses conducted to assess robustness of the synthesized results.	Not applicable
Reporting bias assessment	14	Describe any methods used to assess risk of bias due to missing results in a synthesis (arising from reporting biases).	Not applicable
Certainty assessment	15	Describe any methods used to assess certainty (or confidence) in the body of evidence for an outcome.	Not applicable
RESULTS			
Study selection	16a	Describe the results of the search and selection process, from the number of records identified in the search to the number of studies included in the review, ideally using a flow diagram.	p.9
	16b	Cite studies that might appear to meet the inclusion criteria, but which were excluded, and explain why they were excluded.	p.9
Study characteristics	17	Cite each included study and present its characteristics.	p.9-15
Risk of bias in studies	18	Present assessments of risk of bias for each included study.	p.15
Results of individual studies	19	For all outcomes, present, for each study: (a) summary statistics for each group (where appropriate) and (b) an effect estimate and its precision (e.g. confidence/credible interval), ideally using structured tables or plots.	Table 2
Results of syntheses	20a	For each synthesis, briefly summarise the characteristics and risk of bias among contributing studies.	p.15, and Table 3
	20b	Present results of all statistical syntheses conducted. If meta-analysis was done, present for each the summary estimate and its precision (e.g. confidence/credible interval) and measures of statistical heterogeneity. If comparing groups, describe the direction of the effect.	Not applicable
	20c	Present results of all investigations of possible causes of heterogeneity among study results.	Not applicable
	20d	Present results of all sensitivity analyses conducted to assess the robustness of the synthesized results.	Not applicable

Section and Topic	Item #	Checklist item	Location where item is reported
Reporting biases	21	Present assessments of risk of bias due to missing results (arising from reporting biases) for each synthesis assessed.	Not applicable
Certainty of evidence	22	Present assessments of certainty (or confidence) in the body of evidence for each outcome assessed.	Not applicable
DISCUSSION			
Discussion	23a	Provide a general interpretation of the results in the context of other evidence.	p.15-20
	23b	Discuss any limitations of the evidence included in the review.	p.21
	23c	Discuss any limitations of the review processes used.	p.21
	23d	Discuss implications of the results for practice, policy, and future research.	p.22
OTHER INFORMATION			
Registration and protocol	24a	Provide registration information for the review, including register name and registration number, or state that the review was not registered.	p.5
	24b	Indicate where the review protocol can be accessed, or state that a protocol was not prepared.	p.5
	24c	Describe and explain any amendments to information provided at registration or in the protocol.	p.5
Support	25	Describe sources of financial or non-financial support for the review, and the role of the funders or sponsors in the review.	p.23
Competing interests	26	Declare any competing interests of review authors.	p.23
Availability of data, code and other materials	27	Report which of the following are publicly available and where they can be found: template data collection forms; data extracted from included studies; data used for all analyses; analytic code; any other materials used in the review.	Other materials in the supplementary material.

From: Page MJ, McKenzie JE, Bossuyt PM, Boutron I, Hoffmann TC, Mulrow CD, et al. The PRISMA 2020 statement: an updated guideline for reporting systematic reviews. BMJ 2021;372:n71. doi: 10.1136/bmj.n71. This work is licensed under CC BY 4.0. To view a copy of this license, visit <https://creativecommons.org/licenses/by/4.0/>

ARTIGO 3

Submetido ao periódico *Trials* (fator de impacto 2.0), conforme a diretriz para autores (Anexo V), em 12 de abril de 2024 com retorno da revisão por pares em 3 de março de 2025, e nova submissão em 8 de março de 2025

Title

Remote and In-person Supervised Exercise in Patients with Knee Osteoarthritis (RISE-KOA): study protocol for a non-inferiority randomized controlled trial.

Names protocol contributors

Maurício Tatsch Ximenes Carvalho, Cristine Lima Alberton.

Abstract

- **Background:** Knee Osteoarthritis (OA) is a prevalent joint condition resulting in years lived with disability. A first-line treatment recommended by clinical guidelines is the therapeutic exercise to control pain and improve physical function. One possible approach for exercise supervision is telehealth using video calls, as it can be an effective alternative to in-person physical therapy for treating musculoskeletal conditions, expanding community access to physical rehabilitation. In this scenario, this study aims to investigate whether a muscle-strengthening exercise program for the lower limbs supervised remotely via video calls is as effective as the same exercise applied in person for improving pain, physical function, condition-specific patient-reported outcomes (PROMs), psychological well-being, sleep quality, functional performance, and quadriceps muscle architecture.
- **Methods:** A Remote and In-person Supervised Exercise in Patients with Knee Osteoarthritis (RISE-KOA) study is a parallel, two-armed, single-blinded protocol for a non-inferiority randomized controlled trial. Forty-eight participants aged 45 years or more, with a symptomatic and radiographic diagnosis of unilateral or bilateral knee OA (grade II or III according to Kellgren & Lawrence) will be randomly assigned to a remote exercise group supervised by video calls or in-person exercise group supervised at a physiotherapy clinic. Both groups will receive the same muscle-strengthening exercises for the lower extremities for 12 weeks. Follow-ups will be conducted during treatment (6 weeks), after treatment (12 weeks), and 18 weeks after randomization. The primary outcomes will be pain intensity and physical function during (6 weeks) and after treatment (12 weeks). Secondary outcomes will be condition-specific PROMs, psychological well-being, sleep quality, functional performance, and quadriceps muscle architecture.
- **Discussion:** We hypothesize that muscle strengthening exercise supervised remotely via video calls will not be inferior to in-person exercise at a physiotherapy clinic in terms of primary and secondary outcomes in patients with knee OA.
- **Trial registration:** The study was prospectively registered at ClinicalTrials.gov (NCT06101797. Registered on Oct 26, 2023).

Keywords

Musculoskeletal conditions, Telehealth, Physical exercise, Patient-reported outcomes, Muscle architecture.

Administrative information

Trials guidance: please include this text in your protocol just above the Administrative information table:

Note: the numbers in curly brackets in this protocol refer to SPIRIT checklist item numbers. The order of the items has been modified to group similar items (see <http://www.equator-network.org/reporting-guidelines/spirit-2013-statement-defining-standard-protocol-items-for-clinical-trials/>).

Title {1}	Remote and In-person Supervised Exercise in Patients with Knee Osteoarthritis (RISE-KOA): study protocol for a non-inferiority randomized controlled trial.
Trial registration {2a and 2b}.	Remote and In-person Supervised Exercise in Patients With Knee Osteoarthritis (RISE-KOA) - https://classic.clinicaltrials.gov/ct2/show/study/NCT06101797?term=NCT06101797&draw=2&rank=1 ClinicalTrials.gov: NCT06101797
Protocol version {3}	Initial released at ClinicalTrials.gov: October 26, 2023. Last update at ClinicalTrials.gov: February 18, 2025. Version 3 of February 18, 2025.
Funding {4}	This study did not receive any financial support.

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Name and contact information for the trial sponsor {5b}	Maurício Tatsch Ximenes Carvalho (Study manager) carvalhomauricio960@gmail.com
Role of sponsor {5c}	Not applicable

Introduction

Background and rationale {6a}

Knee osteoarthritis (OA) is a multifactorial joint condition with increased prevalence and global burden of the disease, which is one of the predictive factors for the years lived with disability [1, 2]. Specifically, the global prevalence of knee OA, standardized by age, in 2019 was 4,376.0 per 100,000 individuals (95% CI - 3,793.0 to 5,004.9), an increase of 7.5% between 1990 and 2019 [3]. OA is a disorder that manifests first as a molecular derangement, leading to cartilage degradation, bone remodeling, osteophyte formation, inflammation, and loss of normal joint function [4]. The main symptom of knee OA is joint pain, and other clinical manifestations include joint stiffness, reduced range of motion, functional decline, and muscle weakness [5]. Worse symptoms and functional disability can be associated with muscle quality loss, particularly in the vastus medialis muscle [6]. In addition, as well as repercussions on the knee joint and functional performance, sleep quality and psychological well-being are often impacted in people with knee OA, including increased pain catastrophizing and symptoms of depression, anxiety, and stress [7–10].

According to clinical guidelines, structured exercise and arthritis education are the core treatments for patients with knee OA [11, 12]. Interventions that include aerobic exercises, strength exercises, or a combination of them are considered effective ways to improve condition-specific patient-reported outcomes measures (PROMs), such as pain and physical function, with no superiority from one form of exercise compared to the other [12]. On the other hand, regarding psychological well-being, findings of a network

meta-analysis showed that muscle-strengthening exercise is a superior treatment strategy for knee OA patients to improve overall mental health compared to other exercises modalities [13]. However, some barriers are recognized to patient engagement in traditional exercise programs, including physical (patients reporting pain and functional limitations), psychological (some patients believe that physical activities are ineffective, harmful, or of doubtful effectiveness, as well as reporting lack of motivation), and social-environmental factors (patients experience lack of advice and encouragement from health professionals and have lack of social support) [14]. To address these challenges, it is essential to develop alternative strategies that promote treatment engagement. One such strategy is implementing inclusive telehealth systems, such as video calls, which allow real-time supervision of exercise performance, and strengthening the facilitators for physical activity for patients with knee OA at home [14,15]. Therefore, developing alternative strategies to promote treatment engagement for patients with knee OA is imperative, specifically in developing countries [15].

Knee OA treatment is traditionally delivered in a face-to-face modality with the supervision of a physiotherapist in the clinic or at home [16, 17]. On the other hand, there has been growing interest in exercise remotely supervised via telehealth, also known as telerehabilitation, as this mode of intervention uses information and communication technologies to improve exercise participation in patients with musculoskeletal conditions [18–23]. Several factors highlight the need to apply remote rehabilitation, including cost-effectiveness, delivered treatment for patients who live in rural and remote areas, patients' preferences or convenience, limited physiotherapy services, or other challenges to community access to physical rehabilitation [24, 25]. Tools used for this treatment approach include websites, mobile applications, phone calls, text messages, and video calls [26]. From patients' and physiotherapists' perspectives, video calls are considered viable and well-evaluated real-time therapeutic intervention tools [27, 28]. This resource is commonly used for telehealth consultations and is considered as effective as face-to-face outpatient consultations for managing patients with knee OA [29]. In this context, adopting telerehabilitation into clinical practice is a promising way to reduce costs and expand access to treatment for patients with knee OA [26, 30].

A systematic review found that remote exercise programs were not less effective than in-person physical therapy in patients with knee OA [19]. A non-inferiority randomized controlled trial showed that periodized circuit training via recording videos or face-to-face resulted in equivalent effects for pain intensity, physical function, muscle strength, pain catastrophizing, thigh composition, intermuscular adipose tissue, and muscle architecture [18]. Another study found

that remote exercise supervised by video calls for patients with knee OA is more effective than self-management exercise programs for outcomes such as physical performance and emotional status [31]. In this context, a gap in the literature is whether fully supervised muscle-strengthening exercises by video calls are non-inferior to in-person in condition-specific PROMs, psychological well-being (including pain catastrophizing, symptoms of depression, anxiety, and stress) sleep quality, functional performance, and quadriceps femoris architecture. In addition, increasing literature has highlighted the changes in quadriceps muscle architecture in patients with knee OA, including alterations in muscle thickness, pennation angle, fascicle length, and muscle echo intensity [32-35]. In this context, investigating the effects of exercise on these parameters will assist clinicians in adopting remote supervision methods to address changes in quadriceps muscle architecture. Current studies indicate that the primary changes in the quadriceps muscle are related to muscle quality rather than muscle structure [6, 36]. Future results from this trial will enhance our understanding of how exercise influences changes in muscle quality, particularly in relation to reducing intramuscular fat infiltration. Therefore, the present randomized clinical trial aims to answer the question: Does a remote exercise program have comparable responses to the in-person exercise program regarding condition-specific PROMs, psychological well-being, sleep quality, functional performance, and quadriceps muscle architecture in patients with knee OA?

Objectives {7}

The primary aim of this non-inferiority randomized controlled trial is to determine if a muscle-strengthening exercise program for the lower limbs supervised remotely is as effective as the same exercise applied in person for improving pain and physical function (primary outcomes).

The secondary aim of this study is to determine if a muscle-strengthening exercise program for the lower limbs supervised remotely is as effective as the same exercise applied in person for improving condition-specific PROMs, psychological well-being, sleep quality, functional performance, and quadriceps

muscle architecture (secondary outcomes).

Trial design {8}

The Remote and In-person Supervised Exercise in Patients with Knee Osteoarthritis (RISE-KOA) study protocol, designed as a noninferiority trial, is an investigator-blinded randomized clinical trial aiming to assess whether a remotely supervised intervention of muscle-strengthening exercises is non-inferior to an in-person intervention in patients with knee OA. This study will be conducted in a single center, using a 1:1 allocation ratio, two-armed, with parallel groups. The RISE-KOA protocol adheres to the Standard Protocol Items: Recommendations for Interventional Trials (SPIRIT) and OARSI Clinical Trials Recommendations and was registered at www.ClinicalTrial.gov (NCT06101797).

Methods: Participants, interventions and outcomes

Study setting {9}

The clinical trial is being conducted in the city of Bagé, located in the southern region of Brazil. The study assessments occur in person at the University Hospital of the Center of Campaign Region at the Physiotherapy School Clinic and remotely via *WhatsApp* video calls. The Physiotherapy School Clinic treats community patients with musculoskeletal conditions, such as low back and neck pain, hand, hip, or knee osteoarthritis, and rheumatological diseases. In this study, the exercise intervention is supervised by a physiotherapist, either in the remote exercise group via video calls, or in the in-person exercise group at the physiotherapy clinic.

Eligibility criteria {10}

Volunteers, both male and female patients with knee OA diagnosis, are recruited from the waiting list for physiotherapy treatment at the Physiotherapy School Clinic and through a social media invitation. Subsequently, a researcher contacts the volunteers via telephone to check their initial eligibility based on the following criteria:

- Age $\geq$ 45 years.
- History of pain lasting more than three months.
- History of reduced knee function.

Eligible patients are invited for an in-person consultation, and a screening process is performed based on the clinical manifestations and recent radiographic exam. Participants without an exam with the radiographic classification, or if the X-ray was carried out over 12 months, are required to undergo a new exam at the radiology department of the University Hospital. The exam is conducted bilaterally and involves standard anteroposterior weight-bearing and lateral radiographs. The radiographs are evaluated by a blinded, experienced radiologist using the Kellgren and Lawrence grading, in which 0 means no OA and 4 refers to severe OA [37].

Specific inclusion and exclusion criteria for enrollment in this trial are as follows:

Inclusion Criteria

1. Patients with a radiographic diagnosis of unilateral or bilateral knee OA, classified as grades II or III according to the Kellgren and Lawrence criteria [37].
2. Symptomatic patients meeting the following American College of Rheumatology criteria: average pain score ≥ 3 in the last week on the numerical rating scale (0-10), morning stiffness < 30 minutes, and joint crepitus [38].
3. Independent walking and internet access.

Exclusion Criteria

1. Patients with systemic inflammatory diseases, including rheumatoid arthritis, ankylosing spondylitis, and systemic lupus erythematosus.
2. Neurological diseases with motor disability.
3. Unstable heart diseases.
4. History of total knee arthroplasty or lower extremity surgery.
5. Body mass index (BMI) ≥ 35 kg/m².
6. Physical therapy treatment or participation in a supervised exercise program in the last six months.

Who will take informed consent? {26a}

The researcher conducts a detailed explanation of in-person consultation for eligible patients about all study stages, including information about the objectives,

outcome measures, intervention characteristics, risks, benefits, and the confidentiality of data management. Data collection only begins after signing the informed consent form.

Additional consent provisions for collection and use of participant data and biological specimens {26b}

It is not applicable since this trial does not involve collecting biological specimens for storage. The study's primary and secondary outcomes use PROMs, physical functional tests, and ultrasound measurements.

Interventions

Explanation for the choice of comparators {6b}

In-person supervised exercise is a well-established and effective treatment method in patients with knee OA [17]. However, there is a need for more research to establish whether remote exercise is non-inferior to in-person training. There is also an increasing interest in telerehabilitation strategies to treat patients with musculoskeletal disease, particularly in developing countries where socioeconomic reality limits community access to specialized healthcare. Therefore, this study was designed to provide a supervised muscle-strengthening exercise program for the lower extremities, with both groups receiving the same level of supervision. The aim of this protocol is to improve the strength of the quadriceps femoris and, functionally, strengthen the lower limb muscles. The only difference between the two groups will be the supervision format, with one group participating in in-person sessions and the other in remote sessions.

Intervention	description	{11a}

Patients in this study are randomly assigned to receive one of two modes of supervised exercise programs. One group is supervised by a physical therapist remotely via video calls in *WhatsApp* (remote supervised exercise group), while the other receives in-person supervision (in-person supervised exercise group). The treatment will last for 12 weeks and consists of approximately 40-minute sessions, twice a week for the first two weeks and three times from the third week until the end of the protocol.

The treatment protocol consists of six guided muscle-strengthening

exercises for the lower extremities, performed in alternating muscle groups based on exercise programs of previous randomized controlled trials [39–43]. In the first treatment block, the exercise sequence addresses the knee extensors, hip adductors, and plantar flexors, and in the second block, the knee extensors, hip adductors, and knee flexors. The exercises encompass weight-bearing (with body weight support through the affected lower limb) and no-weight-bearing exercises (where participants do not support their body weight through the affected lower limb). Stationary walking precedes the first training block and concludes the exercise program.

Supervision is conducted in an individualized format, so the professional responsible for the intervention supervises a patient at each meeting, and the physiotherapist can make adaptations according to the functional characteristics of each participant. The physiotherapist responsible for the intervention records the entire exercise program, describing any necessary adaptations throughout the training weeks. The study participants are encouraged to perform movements in both open and closed kinetic chains, encompassing a full range of motion. In those subjects who report pain ≥ 3 during the movement on the numerical pain scale, the exercises are adapted and guided toward a smaller range of motion.

During the first two weeks of treatment, exercise intensity is monitored for each participant to complete two sets of 8-12 repetitions in dynamic exercises and 5-8 repetitions of 20 seconds in isometric exercises. From the third week onward, participants are instructed to include one additional set. The interval is set at 1 minute between sets and 30 seconds between exercises. In addition, an interval of 1 minute is maintained between the first and second blocks in the initial six weeks, followed by an interval of 30 seconds in the subsequent weeks. An additional file presents the full exercise periodization of the study in more detail (see Additional File 1).

The patient completes the sets and repetitions of the exercises for each muscle group within the block before proceeding to the next one. In all exercises, the physiotherapists responsible for the intervention guide the progression. Adjustments to weight-bearing, the external load imposed by the elastic band (low to moderate), and exercise position throughout the protocol are performed to maintain the target participant's level of effort. Perceived exertion is monitored using the rating of perceived exertion by the Borg scale – index five on week one

to seven weeks and index seven on week eight to twelve weeks [44].

Once the 12-week supervised treatment period is over, all study participants, regardless of group allocation, will be encouraged to continue exercising at home without the supervision of a physiotherapist. All participants will receive reference material for independent performance (a booklet with photos depicting the exercises) to maintain consistency in treatment. The material will instruct participants to continue with the same treatment program as carried out during 12 weeks of the exercise protocol.

Remote supervised exercise group or in-person supervised exercise group

Following pre-intervention assessments and randomization, all subjects included in the study undergo a face-to-face familiarization session with the exercise program. This session includes specific guidance on the format for providing the intervention (either remote or in-person), and instructions on using the modified Borg effort rating scale during treatment.

In the remote exercise group, participants will receive guidance on video calls, emphasizing positioning the mobile device to ensure the quality of real-time supervision. Subsequently, each exercise will be carried out with safe home performance guidelines. For example, keep a chair and a broom nearby to carry out standing movements to prevent falls and avoid moving near rugs that could slip. At this same meeting, elastic bands will be made available to participants. The physiotherapist conducts all sessions in an individualized format using video calls from *WhatsApp*.

In the in-person supervised exercise group, participants will also be familiarized with each exercise under the supervision of the physiotherapist and guided about the weekly meetings scheduled at the physiotherapy clinic for treatment.

Criteria for discontinuing or modifying allocated interventions {11b}

Participants in the study are free to discontinue the treatment at any time and for any reason without penalty. Participation in the study may be interrupted for

safety reasons, such as medical advice, complications related to pre-existing illnesses, or worsening of a clinical condition that makes participation in the exercise program contraindicated.

Strategies to improve adherence to interventions {11c}

One of OARSI's recommendations for developing the best therapeutic exercise practices for people with knee OA is to motivate patients to engage in and adhere to exercise programs [45]. To ensure participants maintain adherence to their exercise regimens, regardless of remote or in-person supervised exercise format, the researcher responsible for delivering the intervention explains relevant education content throughout the treatment process. Physiotherapists provide real-time instructions remotely (via video call) or in person, based on group allocation, for approximately 10 minutes preceding selected exercise sessions. Three educational sessions will focus on the clinical characteristics of knee OA and exercise treatment. These sessions are scheduled for the initial week of supervised exercise, the third week, and the eighth week. The researcher presents a brief illustrated presentation according to the following approach.

1. Guidance about knee OA and the importance of treatment-based exercises.
2. Patient-centered approach, facilitating an understanding of the symptomatic presentation of knee OA.
3. Positive and simple communication to explain OA, aiming to prevent kinesiophobia.
4. Explanation of long-term exercise benefits and their repercussions on pain and function. The physiotherapist emphasizes that exercise is an effective way for managing OA.
5. Highlights regarding the role of exercise as a treatment, considering it is not associated with an increased risk of joint injury or replacement.
6. Guidance about the difference between pain as an OA symptom and pain after exercise. The physiotherapist emphasizes that short-term pain does not indicate joint damage.
7. Addressing patients' reported fear of exercise by ensuring treatment safety and dispelling any misconceptions about the effectiveness of therapeutic exercise.

Relevant concomitant care permitted or prohibited during the trial {11d}

Participants are encouraged not to participate in a simultaneous physiotherapeutic treatment program, including any therapeutic modality such as manual therapy, electrophysical agents, or another supervised exercise program. Participants can maintain usual care treatment for knee OA, including pharmacological treatment for other health conditions. However, the researcher advises them to avoid treatment through intra-articular injections of glucocorticoids for symptomatic management of knee OA.

Provisions for post-trial care {30}

Our goal is to ensure that all participants receive the highest level of care and support throughout the trial. After completing the RISE-KOA study, patients will receive a report of the results. In addition, during the trial, participants will be provided with a description of the X-ray exam.

At the end of the supervised exercise treatment, all participants will receive reference material (a booklet with photos depicting the exercises) for independent exercise performance in the following weeks to maintain consistency in treatment and encourage self-efficacy. The material will instruct participants to continue the same treatment program during the 12 weeks of the exercise protocol.

Outcomes {12}

Primary outcome measure

The primary outcomes are pain intensity and physical function in sixth week (during treatment), 12th week (after treatment). These outcomes were selected as they are strongly recommended in clinical trials involving patients with knee OA [46].

Pain intensity

The average pain intensity in the last week is measured using an 11-point Pain Intensity Numerical Rating Scale (NRS), in which 0 corresponds to "no pain," and 10 represents "worst possible pain." NRS is a PROM for assessment and

clinical decision-making in patients with knee OA with good psychometric properties [47].

Physical function

Physical function is measured by Knee Injury and Osteoarthritis Outcome Score (KOOS) using an Activities of Daily Living subscale. The KOOS is a PROM comprising 42 items divided into five subscales: Pain, other Symptoms, Activities of daily living, Sport and Recreation Function, and Knee-related Quality of Life. Its score ranges from 0 (extreme problem) to 100 (no problems) separately in each subscale [48]. The Brazilian version of the KOOS questionnaire was recently validated, consisting of an instrument with validity, reliability, and responsiveness in patients with knee OA [49].

Secondary outcome measures

The secondary outcomes involve PROMs related to joint condition, psychological well-being, sleep quality, functional performance, and quadriceps muscle architecture.

Condition-specific PROMs

Pain intensity is measured using NRS, and physical function using KOOS Activities of Daily Living subscale as secondary outcomes after 18 weeks (follow-up). Pain score, other symptoms (hear clicking, swelling, catching, restricted range of motion, and stiffness), sport and recreation function, and knee-related quality of life before and after 6 (during treatment), 12 (after treatment), and 18 weeks (follow-up) are measured by each KOOS subscales which range from 0 (extreme problem) to 100 (no problems).

Psychological well-being

Pain catastrophizing; symptoms of depression, anxiety, and stress; are measured

before, after 6 (during treatment), 12 (after treatment), and 18 weeks (follow-up) with the following instruments, respectively:

1. The Pain Catastrophizing Scale is an instrument validated and translated into Brazilian Portuguese used to classify subjects with chronic pain as potentially catastrophic patients [50, 51]. Catastrophizing is a maladaptive reaction to pain and can be considered one of the factors that contribute to the chronicity of some pain syndromes. The scale comprises 13 items involving self-reported catastrophic thoughts, feelings, and behaviors. Items are rated on a 5-point Likert scale, ranging from 0 to 4, and the total score is generated by summing the scores of all items (0-52). Higher values indicate catastrophic thoughts about pain.
2. Depression, Anxiety, and Stress Scale is a self-reported instrument validated and translated into Brazilian Portuguese [52]. It consists of 21 items ranging from 0 (did not apply at all) to 3 (applied very much or most of the time), divided into subscales of seven questions each. The highest score on each subscale represents more significant symptoms severity of depression, anxiety, and stress.

Sleep quality

Sleep quality are measured before, after 6 (during treatment), 12 (after treatment), and 18 weeks (follow-up) with the following instrument:

The Pittsburgh Sleep Quality Index Self-report Questionnaire, validated for the Brazilian population, assesses sleep quality over a 1-month period through questions related to sleep habits [53]. The questionnaire consists of 19 self-reported questions and five questions that should be answered by bedmates or roommates. The study will not consider the last questions as they are used to obtain clinical information. In this sense, 19 questions will be graded on a score ranging from 0 to 3 and categorized into seven components: (1) Subjective Sleep Quality; (2) Sleep Latency; (3) Sleep Duration; (4) Habitual Sleep Efficiency; (5) Sleep Disturbances; (6) Use of Sleeping Medication, and (7) Daytime Dysfunction. The sum of the scores of the seven components will result in a global score (0 to 21), with the highest value indicating worse sleep quality.

Functional performance

The functional tests recommended by OARSI for knee OA patients assess the participants' functional profiles [54]. Sit-to-stand, ambulatory transition, short-distance walking, and stair negotiation activities are measured before and after 12 weeks of treatment with the following instruments, respectively: the 30-s chair-stand test, the Timed Up and Go test, the 40-meter fast walk test, and the Stair Climb test. The assessor applies the functional tests described below in random order.

1. In the 30-s chair-stand test, patients are instructed to sit in the center of the chair 42 cm high from the seat, positioned against the wall, without the aid of the upper limbs, and perform the test movements for familiarization. Subsequently, sit down and get up from the chair as quickly as possible within 30 seconds. Thus, the measurement result will consist of a total number of complete chair stands in 30 s (up and down represent one stand).
2. In the Timed Up & Go test, patients are instructed to move from a seated position to standing, walking to a mark 3 m away, turn around, and return to the seated position. The measurement result will be expressed in seconds, corresponding the time taken to complete the task.
3. In the 40-meter fast walk test, patients are instructed to walk as quickly but as safely as possible without running. They walk to the 10-m mark, turn around, and return, repeating for a total distance of 40m. The measurement of walking time only includes the 10-m walking period, excluding turns. The speed measurement will be expressed in m/s, dividing the 40 m by the time (seconds) needed to travel through the test area.
4. In the Stair Climb Test, patients are instructed to ascend and descend stairs as quickly as possible while wearing their usual shoes. The measurement will be expressed in seconds, corresponding to the total time taken to complete both ascending and descending the stairs.

Quadriceps femoris architecture

Quadriceps femoris architecture is measured before and after 12 weeks of

treatment. For this measurement, quadriceps femoris images are generated through a B-mode imaging device (Versana Balance Ultrasound– GE Healthcare) equipped with a 12 MHz linear-array probe with optimized ultrasound settings (image depth: 4 to 6cm, 60-dB general gain, time gain compensation at neutral position) [55]. The sonographer considers the symptomatic lower limb for measurement, and the more symptomatic side will be in bilateral OA. The same evaluator with expertise in musculoskeletal ultrasound generates the images.

For image acquisition, participants remain rested in the supine position for 5 minutes with the lower limbs at the neutral position, extended and relaxed, preventing muscle activation [56]. The transducer is coated with a generous amount of water-soluble transmission gel and positioned perpendicularly, applying the minimum pressure at each point of the quadriceps femoris to visualize the ultrasound image.

Three transverse images are obtained for all quadriceps femoris muscles: Rectus femoris (RF), Vastus intermedius (VI), Vastus medialis (VM), and Vastus lateralis (VL). Additional longitudinal images of VL are also acquired to visualize muscle fascicles. Similar to a previous study [57], RF and VI capture occurs by transducer positioning between the anterior superior iliac spine and the proximal end of the patella (a midpoint). For VL, the transducer is positioned midway between the greater trochanter and the lateral epicondyle of the femur. To identify the VM, the transducer is positioned at a 30% distal between the greater trochanter and the lateral epicondyle of the femur. To ensure a similar probe position in subsequent tests, the assessment site of each muscle is marked on transparent paper and used for probe repositioning. After image acquisition, a second investigator will be measure quadriceps femoris architecture using Image-J software (National Institutes of Health, USA, version 1.53) according to the following outcomes.

1. Quadriceps femoris muscle thickness

The quadriceps muscle thickness is measured considering the distance between muscle fascia or at the fascia and bone structure interface [57]. The muscle thickness will be expressed in centimetres and presented as the sum of the measurements of each quadriceps femoris muscle (i.e. RF+VL+VM+VI), with

individual muscle values also shown separately.

2. Quadriceps femoris muscle quality

Quadriceps muscle quality, expressed as muscle echo intensity (EI), is measured using a greyscale function in Image J software. The EI is an echo or brightness reflected by the muscular structure. It will be calculated based on a region of interest in each muscle, including as much of the muscle as possible, and shown in arbitrary units, with values ranging between 0 (black) and 255 (white) [58]. The highest value represents decreased muscle quality and deposition of non-contractile tissue within the muscle. Subsequently, a researcher will correct the EI data according to subcutaneous fat thickness; thus, the correction of echo intensity will be calculated as $\text{uncorrected EI} + (\text{subcutaneous fat thickness [cm]} \times 40.5278)$. Data will be presented as the mean of the quadriceps femoris EI corrected $((\text{RF} + \text{VL} + \text{VM} + \text{VI})/4)$, with individual muscle values also shown separately [59,60].

3. Pennation angle

Due to the alignment of the fascicles, the pennation angle is measured using only images of the vastus lateralis [61]. The pennation angle is formed between the muscle fascicle line and the deep aponeurosis. It will be expressed in degrees. The data analysis will include the mean of three measurements for pennation angle.

4. Fascicle length

Fascicle length is measured using only images of the VL [62]. Fascicle length (cm) is the length of the fascicle insertion between the superficial and deep aponeurosis. When the fascicle extends out of the acquired ultrasound image, the length of the missing portion will be estimated by linear extrapolation of both the fascicular path and the aponeurosis. In addition, an experienced evaluator will normalize the data

by analyzing the ratio between the fascicle length of the VL and the femur length. Femur length is the distance (cm) between the lateral femoral condyle and trochanter major.

Other outcomes

Number of medications

The number of analgesic and anti-inflammatory medications ingested is being registered considering information reported by the patient before, after 6, 12, and 18 weeks of treatment.

Participant timeline {13}

The schedule of trial enrolment, interventions, and assessments are presented in Figure 1.

Sample size {14}

The sample size calculation was performed using the Sealed Envelope Power (sample size) calculators [63]. We based our sample size calculation on a previous study [64], considering an alpha level of 0.05, power of 0.80, standard deviation of 2 in pain level, and a non-inferiority margin of -1.6 points. The minimum required sample size was determined to be at least 40 participants. Considering an expected sample loss of ≈20% between baseline and follow-up, 48 participants are needed, 24 per group. According to previous recommendations [65,66], we established a non-inferiority margin in primary outcome pain level, measured by NRS, of -1.6 points (20% less than the minimum clinically significant difference reported for the NRS [67]).

Recruitment {15}

The recruitment period started in December 2023 and will be completed in October 2024. Subjects for the Bagé, Brazil, will be recruited through notes shared in local newspapers and social media, as well as the waiting list of the Physical Therapy School Clinic.

Assignment of interventions: allocation

Sequence generation {16a}

Each participant is assigned an internal code (ID) for de-identification purposes (i.e., RISE-KOA-256), and a randomization process is implemented using an allocation ratio 1:1. The randomization sequence is generated by a single researcher using a specific Excel random function.

Concealment mechanism {16b}

The researcher responsible for participant matching and randomizing is not involved in the study's recruitment and intervention stages. Exclusive access to the age variable is granted solely for the purpose of randomizing participants into study groups. Following randomization, the team responsible for the intervention is informed via text messages regarding the group assignment of each patient.

Implementation {16c}

After participants sign the informed consent form and complete baseline measurements, a randomization sequence is carried out by a researcher not involved in any other study step. Patients will be assigned to either the remote or in-person exercise groups. The sociodemographic characteristic of age will be used as stratification to balance the groups (in the categories of participants aged 45 to 54 or 55 to 80). The age was selected because it impacts the symptomatic presentation of patients with knee OA and the years lived with disability [1, 69].

Assignment of interventions: Blinding**Who will be blinded {17a}**

Outcome assessors will remain unaware of the intervention assignment (remote or in-person). Participants are instructed not to discuss their interventions during evaluation outcomes to ensure evaluator masking. However, due to the nature of the intervention, neither the participants nor the team conducting the exercise sessions can be blinded.

Procedure for unblinding if needed {17b}

RISE-KOA is a single-blind study, with only the outcome assessors being blinded. For this reason, unblinding will not be anticipated; however, in the case of unintentional unblinding, the study coordinator will be contacted..

Data collection and management

Plans for assessment and collection of outcomes {18a}

The study assessment is conducted over two days. On the first day, assessments take place in-person at the Physiotherapy School Clinic and the Radiology Department within the University Hospital of the Center of Campaign Region. On the second day, assessments are conducted remotely via video call using *WhatsApp*.

On the first day, a research team conducts a physical therapy anamnesis, followed by ultrasound measures and functional assessments performed by independent assessors. Ultrasound scanning and functional assessments are conducted at two-time points (baseline and after 12 weeks).

Anamnesis comprises an evaluation of the clinical profile (inspection, palpation, ligament integrity, blood pressure, past medical history, medication consumption, intraarticular injection therapy, fear of movement, the wait list for knee arthroplasty surgery) and a sociodemographic characterization (age, sex, height, weight, body mass index, educational level, and work status).

On the second day, condition-specific PROMs, psychological well-being, sleep quality, and medication use are assessed by another researcher who conducts the evaluation remotely via *WhatsApp* video calls. These measurements occur at three time points: after 6 (during treatment), 12 (after treatment), and after 18 weeks (follow-up). Even if participants withdraw from the study or do not adhere to treatment, they are invited to participate in all assessment time points. After completing all evaluations, the intervention team contacts patients to schedule a familiarization session and subsequent treatment.

The research team underwent comprehensive training on the assessment and intervention methods prior to the study. The training process started with the provision of illustrated materials in a virtual environment, covering the essential themes of the intervention. Subsequently, in-person training was conducted in

several stages. During the initial meeting, the assistant researcher explained the concepts related to the joint condition, and the intervention program was thoroughly discussed. This explanation encompassed the definition of knee OA, the crucial role of exercises in physiotherapeutic treatment, elucidating methods for conducting this therapeutic approach both in person and remotely, and the topics related to the educational approach to OA.

In the subsequent meeting, the study team received training on how to conduct the protocol in both modalities. They experienced one session of the intervention program exercises, both in person and via video calls. In addition, the team responsible for the assessment received training related to each outcome and measurement. Training sessions for both intervention and assessment teams were conducted in focal groups.

Furthermore, each topic of the educational approach was discussed from a theoretical and practical perspective. Decision-making related issues were emphasized concerning possible challenges encountered during video calls, such as connectivity loss or transmission quality concerns. During the third meeting, a pilot study involving real patients was conducted to train the team.

Plans to promote participant retention and complete follow-up {18b}

During the recruitment period, patients receive thorough explanations regarding the importance of participating in all assessment time points. In weeks one, three, and eight, education strategies aimed at enhancing adherence to exercise programs are implemented to promote patient engagement with study assessments. Additionally, all patients receive regular follow-ups from staff and are provided priority access to schedule appointments at the clinic or remotely to address any concerns or manage worsening joint symptoms.

Data management {19}

The collected data will be stored in a digital file on the responsible researcher's drive, with the names of the participants coded as IDs, thus allowing more accessible access to the information collected for future data analysis. Therefore, to maintain participants' safety and resolve any doubts about the research, the information collected will be stored for five years after the end of the study.

Confidentiality {27}

All data collected will be anonymous and identified by ID. The data will be stored in a secure drive accessible only by the research team.

Plans for collection, laboratory evaluation and storage of biological specimens for genetic or molecular analysis in this trial/future use {33}

There is no need to collect any specimens as it is not applicable.

Patient Public Involvement

In this trial, we did not plan for direct involvement of patients in the study design. However, the study manager (MTXC), a physical therapist at the Physical Therapy Clinic of the University Hospital, regularly interacted with knee OA patients who had similar expectations regarding physical therapy treatment. Based on gaps identified in the available literature and the main concerns reported by patients, the study was designed by the study manager (MTXC) and the principal investigator (CLA).

Statistical methods

Statistical methods for primary and secondary outcomes {20a}

The study will use descriptive statistics to present the baseline characteristics of the participants. The between-groups difference and 95% confidence interval (95%CI) after 6, 12, and 18 weeks of treatment will be calculated using linear mixed models using interaction terms of treatment group versus time. A non-inferiority of the remotely supervised exercise would be demonstrated if the lower bound of the two-sided 95% CI for the between-group difference (remotely supervised exercise minus in-person supervised exercise) would be above -1.6 points for pain and -6.4 points for physical function (KOOS Activities of daily living subscale) (corresponding to 20% less than the minimum clinically significant difference reported by these outcome) [67,69]. Effect sizes (Cohen's d) between groups will be calculated and classified as small (0.2 to 0.5), moderate (0.5 to 0.8) or large (above 0.8). The significance level adopted in this study will be $\alpha =$

0.05. All statistical analyses will be performed on SPSS statistical software (Statistical Package for Social Science), version 20.0 for Windows (IBM corporation, Somers, New York, USA).

Interim analyses {21b}

No interim analyses are planned for this study because it was designed to assess the effect of interest according to a predefined non-inferiority margin for the primary outcome pain level, based on a prior sample size calculation. In addition, given that the international guidelines strongly recommend the intervention proposed in the study, we do not anticipate any issues that could be detrimental to participants, which would necessitate an interruption of the trial.

Methods for additional analyses (e.g. subgroup analyses) {20b}

None planned.

Methods in analysis to handle protocol non-adherence and any statistical methods to handle missing data {20c}

The study's primary and secondary outcomes will be analyzed using two methods: intention-to-treat analysis, which involves all patients randomized into the study, and per-protocol analysis, which focuses only on patients who followed the intervention with an adherence rate of more than 85%. Multiple imputations will be used to impute missing data using a specific function on SPSS software.

Plans to give access to the full protocol, participant level-data and statistical code {31c}

The full study protocol, participant-level data, and statistical code can be made available by the Trial Coordinator upon reasonable request.

Oversight and monitoring

Composition of the coordinating centre and trial steering committee {5d}

Due to the study's single-center nature, a specific monitoring committee was not considered. However, the main researcher (CLA) supervises all trial steps

through continuous communication with the study manager (MTXC), who coordinates the research team. The study manager is responsible for training the work team, providing constant support, and taking all the necessary precautions to avoid unmasking treatment allocation.

Composition of the data monitoring committee, its role and reporting structure {21a}

A data monitoring committee was not considered as this study will be conducted in one center and adopts a low-risk intervention.

Adverse event reporting and harms {22}

In the context of knee osteoarthritis patients, adverse events encompass any increase in pain intensity during the trial or other joint symptoms presentation (such as clicking, swelling, catching, restricted range of motion, and stiffness) during assessments or intervention periods. In this sense, adverse events will be monitored and categorized according to the severity of pain, classified as mild (1-3), moderate (4-7), or severe (8-10). In addition, the research team will monitor predictability (expected or unexpected) and possible association with the timing of outcome measures, the exercise protocol, and the mode of supervision (associated, possibly associated, or not associated). All potential adverse events will be discussed by at least two researchers (the principal investigator and study manager) and, if necessary, consultants and experts in the field.

Frequency and plans for auditing trial conduct {23}

The research team meets weekly to discuss the trial development, any necessary adaptations, and the quality of delivering the exercise protocol for knee OA participants. Study documents are constantly checked for an independent researcher not involved with the present study to guarantee the accuracy of data tabulation at all time points. If any records are missing, the research team will report it to the local ethics committee. The research team will contact the patient if any information needs consistency. The composition of the research team that discusses the trial development, and delivery of exercise consists of the main researcher (CLA) and the study manager (MTXC), who maintains periodic

contact with the intervention and evaluation team, providing support weekly while maintaining blinding. As detailed in the "Composition of the Data Monitoring Committee, Its Role, and Reporting Structure" section, we did not establish a data monitoring committee because the intervention poses a low risk to patients.

Plans for communicating important protocol amendments to relevant parties (e.g. trial participants, ethical committees) {25}

All possible amendments to the Protocol are primarily discussed between the study manager and main researcher, and subsequently communicated and approved by the Human Research Ethics Committee from the Federal University of Pelotas – RS. After Ethical approval, the researcher adjusted the ClinicalTrials.gov register to maintain public any amendments in the Protocol. All deviations from the Protocol will be documented thoroughly using a breach report form or described in the future publication of the original article of the randomized controlled trial. Possible amendments did not include changes in intervention, delivery format, or assessment instruments. Changes may include some adaptations in data analysis that did not affect the quality of intervention delivery.

Dissemination plans {31a}

We planned to disseminate our results in three ways:

1. Through the Scientific community by submitting papers to journals,
2. Through our future randomized patients,
3. Through social media and local newspapers.

All positive and negative results will be disseminated, ensuring transparency in research.

Discussion

The RISE-KOA study aims to investigate whether a muscle-strengthening exercise program for the lower limbs, supervised remotely, is as effective as in-person exercise for patients with knee OA. We hypothesized that the supervised training remotely via video call is no inferior to supervised in-person training, and it will equally improve condition-specific PROMs, psychological well-being, sleep

quality, functional performance, and quadriceps architecture of patients with knee OA.

Video calls are a relatively simple and common way to promote teleconsultations, increasing community access to rehabilitation services [70]. Previously published studies or those in development have explored the effectiveness of remote exercises for patients with knee OA using video calls for the prescription; however, the supervision throughout the entire treatment in this format remains underinvestigated [71–73]. Thus, although telerehabilitation is an attractive mode and cost-effective strategy for delivering treatment equal to traditional face-to-face rehabilitation, studies focusing primarily on the comparability of supervised exercise remotely using video calls or in-person in patients with knee OA are scarce [29]. In this sense, our study aims to fill this gap in the literature, offering alternative ways for delivering the core treatment for knee OA. Furthermore, by confirming our hypothesis, the study findings will contribute to changing a "hands-on" care culture, offering other forms to deliver recommended treatment beyond the conventional face-to-face physiotherapeutic consultation in clinical settings.

The exercise protocol implemented in the RISE-KOA study exhibits some relevant characteristics. Firstly, the exercise program was designed to be pragmatic, employing straightforward exercises that can be easily performed in both scenarios at home (remotely) or the clinic (in-person). Secondly, the protocol includes weight-bearing and non-weight-bearing quadriceps exercises. This approach aims to improve the strength of the quadriceps femoris while simultaneously strengthening the lower limb muscles functionally, progressing through weight-bearing exercises (i.e., squat on the wall, wall push, and chair stand), with instructions provided to the patients distributing the weight during movements onto the arthritic leg or the more symptomatic knee. Thirdly, this exercise protocol does not only focus on quadriceps femoris function but also on entire lower limb muscles, with patients guided in each session to alternating muscular groups. Finally, a detailed periodization and prescription of exercise protocol is a positive characteristic of this study, given that many other studies need more accurate information about exercise protocol.

Knee OA is a highly prevalent condition that continues to rise with implications for physical disability and psychological well-being [74]. In this sense,

patients experience changes in the quadriceps femoris muscle characterized by loss of muscle quality [75]. Also, some patients self-reported symptoms of anxiety, depression, stress, pain catastrophizing, and reduced sleep quality [76-78]. Considering these particular characteristics, a RISE-KOA study will provide a relevant social impact, addressing gaps in the literature concerning the comparability of exercises remotely supervised by video call or in-person in clinical, physical, and psychological outcomes.

High-quality studies with large samples are necessary to increase knowledge concerning telerehabilitation for patients with knee OA [79]. In this sense, our study will improve evidence about telerehabilitation using video calls, providing insights into the comparable effects of remote and in-person rehabilitation. It will help physiotherapists make better treatment options, particularly for patients who cannot attend in-person sessions. Also, our future findings can increase community access to exercise and empower people to choose the better a supervision modality (remote or in-person), considering patient preferences.

The study has a few limitations that need to be taken into consideration. Initially, patients participating in the remote exercise group, just like those in the in-person exercise group, will be invited to attend an in-person familiarization session before the intervention period. This familiarization session is crucial for learning exercises and adherence to the program. However, it does not accurately represent a completely remote intervention. Moreover, the study will investigate muscle architecture at only one site in each muscle; in this sense, future morphological changes obtained with this study will not reflect changes in the entire muscle volume. While recognizing these limitations, one of the strengths of this study is that it examines the effectiveness of two exercise delivery methods that will contribute to expanding access to therapeutic exercise for patients with knee OA in developing countries.

Trial status

This protocol was initially approved by ClinicalTrials.Gov on October 26, 2023 (Version 1). An update was published on December 21, 2023 (Version 2). A new update was published on February 18, 2025 (Version 3). The most recent update

involved a revision of the sample size calculation. This adjustment was necessary because we initially established a very strict non-inferiority margin for the primary outcome, pain level, which led us to update the sample size calculation. We estimated a new sample size considering a non-inferiority margin of 20% less than the minimum clinically significant difference for pain level according to CONSORT recommendations to conduct non-inferiority clinical trials. The first sample size calculation estimated 68 patients for the study, and the new sample size was 48 patients. Recruitment started on December 4, 2024, and ended on October 15, 2024. Study completion was estimated on March 8, 2025. The study protocol was submitted to Trials for publication in the initial recruitment on April 12, 2024.

Abbreviations

OA: Osteoarthritis

PROMs: Patient-reported outcomes measures

RISE-KOA: Remote and in-person supervised exercise in patients with knee osteoarthritis

SPIRIT: Standard Protocol Items: Recommendations for Interventional Trials

OARSI: Osteoarthritis Research Society International

BMI: Body mass index

NRS: Numerical rating scale

KOOS: Knee Injury and Osteoarthritis Outcome Score

RF: Rectus femoris

VI: Vastus intermedius

VM: Vastus medialis

VL: Vastus lateralis

EI: Echo intensity

ID: Internal code

Declarations

Trials guidance: All manuscripts must contain the following subheadings:

- Acknowledgements
- Authors' contributions
- Funding

- Availability of data and material
- Ethics approval and consent to participate
- Consent for publication
- Competing interests
- Authors' information (optional)

Acknowledgements

The authors would like to thank the team from the radiology department of the university hospital for carrying out the radiographic examinations.

Authors' contributions {31b}

MTXC and CLA conceived the study idea. MTXC took the lead in writing the manuscript. CLA revised the manuscript. All authors read and approved the final manuscript.

Funding {4}

The authors declare that they have not received any assistance from any funding sources, such as funding agencies in public, commercial, or non-profit sectors. The study manager provides the materials used in this clinical trial. The Physiotherapy School Clinic and Radiology Department of the University Hospital of Campaign Region provide educational support, such as the availability of equipment and consumables.

Availability of data and materials {29}

The datasets analyzed during the current study will be made available from the corresponding author upon reasonable request after study completion.

Ethics approval and consent to participate {24}

The RISE-KOA study procedures were performed according to the Declaration of Helsinki and approved by the Human Research Ethics Committee of the Physical Education School of the Federal University of Pelotas (Brazil) (CAAE: 74411723.0.0000.5313). Recruited participants are informed about all study stages, including information about the objectives, outcome measures,

intervention characteristics, risks, benefits, and the confidentiality of data management. Data collection only begins after participants accept to participate in the study and sign the informed consent form.

Consent for publication {32}

Not applicable: no identifying images or other clinical and demographic data that could identify participants.

Competing interests {28}

The authors declare that they have no competing interests.

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ARTIGO 4

Artigo para submissão futura no periódico *Archives of Physical Medicine and Rehabilitation* (fator de impacto 3.6) conforme a diretriz para autores (Anexo VI)

Remote and In-person Supervised Exercise in Patients with Knee Osteoarthritis (RISE-KOA study): a non-inferiority randomized clinical trial

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Abstract

Objective

This study evaluates whether a remotely supervised exercise program for the lower limbs via video calls is non-inferior to the same in-person supervised exercise program in patients with knee osteoarthritis (OA) in pain level and physical function.

Design

Single-blind, non-inferiority, randomized controlled trial.

Setting

Physical therapy clinic of the University Hospital and virtual setting.

Participants

Patients with radiographic and symptomatic knee OA, pain level ≥ 3 in the last week, independent walking, and internet access were included.

Interventions

Twelve weeks of the muscle-strengthening program for the lower limbs supervised remotely (remote exercise group) using video calls or in-person (in-person exercise group) at a physical therapy clinic.

Main Outcome Measure

The primary outcome was pain level (Numerical Rating Scale) and physical function (Knee Injury and Osteoarthritis Outcome Score (KOOS) - Activities of Daily Living subscale) at Weeks 6 and 12. The secondary outcomes include the remaining KOOS subscales (Pain, Symptoms, Sports and Recreation, and Knee-related Quality of Life), psychological well-being (Pain Catastrophizing Scale, Depression, Anxiety and Stress Scale), and sleep quality (Pittsburgh Sleep Quality Index) at Weeks 6 and 12. In addition, physical performance and quadriceps muscle architecture and muscle quality at Week 12.

Results

The remote supervised exercise group was non-inferiority to the in-person group for pain level and physical function, as the lower bound of the 95% CI of the mean difference did not cross the non-inferiority margins (-1.6 for pain; -6.4 to physical function) at week 12 (pain: 0.7, 95% CI -1.3 to 2.6; physical function: 13.2, 95% CI -4.0 to 30.4). Secondary outcomes (KOOS subscales, symptoms of stress, physical performance, pennation angle, and quadriceps muscle quality) improve similarly in the two supervision formats after 12 weeks.

Conclusion

Remotely supervised exercise using video calls is non-inferior to the same in-person supervised exercise program in patients with knee OA.

Keywords

Chronic Pain; Joint Diseases; Telerehabilitation; Patient Reported Outcome Measures.

Introduction

Osteoarthritis (OA) is a multifactorial joint condition with a high prevalence in the adult population and a leading cause of global disability¹. In 2020, 595 million people had OA worldwide, reflecting an increase of 132.2% in total cases since 1990². Projections indicate that by the year 2050, the number of new knee OA cases is expected to rise by 74.9%³. Knee OA is a condition characterized by inflammation and changes in joint metabolism, resulting in cartilage damage, osteophyte formation, subchondral bone sclerosis, various degrees of synovitis, and impairment of normal joint function^{4,5}. Symptoms include activity-related knee pain, functional limitation, morning stiffness, swelling, and buckling or giving away⁶.

According to the clinical guidelines, exercise and arthritis education are the primary recommended treatments for managing knee OA symptoms^{7,8}. Aerobic exercise, muscle strengthening exercise, or a combination of both are considered effective interventions for improving patient-reported outcomes (PROMs), such as pain and physical function⁷. Physical rehabilitation professionals traditionally provide exercise-based treatments in clinical settings⁹. However, in recent years, a growing body of literature has highlighted the effectiveness of telerehabilitation in delivering treatment for patients with knee OA^{10–13}. The advantages of telerehabilitation include cost-effectiveness, increased healthcare accessibility, the ability to deliver exercise programs remotely, the potential to overcome geographical barriers, and reduced economic burden on the healthcare system^{14,15}.

Physical rehabilitation professionals use telehealth tools such as websites, mobile applications, phone calls, text messages, or video calls¹⁶. Both patients and physical therapists perceive video calls as an effective and well-established tool for real-time remote therapeutic interventions^{17,18}. This method is commonly employed in telehealth consultations and has been shown to be as effective as face-to-face outpatient consultations in managing patients with knee OA¹⁹. However, the effectiveness of such a telerehabilitation resource for exercise supervision in extended rehabilitation programs (12 weeks) is not well known.

A study found that implementing remote exercise via video calls over eight weeks was more effective than self-managed exercise programs for patients with knee OA across several outcomes, including pain levels, condition-specific PROMs, physical performance, kinesiophobia, emotional status, fatigue, and physical activity levels²⁰. Findings from a recent randomized clinical trial indicate that four weeks of real-time supervised exercise through video calls is not inferior to the same intervention delivered in person at rehabilitation clinics on pain reduction and quality of life improvement in patients with knee OA ²¹.

Therefore, to our knowledge, no studies in the literature have yet investigated whether 12 weeks of remote exercise supervised by video calls is non-inferior to a comparable in-person program on pain, physical function, other condition-specific PROMs, psychological well-being, sleep quality, physical performance, and quadriceps muscle architecture and quality. In this context, with the increasing burden of knee OA and growing interest in telerehabilitation, it is crucial to understand the potential of remote supervision using video calls to optimize rehabilitation strategies worldwide.

Furthermore, a systematic review and meta-analysis have highlighted the need for more high-quality clinical trials on telerehabilitation for patients with knee OA²². Therefore, our study was designed to fill these gaps in the literature, particularly considering the socioeconomic context of developing countries. Our single-blinded clinical trial aims to evaluate whether a remotely supervised muscle-strengthening program for the lower limbs using video calls is non-inferior to an in-person program on pain and physical function improvements. Additionally, we assess its effectiveness in enhancing other condition-specific PROMs, psychological well-being, sleep quality, functional performance, and quadriceps muscle architecture and quality.

Methods

Trial design

The Remote and In-person Supervised Exercise in Patients with Knee Osteoarthritis (RISE-KOA) study was a single-center, non-inferiority randomized clinical trial (RCT) conducted in the city of Bagé, located in the southern region

of Brazil. Recruitment, in-person assessments, and intervention took place at the Physical Therapy Clinic of the University Hospital of the Center of Campanha Region. The study adhered to the CONSORT reporting guidelines for RCTs, including an extended version for non-inferiority trials²³. Ethical approval was obtained from the Institutional Research Ethics Committee (registration number: 74411723.0.0000.5313), and the protocol was previously registered on ClinicalTrials.gov (registration number: NCT06101797). The research was conducted in accordance with the ethical standards outlined in the Helsinki Declaration, and all participants provided written informed consent before participating in the study.

Participants

Participants were recruited from the waiting list for physical therapy treatment and through a social media invitation, between December 2023 and October 2024. The inclusion criteria were as follows: 1. Patients with a radiographic diagnosis of unilateral or bilateral knee OA, classified as grades II or III according to the Kellgren and Lawrence criteria²⁴; 2. Symptomatic patients meeting the following criteria: average pain score of ≥ 3 in the last week on the numerical rating scale (0-10), morning stiffness of < 30 minutes, and joint crepitus²⁵; and 3. Ability to walk independently and internet access. Exclusion criteria included: 1. Patients with systemic inflammatory diseases, including rheumatoid arthritis, ankylosing spondylitis, and systemic lupus erythematosus; 2. Neurological diseases causing motor disability; 3. Unstable cardiac diseases; 4. History of total knee arthroplasty or lower extremity surgery; 5. Body mass index (BMI) ≥ 35 kg/m²; and 6. Undergoing physical therapy treatment or participation in a supervised exercise program within the last six months.

Procedures

Participants underwent an initial telephone screening, and eligible patients were subsequently invited for an in-person consultation. A screening process was performed based on their clinical manifestations and a recent radiographic examination. Participants who did not have a radiographic exam to ensure classification, or whose X-ray had been performed more than 12 months earlier were forwarded to undergo a new exam at the radiology department of the

University Hospital. Data collection only began after participants had signed the informed consent form.

The study assessments were conducted over two days. On the first day, assessments were conducted in person at the physical therapy clinic. Clinical and demographic data were collected by independent blinded assessors, followed by ultrasound measurements and functional assessments. Ultrasound scanning and functional performance were conducted at two time points (Week 0 and Week 12). On the second day, assessments were conducted remotely via video call using WhatsApp. Another researcher assessed condition-specific PROMs, psychological well-being, sleep quality, and medication use. These measurements were taken at the three time points (Week 0, Week 6, and Week 12).

Outcomes

Primary outcomes

The primary outcomes were pain and physical function at Weeks 6 and 12. The average pain intensity over the last week was measured using an 11-point Pain Intensity Numerical Rating Scale (NRS), in which 0 corresponds to "no pain," and 10 represents "worst possible pain" ²⁶. Physical function was measured using the Activities of Daily Living subscale of the Knee Injury and Osteoarthritis Outcome Score (KOOS)²⁷. The KOOS is a self-reported questionnaire comprising 42 items divided into subscales: Pain, Symptoms, Activities of daily living, Sports and Recreation, and Knee-related Quality of Life. Each subscale is scored separately, ranging from 0 (extreme problems) to 100 (no problems).

Secondary outcomes

The secondary outcomes included condition-specific PROMs, psychological well-being, and sleep quality at Weeks 6 and 12. In addition, functional performance, and quadriceps muscle architecture were assessed at Week 12. Condition-specific PROMs were collected based on the remaining KOOS subscales (Pain, Symptoms, Sport and Recreation, and Knee-related quality of life). Psychological

well-being included pain catastrophizing and symptoms of depression, anxiety, and stress. Pain catastrophizing was measured using the Pain Catastrophizing Scale, in which scores range from 0 to 52, with scores greater than 30 indicating high levels of catastrophism about pain²⁸. Symptoms of depression, anxiety, and stress were measured according to the Depression, Anxiety, and Stress Scale (DASS)²⁹, with subscale scores ranging from 0 to 42. Depression score was classified as “normal” (less than 9), “mild” (10-13), “moderate” (14–20), “severe” (21–27), “extremely severe” (greater than 28). Anxiety score was classified as “normal” (less than 7), “mild” (8–9), “moderate” (10–14), “severe” (15–19), “extremely severe” (scores above 20). Stress score was classified as “normal” (below 14), “mild” (15-18), “moderate” (19-25), “severe” (26–33), “extremely severe” (greater than 34)³⁰. Sleep quality was assessed using the Pittsburgh Sleep Quality Index (PSQI), a self-report questionnaire with scores ranging from 0 to 21. A score greater than 5 indicates major difficulties in at least two components or moderate difficulties in more than three components of sleep quality³¹.

Functional performance was measured according to OARSI recommendations³² using the following tests: 30 seconds chair stand test, Timed Up and Go test, the 40-meter fast walk test, and the Stair Climb test. Quadriceps muscle architecture was measured based on the quadriceps femoris muscle thickness³³, considering each muscle portion (RF+VL+VM+VI expressed in centimeters), vastus lateralis pennation angle³⁴ (expressed in degrees), and fascicle length³⁵ (expressed as femur length/fascicle length ratio). Quadriceps muscle quality was measured using muscle echo intensity, based on pixel intensity scores ranging from 0 (black) to 255 (white) in arbitrary units (a.u.)³⁶. Higher values represent decreased muscle quality and increased intramuscular fat infiltration³⁷. The mean echo intensity of the quadriceps muscle portions (RF+VL+VM+VI/4) was presented with data both uncorrected and corrected for subcutaneous fat thickness³⁸.

Other outcome measures

The number of analgesic and anti-inflammatory medications ingested was measured considering information reported by the patient.

Randomization and blinding

All details about the randomization were previously described in the study protocol. Here, we summarized the main aspects. Participants were randomized baseline assessments. Both groups underwent a 12-week exercise program. Each participant was assigned an internal code (ID) for de-identification purposes (e.g., RISE-KOA-48). The randomization sequence was generated by a single researcher using a specific Excel random function. Subsequently, the team responsible for the intervention was informed via text messages regarding the group assignment of each patient.

Outcome assessors remained blinded to treatment allocation. Participants were instructed not to discuss details of their interventions during outcome evaluations to ensure evaluator masking. However, due to the nature of the interventions, neither participants nor the exercise intervention team could be blinded.

Intervention

Participants in this trial were randomly assigned to receive one of two formats of individualized, physical therapist-supervised exercise programs. The remote exercise group received supervision through video calls on WhatsApp, whereas, the in-person exercise group attended supervised sessions at a physical therapy clinic. The intervention protocol consisted of six guided muscle-strengthening exercises for the lower limbs, performed in alternating muscle groups, based on exercise programs from previous randomized controlled trials^{39–41}. Each session was divided into two blocks, each consisting of a sequence of three muscle group exercises: in the first block, exercises addressed the knee extensors, hip adductors, and plantar flexors, and in the second block, the knee extensors, hip abductors, and knee flexors. The exercises encompassed weight-bearing and non-weight-bearing exercises. Stationary walking preceded the training block and concluded the exercise program. Progression, as determined by a physical therapist, was provided through sets,

repetitions, weight-bearing adjustments, and the external load imposed by the elastic band (low to moderate). During the exercise, perceived exertion was monitored using Borg's scale rating of perceived exertion (RPE), based on RPE 5 from Week 1 to 7 and RPE 7 from Week 8 to 12⁴². At the end of the supervised exercise protocol, participants in both groups were encouraged to maintain their exercise routine. The physical therapist provided a booklet with photos depicting the exercises for participants' independent performance.

One recommendation for effectively delivering therapeutic exercise is to provide education about OA and the role of exercise⁴³. In this sense, physical therapists provided real-time educational sessions remotely (via video call) or in person to engage participants in the exercise program, according to group allocation. These educational sessions were conducted for approximately 10 minutes preceding exercise program during the first, third, and eighth weeks of supervised exercise. The researcher presented a brief illustrated presentation on relevant topics previously published⁴³.

Data analysis

The sample size calculation was conducted using data from a previous study, considering an alpha level of 0.05, a power of 0.80, a standard deviation of 2 in pain level, and a non-inferiority margin of -1.6 points. The minimum required sample size was determined to be at least 40 participants. Considering an expected dropout of $\approx 20\%$ between baseline and follow-up, 48 participants were needed, with ≈ 24 per group. According to previous recommendations^{23,44}, we established a non-inferiority margin for primary outcome of pain level, measured by the NRS, of -1.6 points (20% less than the minimum clinically significant difference reported for the NRS⁴⁵). For the other primary outcome, physical function, the minimum clinically significant difference for the Activities of daily living subscale of the KOOS is 8 points⁴⁶. We defined a non-inferiority margin of -6.4 points (corresponding to 20% less than the minimum clinically significant difference reported for this outcome). The sample size was estimated based on the non-inferiority margin for the pain level.

We performed an intention-to-treat analysis involving all patients 1baseline characteristics of the participants. Between-group difference and 95% confidence interval (95% CI) for both endpoints (6 and 12 weeks) of treatment were calculated using linear mixed models with fixed effects for group, time, and interaction terms of the treatment group versus time. A non-inferiority of the remotely supervised exercise would be demonstrated if the lower bound of the two-sided 95% CI for the between-group difference (remotely supervised exercise minus in-person supervised exercise) would be above -1.6 points for pain and -6.4 points for physical function (KOOS Activities of daily living subscale). All analyses were conducted using SPSS statistical software (Statistical Package for Social Sciences), version 20.0 for Windows (IBM Corporation, Somers, New York, USA).

Results

Flow of participants through the study

A total of ninety-six participants were evaluated for eligibility, and fifty-one were assigned to the treatment groups (see Figure 1). Among those who were randomized, twenty-three participants in the remote supervised exercise group and twenty-five participants in the in-person supervised exercise group received their assigned intervention. By week 6, twenty-two participants from the remote supervised exercise group and twenty-five from the in-person group completed their assessments. For the week 12 assessments, twenty-one participants from the remote group and twenty-four from the in-person group attended. Finally, all randomized participants were included in the analysis at each time point.

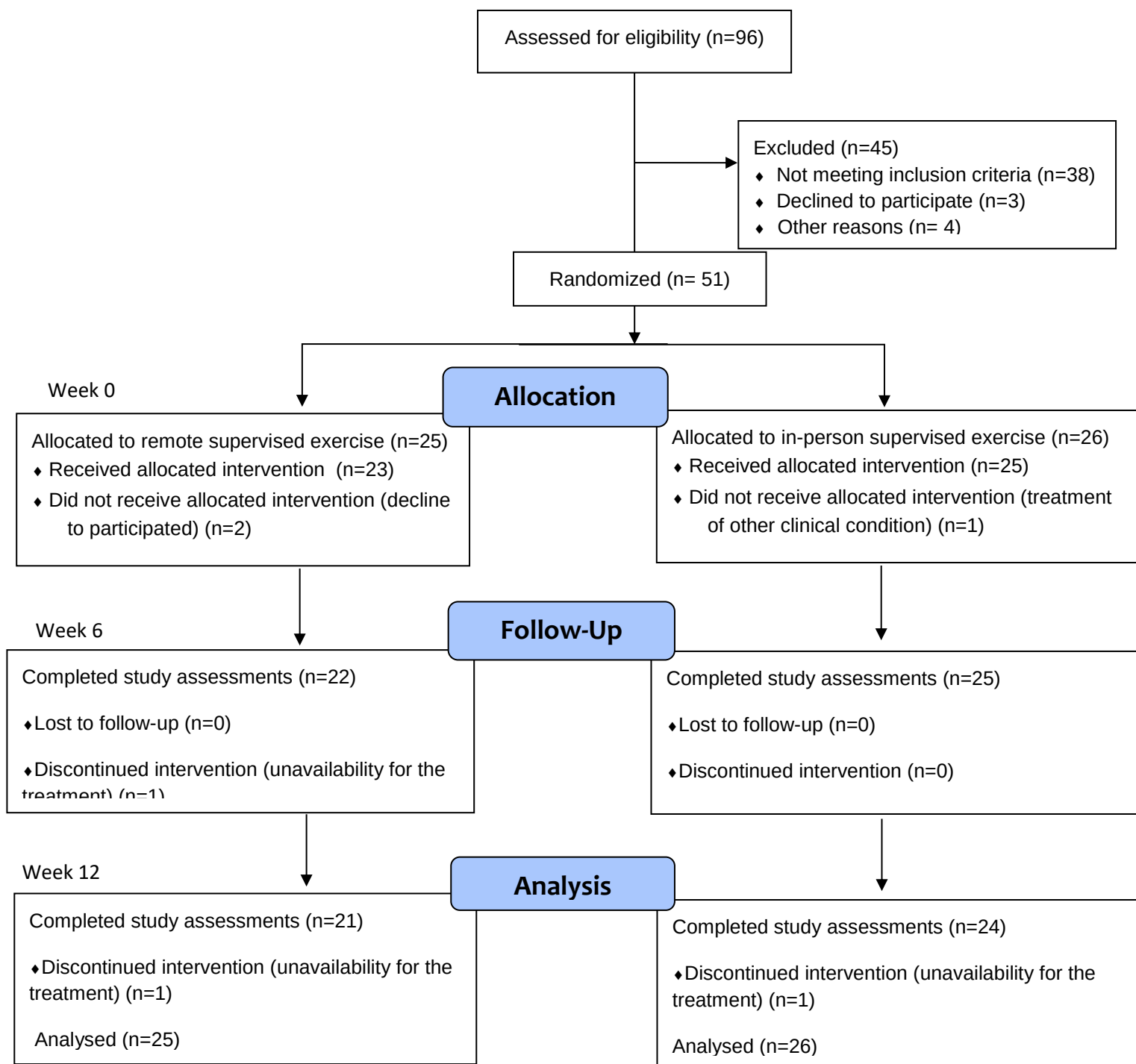


Fig 1. CONSORT flowchart.

Compliance with the study protocol

According to the intention-to-treat analysis, all patients were invited to participate in data collection at all time points (Week 6 and Week 12). In Figure 1, we described the patients who completed the study assessments. Along the 12-week intervention, of the 34 sessions planned for remote or in-person supervised exercise programs, the median number of sessions (IQR) of the remote supervised exercise group completed was 27 (19 to 33) (79.4%), while participants of the in-person supervised exercise group completed 29 (26 to 33) (85.3%).

Characteristics of the study participants

Table 1 summarizes the baseline characteristics. Among the 51 randomized participants, most had a low educational level, with 36% in the remote supervised exercise group and 50% in the in-person supervised exercise group. In the remote supervised exercise group, 80% of participants were diagnosed with grade II osteoarthritis, compared to 73.1% in the in-person exercise group. The duration of symptoms in most patients ranged from 2 to 10 years, with 36% of participants in the remote supervised exercise group and 57.7% in the in-person supervised exercise group. At baseline, 88% of patients in the remote supervised exercise group reported a fear of movement, while this percentage was 65.4% in the in-person supervised exercise group.

Table 1. Baseline characteristics.

Outcomes	Remote supervised exercise group (n=25)	In-person supervised exercise group (n=26)
	Mean $\pm$ SD	Mean $\pm$ SD
Age, y	61.3 $\pm$ 8.9	61.5 $\pm$ 6.9
Height, m	1.6 $\pm$ 0.09	1.6 $\pm$ 0.01
Mass, kg	83.6 $\pm$ 14.1	87.2 $\pm$ 15.7
BMI, kg/m ²	32.0 $\pm$ 5.0	33.3 $\pm$ 5.0
	Frequency, n (%)	Frequency, n (%)
Female	17 (68%)	19 (73%)
Skin color		
White	19 (76%)	21 (80.8%)
Black	6 (24%)	5 (19.2%)
Marital status		
Single	5 (20%)	6 (23.1)
Married	11 (44%)	14 (53.8)
Widow	4 (16%)	4 (15.4)
Divorced	5 (20%)	2 (7.7)
Education		
Low school	9 (36%)	13 (50.0%)
Middle school	8 (32%)	4 (15.4%)
High school	4 (16%)	7 (26.9%)
College	4 (16%)	2 (7.7%)
Working status		
Work	10 (40%)	8 (30.8)
Not-work	15 (60%)	18 (69.2)
OA side		
Bilateral	12 (48%)	15 (57.7%)
Unilateral	13 (52%)	11 (42.3%)
OA radiographic stage		
Grade 2	20 (80%)	19 (73.1%)
Grade 3	5 (20%)	7 (26.9%)
Symptoms duration		
< 2 years	8 (32%)	5 (19.2%)
2 to 10 years	9 (36%)	15 (57.7%)
> 10 years	8 (32%)	6 (23.1%)
Family history of knee OA	16 (64%)	18 (69.2%)
Fear of movement	22 (88.0%)	17 (65.4%)
Comorbidities	14 (56%)	13 (49.9%)
Metabolic	5 (20%)	7 (26.9%)
Cardiovascular	3 (12%)	3 (11.5%)
Respiratory	0 (0%)	2 (7.7%)
Neurological	0 (0%)	0 (0%)
Renal	0 (0%)	0 (0%)
Mental	6 (24%)	1 (3.8%)

BMI=Body mass index; OA=Osteoarthritis.

Effect of the intervention

Primary outcomes

The pain levels and physical function outcomes at each assessment period are summarized in Table 2. There was no significant group-by-time interaction effect for pain, with an estimated between-group difference in pain levels of 0.1 (95% CI -1.8 to 2.0) at Week 6 and 0.7 (95% CI -1.3 to 2.6) at Week 12 (Table 2). Similarly, there was no significant group-by-time interaction effect for physical function, with an estimated between-group difference in physical function of 12.8 (95% CI -4.0 to 29.7) at Week 6 and 13.2 (95%CI -4.0 to 30.4) at Week 12. (Table 2). Remotely supervised exercise was found to be non-inferior to in-person supervised exercise, as the lower bound of the CI for the primary outcomes (pain and physical function) remained within the non-inferiority margin after 12 weeks of intervention. However, non-inferiority at 6 weeks was observed only for physical function (Figure 2). Significant reductions in pain levels and increases in physical function were observed during the treatment period (Week 6) and after the intervention (Week 12) in both groups combined (Table 4).

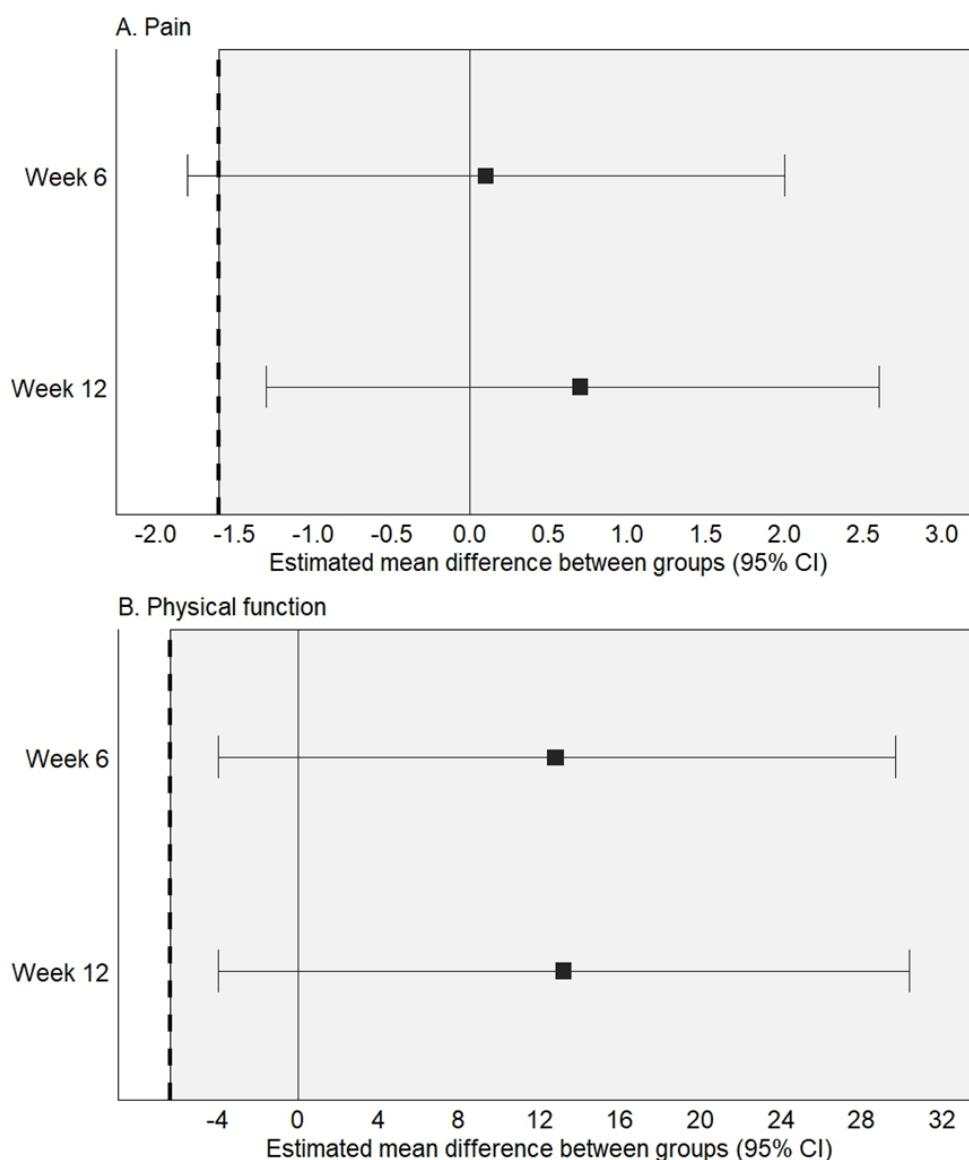


Figure 2. Non-inferiority analysis of pain and physical function outcomes at weeks 6 and 12. The estimated mean difference (95% CI) between groups is plotted relative to the non-inferiority margins (dotted lines) for (A) pain and (B) physical function. The grey area represents the non-inferiority zone.

Secondary outcomes

Condition-specific PROMs

In Week 6, there was no significant group-by-time interaction effect for condition-specific PROMs. The estimated differences between groups for the KOOS subscales were as follows: pain, 12.3 (95% CI -4.3 to 29.0); symptoms, 8.8 (95%

CI -7.1 to 24.7); sport and recreation, 11.7 (95% CI -7.1 to 30.6); and knee-related quality of life, 13.9 (95% CI -4.0 to 31.8) (Table 2). In Week 12, there was no significant group-by-time interaction effect for condition-specific PROMs. The estimated differences between groups for the KOOS subscales were as follows: pain, 7.8 (95% CI -9.1 to 24.8); symptoms, 4.4 (95% CI -11.9 to 20.6); sport and recreation, 1.3 (95% CI -17.9 to 20.6); and knee-related quality of life, 1.1 (95% CI -17.2 to 19.3) (Table 2). A significant improvement in KOOS pain and symptoms during treatment (Week 6) and after treatment (after 12 weeks) was observed for both groups combined (Table 4). Additionally, a significant improvement in KOOS sport and recreation, and knee-related quality of life was observed only after treatment (Week 12) for both groups combined (Table 4).

Psychological well-being

In Week 6, there was no significant group-by-time interaction effect on psychological well-being outcomes with the estimated between-group difference as follows: pain catastrophizing, -5.8 (95% CI -16.9 to 5.3), depression score, -3.0 (95% CI -9.7 to 3.8), anxiety score, -4.7 (95% CI -10.9 to 1.6), and stress score, -5.6 (-12.8 to 1.6) (Table 2). Similarly, in Week 12, there was no significant group-by-time interaction effect in psychological well-being outcomes, with the estimated between-group difference as follows: pain catastrophizing, -0.08 (95% CI -11.2 to 11.40), depression score, -2.0 (95% CI -8.8 to 4.7), anxiety score, -4.0 (95% CI -10.3 to 2.1), and stress score, -3.4 (95% CI -10.6 to 3.8) (Table 2). No significant improvements were observed in pain catastrophizing, symptoms of depression, anxiety, and stress during treatment (Week 6), and after treatment, no significant improvement in symptoms of depression and anxiety for both groups combined (Table 4). In contrast, a significant improvement in stress and pain catastrophizing scores was observed only after treatment (Week 12) for both groups combined (Table 4).

Sleep quality

In Week 6, there was no significant group-by-time interaction effect on the sleep quality score, with the estimated between-group difference of -0.4 (95% CI -4.0 to 3.1). Similarly, in Week 12, there was no significant group-by-time interaction effect on the sleep quality score, with the estimated between-group difference of 0.5 (95% CI -3.0 to 4.1). No significant improvements were observed in sleep quality during treatment (Week 6) and after treatment (Week 12) compared to baseline for both groups combined (Table 4).

Functional performance

In Week 12, there was no significant group-by-time interaction effect in functional performance outcomes, with the estimated between-group difference in the outcomes as follows: 30-second chair stand test, -1,6 repetitions (95% CI -4.0 to 0.7), Timed Up and Go test, -0.5 seconds (95% CI -2.6 to 1.5), the 40-meter fast walk test, 0.06 m/s (95% CI -0.2 to 0.3), and Stair Climb test, -1,0s (95% CI -8.7 to 6.6) (Table 2). There was a significant improvement in functional performance (30-second chair stand test, Timed Up and Go test, and the 40-meter fast walk test) after treatment (Week 12) for both groups combined (Table 4). No significant improvement was observed in the Stair Climb test after treatment (Week 12) for both groups combined (Table 4).

Quadriceps muscle architecture

In Week 12, there was no significant group-by-time interaction effect in quadriceps muscle architecture outcomes, with the estimated between-group difference as follows: quadriceps muscle thickness, 0.01 cm (95% CI -1.5 to 1.5), pennation angle, 0.8 degrees (95% CI -1.9 to 3.5), and fascicle length, -0.001 ratio (95% CI -0.04 to 0.04) (Table 2). A significant improvement was observed only in pennation angle after treatment (Week 12) for both groups combined, whereas no significant difference was observed for muscle thickness and fascicle length (Table 4).

Quadriceps muscle quality

In Week 12, there was no significant group-by-time interaction effect in quadriceps muscle quality corrected for subcutaneous fat thickness, with the estimated between-group difference of -7.3 a.u (95%CI -33.5 to 19.0). No significant improvement was observed in quadriceps muscle quality corrected for subcutaneous fat thickness after treatment (Week 12) compared to baseline for both groups combined (Table 4). Similarly, in Week 12, there was no significant group-by-time interaction effect in quadriceps muscle quality uncorrected for subcutaneous fat thickness, with the estimated between-group difference of 2.7 a.u (95%CI -7.1 to 12.5). On the other hand, a significant improvement was observed in quadriceps muscle quality uncorrected for subcutaneous fat thickness after treatment (Week 12) compared to baseline for both groups combined (Table 4).

Other outcome

In Week 6, there was no significant group-by-time interaction effect for number of analgesic and anti-inflammatory medications ingested, with the estimated between-group of 0.6 (95%CI -0.3 to 1.4) (Table 2). Similarly, in Week 12, there was no significant group-by-time interaction effect for number of analgesic and anti-inflammatory medications, with the estimated between-group of -0.1 (95%CI -0.3 to 0.7) (table 2). Significant reduction was observed in the number of analgesic and anti-inflammatory medications ingested during treatment (Week 6), and after treatment (Week 12) compared to baseline for both groups combined (Table 4).

Table 2
Mean (SD) score by group over time, estimated mean difference (IC 95%), and Cohen's d effect size (IC 95%) for patient-reported outcomes during treatment (week 6) and after treatment (week 12).

Outcome measure	Week 6		Week 12		Week 6		Week 12	
	Remote Mean±SD (n=25)	In-person Mean±SD (n=26)	Remote Mean±SD (n=25)	In-person Mean±SD (n=26)	Mean difference between groups (95%CI)	Cohen's d (95%CI)	Mean difference between groups (95%CI)	Cohen's d (95%CI)
Pain NRS (0 to 10)	3.3±2.8	3.7±2.8	2.4±2.1	2.3±2.5	0.1 (-1.8 to 2.0)	-0.2 (-0.7 to 0.4)	0.7 (-1.3 to 2.6)	0.04 (-0.5 to 0.6)
KOOS physical function (0 to 100)	69.7±17.3	66.1±26.9	81.5±16.3	77.6±23.5	12.8 (-4.0 to 29.7)	0.2 (-0.4 to 0.7)	13.2 (-4.0 to 30.4)	0.2 (-0.4 to 0.7)
KOOS pain (0 to 100)	69.8±16.3	64.8±26.0	76.0±17.0	75.5±24.2	12.3 (-4.3 to 29.0)	0.2 (-0.3 to 0.8)	7.8 (-9.1 to 24.8)	0.02 (-0.5 to 0.6)
KOOS symptoms (0 to 100)	69.0±17.9	65.2±23.9	75.9±19.0	76.4±20.0	8.8 (-7.1 to 24.7)	0.2 (-0.4 to 0.7)	4.4 (-11.9 to 20.6)	-0.03 (-0.6 to 0.5)
KOOS sport and recreation function (0 to 100)	26.9±23.0	23.0±24.6	36.0±31.3	42.5±30.8	11.7 (-7.1 to 30.6)	0.2 (-0.4 to 0.7)	1.3 (-17.9 to 20.6)	-0.2 (-0.8 to 0.3)
KOOS knee-related quality of life (0 to 100)	47.8±26.0	39.8±21.5	53.4±22.7	58.3±28.5	13.9 (-4.0 to 31.8)	0.3 (-0.2 to 0.9)	1.1 (-17.2 to 19.3)	-0.2 (-0.7 to 0.4)
Pain catastrophizing (0 to 52)	15.8±14.2	18.1±16.0	13.3±11.8	9.7±13.6	-5.8 (-16.9 to 5.3)	-0.2 (-0.7 to 0.4)	0.1 (-11.2 to 11.4)	0.3 (-0.3 to 0.8)
DASS-21								
Symptoms of depression (0 to 42)	4.2±8.5	6.0±9.8	2.4±4.7	3.3±8.5	-3.0 (-9.7 to 3.8)	-0.2 (-0.8 to 0.4)	-2.0 (-8.8 to 4.7)	-0.1 (-0.7 to 0.4)
Symptoms of anxiety (0 to 42)	4.3±7.4	6.5±8.6	3.2±5.6	4.9±7.3	-4.7 (-10.9 to 1.6)	-0.3 (-0.8 to 0.3)	-4.0 (-10.3 to 2.1)	-0.3 (-0.8 to 0.3)
Symptoms of stress (0 to 42)	7.4±9.0	10.5±10.0	5.4±7.1	6.3±8.2	-5.6 (-12.8 to 1.6)	-0.3 (-0.2 to 0.9)	-3.4 (-10.6 to 3.8)	-0.1 (-0.7 to 0.4)
Sleep Quality (0 to 21)	7.0±4.5	8.2±4.3	6.9±3.9	7.1±4.6	-0.4 (-4.0 to 3.1)	-0.3 (-0.8 to 0.3)	0.5 (-3.0 to 4.1)	-0.05 (-0.6 to 0.5)
Medication ingested	1±1.2	0.6±1	0.4±0.6	0.8±1	0.6 (-0.3 to 1.4)	0.4 (-0.2 to 0.9)	-0.1 (-1 to 0.7)	-0.5 (-1.0 to 0.1)

NRS= Numerical rating scale; KOOS= Knee injury and Osteoarthritis Outcome Score; DASS-21=Depression Anxiety Stress Scale-21.

Table 3

Mean (SD) score by group over time and estimated mean difference for functional tests, quadriceps muscle architecture and quality.

Outcome measure	Week 12		Week 12	
	Remote Mean±SD (n=25)	In-person Mean±SD (n=26)	Mean difference between groups (95%CI)	Cohen's d (95%CI)
30 seconds chair stand test (repetitions)	10.8±3.7	12.0±3.2	-1.6 (-4.0 to 0.7)	-0.4 (-0.9 to 0.2)
Timed Up and Go test (s)	8.2±2.7	8.7±2.0	-0.5 (-2.6 to 1.5)	-0.2 (-0.8 to 0.3)
40-meter fast walk test (m/s)	1.7±0.3	1.6±0.3	0.06 (-0.2 to 0.3)	0.3 (-0.2 to 0.9)
Stair Climb test (s)	14.1±6.6	14.8±9.8	-1.0 (-8.7 to 6.6)	-0.1 (-0.6 to 0.5)
Quadriceps muscle thickness (cm)	6.9±1.9	7.2±2.5	0.01 (-1.5 to 1.5)	-0.1 (-0.7 to 0.4)
Quadriceps muscle quality (a.u) ^a	117.6±26.2	126.5±36.4	7.3 (-19.0 to 33.5)	-0.3 (-0.8 to 0.3)
Quadriceps muscle quality (a.u) ^b	51.0±11.4	46.7±10.1	2.7 (-7.1 to 12.5)	0.4 (-0.2 to 1.0)
Pennation angle (deg)	15.8±3.0	16.4±3.2	0.8 (-1.9 to 3.5)	-0.2 (-0.7 to 0.4)
Fascicle length (fascicle length and fêmur length ratio)	0.1±0.06	0.1±0.04	-0.001 (-0.04 to 0.04)	0.0 (-0.5 to 0.5)

a=muscle echo intensity corrected for subcutaneous fat thickness.

b=muscle echo intensity uncorrected for subcutaneous fat thickness.

Table 4

Mean (SD) score by group over time and estimated mean difference for primary and secondary outcomes.

Outcome measures	Mean within-group difference a (95% CI)	
	Week 6	Week 12
Pain NRS (0 to 10)	-2.8 (-4.2 to -1.6)*	-4.3 (-5.6 to -2.9)*
KOOS physical function (0 to 100)	14.3 (2.7 to 25.9)*	25.7 (14.0 to 37.5)*
KOOS pain (0 to 100)	17.1 (5.7 to 28.6)*	27.8 (16.3 to 39.4)*
KOOS symptoms (0 to 100)	16.7 (5.8 to 27.7)*	28.0 (16.8 to 39.0)*
KOOS sport and recreation (0 to 100)	9.0 (-4.0 to 21.9)	28.5 (15.4 to 41.6)*
KOOS knee-related quality of life (0 to 100)	11.9 (-0.4 to 24.2)	30.4 (17.9 to 42.8)*
Pain catastrophizing (0 to 52)	-7.7 (-15.3 to -0.9)	-16.1 (-23.9 to -8.4)*
DASS-21		
Symptoms of depression (0 to 42)	-2.1 (-6.8 to 2.6)	-4.9 (-9.6 to -0.1)
Symptoms of anxiety (0 to 42)	-2.4 (-6.8 to 1.9)	-4.2 (-8.5 to 0.1)
Symptoms of stress (0 to 42)	-2.5 (-7.6 to 2.5)	-6.8 (-11.8 to -1.7)*
Sleep Quality (0 to 21)	-1.3 (-3.7 to 1.2)	-2.3 (-4.8 to 0.1)
30 seconds chair stand test (repetitions)	-	4.2 (2.5 to 5.8)*
Timed Up and Go test (s)	-	-1.8 (-3.2 to -0.3)*
40-meter fast walk test (m/s)	-	0.3 (0.0 to 0.4)*
Stair Climb test (s)	-	-5.4 (-10.7 to -0.1)
Quadriceps muscle thickness (cm)	-	-0.3 (-1.3 to 0.7)
Quadriceps muscle quality (a.u) ^a	-	-2.2 (-20.2 to 15.8)
Quadriceps muscle quality (a.u) ^b	-	-7.4 (-14.1 to -0.7)*
Pennation angle (deg)	-	2.3 (0.4 to 4.1)*
Fascicle length (fascicle length and fêmur length ratio)	-	-0.01 (-0.04 to 0.02)
Medication ingested	-1.0 (-1.6 to -0.4)*	-0.9 (-1.5 to -0.3)*

NRS=Numerical Rating Scale; KOOS= Knee injury and Osteoarthritis Outcome Score; DASS 21=Depression Anxiety Stress Scale-21. *p<0.05.

a=muscle echo intensity corrected for subcutaneous fat thickness.

b=muscle echo intensity uncorrected for subcutaneous fat thickness.

Discussion

To our knowledge, the RISE-KOA study is the first non-inferiority randomized controlled trial comparing 12 weeks of supervised exercise delivered either remotely by video calls or in-person. Remotely supervised lower-limbs exercise program was non-inferior to an in-person program in improving the primary outcomes of pain (NRS) after 12 weeks of treatment and physical function (KOOS activities of daily living) after both 6 and 12 weeks. Our findings also revealed improvements in other condition-specific PROMs after 6 and 12 weeks (KOOS pain and symptoms subscales) and only after 12 weeks (KOOS sport and recreation, and knee-related quality of life subscales) in both groups. Improvements in psychological well-being (stress score and pain catastrophizing), functional performance (30-second chair stand, Timed Up and Go, and 40-meter fast walk tests), and quadriceps muscle morphology (pennation angle, quadriceps femoris muscle quality uncorrected for subcutaneous fat thickness) were similar between the two delivery formats of supervised exercise program after 12 weeks of treatment in both delivered formats of exercise supervision. Lastly, patients' use of analgesic and anti-inflammatory medications decreased after 6 and 12 weeks of treatment. These findings highlight the relevance of remotely supervised exercise for patients with knee OA in developing countries as an alternative for delivering the main treatment recommended by OA management guidelines^{7,8}.

A growing body of literature has investigated the effectiveness of telerehabilitation strategies for patients with knee OA with promising results concerning pain management^{47,48}. However, randomized clinical trials using video calls as a main telerehabilitation tool for patients with knee OA focus on teleconsultations^{19,49}, and not real-time supervising exercises in each physical therapy session. In several clinical profiles, including patients with musculoskeletal conditions, real-time telerehabilitation has potentially favorable effects on adherence to exercise programs, with similar satisfaction compared to traditional in-person physical therapy treatments^{50,51}. In this context, as activity-related knee pain is one of the main symptoms in knee OA patients, our study advances knowledge in telerehabilitation since exercise treatment guided by

video calls or in-person elicited minimal clinically important difference in pain level and physical function during and after 12 weeks of treatment. Specifically, changes in both groups exceed 2 points in NRS and 8 points in the KOOS activities of the daily living subscale⁴⁶. Changes in pain levels between groups fell within the non-inferiority margin only after 12 weeks of treatment, while improvements in physical function were within the non-inferiority margins as early as week 6. These findings highlight the importance of long-term remote supervised exercise in effectively managing patients with knee OA. Knee OA patients experienced large effects of exercise treatment with 24 total therapeutic sessions, and eight and 12-week treatment duration⁵². Changes in pain score and symptoms KOOS subscales after 6 weeks and 12 weeks, while changes in knee-related quality of life and sport and recreational function KOOS subscales only after 12 weeks reinforce the idea of the relevance of long-term exercise programs delivered by telerehabilitation.

The main clinical guidelines recommended exercise as the first line treatment for patients with knee OA^{7,8}, and telerehabilitation represents a promising exercise delivery alternative. However, most clinical trials investigating the effectiveness of telerehabilitation interventions with patients with knee OA were conducted in developed countries^{19,53–56}. Our study delivered exercise intervention by telerehabilitation in a developing country with a sample of most patients with low educational levels. Patients with knee OA of this educational level have persistent knee pain⁵⁷. Therefore, telerehabilitation using real-time resources has particular relevance in this context, because it ensures the quality of movement during exercise, with individualized supervision, preventing incorrect postures, excessive articular load, and wrong position of elastic bands. In addition, as we confirmed our hypothesis, our study findings contribute to changing a “hands-on” care culture, offering other forms to deliver recommended treatment, specifically beyond the conventional face-to-face physical therapy consultation in clinical settings worldwide.

In line with our study, a previous non-inferiority trial found that pain levels and self-reported function significantly improved in both the telerehabilitation group (with video calls for supervised exercise) and traditional rehabilitation (with in-person supervision)²¹. However, our study differs from that for the following reasons: (1) authors supervised exercises by video calls in small groups with a

maximum of five individuals; (2) exercise intervention was conducted during a period of 4 weeks; (3) authors did not measure objective physical performance and quadriceps muscle architecture and quality; and (4) self-reported function was assessed using physical functioning subscale of Short Form-36 healthy survey. Our study was designed to provide an individualized exercise approach for 12 weeks to elicit changes in PROMs, objective physical performance, and quadriceps muscle morphology of knee OA patients.

Another relevant finding of the previous study was no change in emotional well-being after intervention in the two delivery formats. In line with this finding, in our study, symptoms of depression, and anxiety did not significantly change across the two-time points because most patients were not classified as having symptoms of depression^{28,29}. Concurrently, we observed substantially reduced stress, and pain catastrophizing scores, in both groups combined. The relevance of this finding is uncertain because, in the same way, patients were not classified according to the cut-off values of stress and pain catastrophizing scores at baseline. Concerning symptoms of anxiety, although participants were classified as having anxiety symptoms at baseline, exercise intervention was not sufficient to change this outcome. In this context, according to a network meta-analysis, there is still no exercise recommendation for anxiety symptoms in patients with knee OA. In addition, we found no difference in sleep quality after both delivery intervention formats. We suggested that no change in anxiety and sleep quality findings could be explained by the nature of our intervention, developed as a functional exercise protocol focused on the clinical management of knee OA symptoms. A progression in exercise level was achieved according to the resistance of elastic bands, a dose of weight-bearing in the arthritic leg, and the perception of effort.

Patients with knee OA exhibit a decline in perceived and executed functional abilities⁵⁸. In this context, our study found a similar improvement in both treatment groups in the 30-second chair stand, Timed Up and Go, and 40-meter fast walk tests. These findings were expected because our exercise protocol was designed to strengthen the lower limbs and increase the patient's ability to perform functional activities. Similar to the results of the present study, the literature has also demonstrated telerehabilitation's effectiveness in improving physical performance. An 8-week intervention study showed an increase in

performance of a 30-second sit-to-stand test in patients who received exercises via video calls supervised by physical therapists compared to a control group that received a brochure with exercises²⁰. Another study⁵⁹, conducted over 6 weeks, found a better improvement in the sit-to-stand and ambulatory transition activities in patients who received exercises via a smartphone application compared to those who received routine self-management care. The two above-mentioned studies are aligned with our study findings; however, they did not have the same research design as a non-inferiority trial. In this context, another recent non-inferiority trial¹¹ showed improvement in physical performance in patients with knee OA (the 40-m fast-paced walk test, the 30-second chair stand test, and the stair climb test) after circuit training delivered remotely by recording videos or in a face-to-face format at a physical therapy clinic. Although the authors did not use video calls as a rehabilitation tool, this study's results agree with our findings. Finally, our study protocols in both delivery formats did not significantly change stair climbing abilities, probably because most patients randomly assigned reported fear of movement at baseline, and this outcome (kinesiophobia) is strongly related to more time required to complete the stair climbing performance.

Regarding muscle architecture, our findings are in line with a previous non-inferiority trial that found an increase in pennation angle in both exercise intervention approaches remotely and in-person; however, it differs from our study about increased fascicle length and muscle thickness¹¹. The clinical relevance of pennation angle increase after treatment lies in the fact that knee OA diagnosis is associated with early muscle architecture changes characterized by a reduced pennation angle⁶⁰. In this sense, telerehabilitation using video calls for 12 weeks could change this cycle of muscle architecture decline. In another study that did not use telerehabilitation, findings indicated that different exercises were insufficient to change the vastus lateralis pennation angle in patients with knee OA⁶¹. The authors discuss that this finding is related to a short period of intervention (3 weeks), highlighting the relevance of long-term interventions to elicit muscle architecture changes. Additionally, we did not observe any changes in the thickness of the quadriceps femoris muscle following the exercise program. These findings are expected results, given that even in patients with knee OA experiencing a specific decrease in vastus medialis muscle thickness, alterations in vastus medialis muscle quality and not in muscle structure are clinical

biomarkers of muscle degeneration in knee OA⁶². Therefore, exercise interventions should focus on improving muscle quality.

Muscle quality measurements in patients with knee OA have gained more attention in the last years^{62–64}, specifically as muscle quality changes predicted muscle function in this population⁶⁵. To the best of our knowledge, our study is the first to investigate whether remote supervision exercises by video calls are as effective as the same exercise protocol supervised in person concerning muscle echo intensity. An unexpected result of this study was the lack of changes in quadriceps muscle echo intensity corrected for subcutaneous fat thickness within the groups over time, while a decrease was observed in this outcome when uncorrected for subcutaneous fat thickness for both groups combined. However, there was no consensus in the literature that echo intensity measurements must be corrected for subcutaneous fat thickness. In addition, findings of another clinical trial study⁶⁶ compared circuit training with muscle strength exercises and indicated that only knee OA patients who received circuit training exercises experienced a decrease in intermuscular fat infiltration (better muscle quality). In our study, we measure intramuscular fat infiltration using echo intensity, and the characteristics of our intervention (functional strength exercises) may have influenced the changes in muscle quality. Despite the questions mentioned above, our study strengthens the clinical relevance of telerehabilitation in addressing the intramuscular fat infiltration of knee OA patients.

We recognize some limitations of this study. First, some patients who underwent the initial recruitment did not have access to the internet; in this sense, despite our goal to expand community access to knee OA treatment, social inequalities can limit the delivery of telerehabilitation using video calls in a developing country. In addition, in the remote exercise group, just like those in the in-person exercise group, patients were invited to attend an in-person familiarization session before the intervention period. This familiarization was crucial for learning exercises and how to use video calls to receive treatment. However, it does not accurately represent a completely remote intervention, as participants have had contact in person with rehabilitation professionals before the intervention. Another point is that the outcome measurements before and after treatment were structured to occur at two different times (one day remotely and another in person). This requirement could affect patients' participation due

to the need for availability on both days. Finally, our study strength is delivering exercise treatment via video calls to a sample with the majority of patients with low education levels, expanding community access to physical rehabilitation with individualized supervision of exercises. Therefore, future research should investigate different types of telerehabilitation tools to deliver exercise for patients with knee OA with limited access to healthcare, such as those living in rural areas or low-income countries.

Protocol amendments involved a revision of the sample size calculation. This adjustment was necessary because we initially established a very strict non-inferiority margin for the primary outcome, pain level, which led us to update the sample size calculation. We estimated a new sample size considering a non-inferiority margin of 20% less than the minimum clinically significant difference for pain level according to CONSORT recommendations to conduct non-inferiority clinical trials. The first sample size calculation estimated 68 patients for the study, and the new sample size was 48 patients. These changes were publicly declared in the clinical trials registry and in the study protocol.

Conclusion

This trial finds that a remotely supervised exercise program using video calls is non-inferior to an in-person format in reducing pain levels and improving physical function. In addition, telerehabilitation using video calls for exercise supervision is as effective as an in-person format for improving knee OA symptoms, sport, and recreational function, knee-related quality of life, physical performance, pennation angle, and muscle quality. This trial empowers clinicians, particularly in developing countries, to confidently provide real-time supervised exercise for patients with knee OA. In addition, our findings can enhance community access to exercise, and empower individuals with knee OA to choose the supervision modality (remote or in-person) that best aligns with their preferences.

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NOTA A IMPRENSA

SAÚDE

Pesquisa avalia reabilitação de pacientes com Osteoartrite do joelho

Estudo é desenvolvido no Núcleo de Práticas da Saúde da Urcamp, em projeto de doutorado do professor Maurício Tatsch Ximenes Carvalho

🕒 Em 28/07/2024 às 21:55h



por Giana Cunha



A PESQUISA INÉDITA NA REGIÃO AUXILIA NA REABILITAÇÃO DE PACIENTES

O primeiro estudo clínico voltado para o tratamento fisioterapêutico de pessoas com osteoartrite (artrose) do joelho, na cidade de Bagé, está em andamento no Núcleo de Práticas em Saúde da Urcamp. O projeto é parte do doutorado do professor Maurício Tatsch Ximenes Carvalho, que ministra aulas no curso de Fisioterapia e cursa seu

doutorado na Universidade Federal de Pelotas, sob orientação da professora doutora, Cristine Lima Alberton.

O trabalho busca investigar se um programa supervisionado de exercícios remotos (via videochamada) é tão eficaz quanto um programa de exercícios presenciais (na clínica de fisioterapia), para pacientes com patologia de osteoartrite do joelho. Para isso, estão sendo selecionadas pessoas acima de 45 anos, com acesso à internet, marcha independente (sem necessidade de muleta), e diagnóstico clínico e radiográfico da condição. As pessoas interessadas no estudo, são encaminhadas para uma triagem presencial e, em seguida, aqueles que atendem aos critérios do estudo passam por uma avaliação detalhada.

A primeira etapa da avaliação consiste em uma consulta por videochamada para analisar as características da dor, a presença de sintomas articulares, o bem-estar psicológico e a qualidade do sono. A avaliação também é realizada no setor de radiologia, através de ultrassonografia, para verificação da condição muscular. Além disso, testes funcionais são realizados no Núcleo de Práticas em Saúde da Urcamp, tudo com o auxílio de acadêmicos do curso de Fisioterapia da Urcamp. A acadêmica, Fernanda Silveira da Sena, foi uma das selecionadas para participar do estudo e já pensa em seguir a carreira como pesquisadora. “Desde que iniciei, já comecei nos testes funcionais, fui me entrosando e hoje eu faço, inclusive, a intervenção, que é estar integrada ao tratamento e reabilitação do paciente”, explica.

Os participantes são reavaliados após seis semanas de tratamento e, novamente, ao final de 12 semanas. Após o término do tratamento supervisionado, eles são incentivados a continuar o programa de exercícios através de um material digital, sendo reavaliados após 18 semanas. “Essas pessoas recebem o tratamento de forma remota, com supervisão através de videochamadas ou recebem o tratamento aqui na clínica do HU. Os alunos se envolvem muito neste trabalho, pois, o atendimento prestado à comunidade neste projeto, tanto no remoto ou presencial, é conduzido por estudantes de Fisioterapia, assim como as etapas de avaliação e reavaliação. Isso acrescenta muito na formação”, revela o professor.

PARTICIPANTES DA PESQUISA

O estudo clínico visa ampliar o acesso das pessoas à fisioterapia, oferecendo uma alternativa ao tratamento presencial. A técnica em Enfermagem Ana Delpino, já cansada pelas constantes dores no joelho, aderiu ao tratamento depois de ver pelas redes sociais o recrutamento para a pesquisa. Ela conta que o processo de cura já chega a 98%. “Fui super acolhida e o tratamento remoto é muito bom, tu consegues agendar o horário que fica melhor, juntamente do acompanhamento com o fisioterapeuta. E eu aprendi os exercícios, que me fizeram movimentar melhor os meus joelhos, já posso fazer minha caminhada e hoje sinto muito mais firmeza”, revela.

É o mesmo caso da aposentada, Céles Helena da Silva Ramir. Ela foi ao HU fazer uma revisão e diz que teve as dores estancadas depois de concluir o tratamento. “Foi muito proveitoso. Quando comecei eu tinha dores, principalmente para levantar, agora levanto, agacho tranquilamente, então, estou muito satisfeita. Valeu a pena ter participado dessa pesquisa, fiquei muito agradecida pela oportunidade”, avalia.

Pessoas interessadas em participar do estudo podem entrar em contato com o Núcleo de Práticas em Saúde do Hospital Universitário pelo telefone (53) 3242-7433 ou pelo número (55) 99678-2793 para agendar a triagem.

Link para acesso a notícia:
<https://www.jornalminuano.com.br/noticia/2024/07/28/pesquisa-avalia-reabilitacao-de-pacientes-com-osteoartrite-do-joelho>

CONCLUSÃO

A conclusão da presente tese é amparada nos achados de duas revisões sistemáticas e de um ensaio clínico randomizado de não-inferioridade. Na primeira, encontramos que as evidências são insuficientes para a eficácia da EENM combinada com exercícios para melhorar desfechos reportados pelos pacientes em pessoas com OA de joelho. Na segunda, os achados indicaram variabilidade nos protocolos de ultrassonografia para avaliação muscular de pacientes com OA de joelho, com muitos estudos sem descrições detalhadas dos principais parâmetros ultrassonográficos que poderiam afetar diretamente a qualidade, precisão e confiabilidade dessas medições. Apesar disso, há um interesse crescente na literatura sobre as mudanças na arquitetura muscular do quadríceps femoral em pessoas com OA de joelho, particularmente em termos de espessura muscular e intensidade do eco. As evidências sugerem que as mudanças na morfologia muscular do quadríceps femoral são seletivas, com redução na espessura muscular do vasto medial e na qualidade muscular do vasto medial e do vasto intermédio. Além disso, a espessura muscular do quadríceps femoral está associada a desfechos reportados pelos pacientes específicos da condição articular e ao desempenho funcional de pessoas com OA de joelho. Além disso, observamos relação entre a intensidade do eco com medidas funcionais.

Os achados do estudo RISE-KOA, que incluiu medidas de arquitetura e qualidade muscular do quadríceps femoral, indicaram que um programa de exercícios supervisionados remotamente via videochamadas é não inferior ao formato presencial para melhorar a dor e a função física de pacientes com OA de joelho. Foi observada respostas semelhantes entre os dois formatos de disponibilização da intervenção baseada em exercícios (remoto e presencial) em relação a outros desfechos reportados pelos pacientes relativos a condição articular (como sintomas de OA de joelho, envolvimento em atividades esportivas e de lazer e qualidade de vida relacionada ao joelho), a performance funcional (habilidade de sentar e levantar da cadeira, caminhada habitual e velocidade de marcha) e a arquitetura (ângulo de penação) e qualidade muscular (intensidade do eco) do quadríceps femoral.

Espera-se que os achados desta tese contribuam para a qualidade da assistência a pacientes com OA de joelho em nível global. A ampliação do uso da ultrassonografia na avaliação do quadríceps femoral possibilitará um monitoramento mais preciso da efetividade de intervenções baseadas em exercícios terapêuticos. Os resultados deste estudo podem fortalecer a confiança dos fisioterapeutas na supervisão remota de exercícios via videochamada, proporcionando uma alternativa viável e acessível para o

acompanhamento dos pacientes com OA de joelho. Por fim, ao evidenciar os benefícios dessa abordagem, nossas descobertas podem facilitar o acesso da comunidade a programas de exercícios, aumentando a autonomia de pessoas com OA de joelho a escolher a modalidade de supervisão — remota ou presencial — que melhor se adapte às suas necessidades e preferências.

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ANEXOS

Anexo I – Aprovação do estudo no Comitê de Ética em Pesquisa da UFPEL

ESCOLA SUPERIOR DE
EDUCAÇÃO FÍSICA DA
UNIVERSIDADE FEDERAL DE
PELOTAS - UFPEL



PARECER CONSUBSTANCIADO DO CEP

DADOS DO PROJETO DE PESQUISA

Título da Pesquisa: Respostas de um programa exercícios supervisionados nas modalidades remota e presencial em pessoas com osteoartrite de joelho: um ensaio clínico randomizado de não inferioridade

Pesquisador: Cristine Lima Alberton

Área Temática:

Versão: 2

CAAE: 74411723.0.0000.5313

Instituição Proponente: Escola Superior de Educação Física da Universidade Federal de Pelotas

Patrocinador Principal: Financiamento Próprio

DADOS DO PARECER

Número do Parecer: 6.420.545

Apresentação do Projeto:

De acordo com o projeto a supervisão de exercícios através de recursos online é uma alternativa à modalidade presencial com respostas terapêuticas similares em diferentes perfis clínicos. Especialmente na osteoartrite de joelho (OA), o exercício é uma abordagem recomendada pelas diretrizes internacionais, no entanto, é necessário elucidar a comparabilidade das respostas dos exercícios supervisionados remotamente e presencialmente. Deste modo, o objetivo do estudo é investigar as respostas de um programa de exercícios remotos comparado ao presencial em desfechos reportados pelos pacientes, na arquitetura muscular e na performance funcional de sujeitos com OA de joelho. Serão aleatorizados 68 pacientes com OA de joelho sintomática e radiográfica em dois grupos: de exercícios remotos e presenciais. A intervenção terá duração de 12 semanas e consistirá em exercícios de fortalecimento muscular de extremidades inferiores, os quais serão supervisionados, em um grupo remotamente (por videochamada) e no outro presencialmente (em uma clínica de fisioterapia). Os pacientes realizarão o mesmo programa de tratamento que consistirá em um total de seis exercícios por sessão, em duas sessões semanais, nas primeiras duas semanas e três sessões a partir da terceira semana. No primeiro bloco de tratamento, serão orientados exercícios iniciando pelos grupos musculares dos extensores do joelho, adutores do quadril e flexores plantares, e no segundo bloco, extensores do joelho, abdutores do quadril e flexores do joelho. O monitoramento da percepção de esforço será

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efetuado pela escala modificada de classificação de esforço de Borg. Antes, após seis, 12 e 18 semanas serão mensurados desfechos reportados pelos pacientes relativos à condição articular como dor, sintomas, atividades diárias, atividades esportivas e de lazer e qualidade de vida; desfechos relativos ao domínio psicológico como à catastrofização da dor, sintomas de depressão, ansiedade e estresse e qualidade do sono. Adicionalmente, serão realizadas as medidas de arquitetura muscular do quadríceps femoral, incluindo a espessura muscular, área de secção transversa, ângulo de penetração e ecointensidade. E, a performance funcional através de testes que englobam as habilidades de levantar e sentar, caminhar e subir e descer escadas. As medidas de arquitetura muscular e os parâmetros funcionais serão realizadas somente nas semanas (0, 6 e 12). A análise dos dados será conduzida por Linear Mixed Models e será apresentada a análise por intenção de tratar e por protocolo. O nível de significância adotado neste estudo será de $\alpha = 0,05$.

Objetivo da Pesquisa:

O objetivo do estudo é investigar as respostas de 12 semanas de um programa de exercícios remotos comparado ao presencial em desfechos reportados pelos pacientes, na arquitetura muscular e em parâmetros funcionais de sujeitos com OA de joelho.

Avaliação dos Riscos e Benefícios:

De acordo com o projeto o programa de exercícios envolve mudanças entre as posições sentado e em pé, assim há risco de queda durante o tratamento. Deste modo, tanto na abordagem de tratamento presencial ou por videochamada a equipe responsável pela intervenção será capacitada a proporcionar um ambiente seguro como, por exemplo, orientar o paciente a dispor de uma cadeira por perto para apoio durante os exercícios em pé. Como uma medida adicional para garantir a segurança, os participantes serão aconselhados a ter a presença de um familiar em casa durante os exercícios, sempre que possível. O pesquisador, a frente da intervenção, terá o contato do familiar caso necessite de ajuda para garantir a segurança para condução da intervenção. No caso da impossibilidade da presença do familiar, destaca-se que os participantes serão previamente familiarizados com o exercício e quanto as medidas de segurança em ambiente domiciliar. Durante o estudo, os pesquisadores irão monitorar eventos adversos, os quais serão categorizados conforme gravidade (leve, moderado ou grave), previsibilidade (esperado ou inesperado) e possível associação com o exercício e o modo de supervisão (definitivamente associados, possivelmente associados ou não associados). Em caso de mal-estar ou queda do paciente os pesquisadores imediatamente acionarão o serviço de atendimento móvel de urgência.

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(SAMU) e acompanharão o paciente, tanto no grupo presencial como por videochamada, até a transferência da responsabilidade de atendimento. Especialmente no grupo por videochamada, os pesquisadores capacitados quanto a estes episódios, irão manter contato com o paciente de forma a mantê-lo calmo e monitorando as manifestações clínicas até a chegada do serviço de atendimento. Durante as medidas com questionários os participantes podem relatar fadiga mental, constrangimento ou sentimento de desconforto, assim será assegurado um ambiente calmo e silencioso para a resposta dos questionários. Caso o paciente relate impossibilidade de continuar a responder os questionários devido a fadiga mental, o pesquisador irá oferecer uma nova data para a coleta de dados, ou o fracionamento da coleta em dias diferentes para diminuir o número de questões. No caso de risco de constrangimento e desconforto durante a coleta de dados, o pesquisador reforçará a confidencialidade das informações, esclarecendo que serão utilizadas exclusivamente para compreender os efeitos do protocolo de exercícios nas variáveis investigadas. Além disso, caso o paciente considere necessário, será feita uma pausa na coleta de dados. Persistindo o desconforto, será oferecida a opção de realizar a coleta de dados em outro momento ou será dispensado de responder sem prejuízos na sua participação no estudo. Há risco de queda e fadiga durante os testes funcionais, uma vez que envolve o esforço em tarefas de levantar e sentar, caminhar e subir e descer escadas. O ambiente da clínica será organizado para realização individualizada e sob supervisão atenta de um profissional capacitado. Nas medidas com o equipamento de ultrassom o paciente poderá relatar mal-estar por ficar alguns minutos deitado, mas o profissional realizará as medidas o mais rapidamente possível. De acordo com o projeto o benefício em participar deste estudo consiste na possibilidade de melhorar de diversos parâmetros de saúde articular, psicológica, muscular e funcional de pacientes com osteoartrite de joelho. O estudo possibilitará a compreensão a cerca da comparabilidade dos efeitos de exercícios supervisionados em formato remoto e presencial, o que ampliará as possibilidades de disponibilização deste tratamento aos pacientes.

Comentários e Considerações sobre a Pesquisa:

Trata-se de um projeto de tese, está bem descrito e apresenta coerência dos instrumentos e procedimentos metodológicos em relação aos objetivos propostos.

Considerações sobre os Termos de apresentação obrigatória:

Folha de rosto: ok

TCLE: ok

Termo de Anuência: ok

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Instrumento de coleta das informações: ok

Cronograma: ok

Orçamento: ok

Recomendações:

Não há recomendações

Conclusões ou Pendências e Lista de Inadequações:

Não há pendências

Considerações Finais a critério do CEP:

Prezado(a) Pesquisador(a)

O CEP considera o protocolo de pesquisa adequado, conforme parecer APROVADO, emitido pelo(a) relator(a). Solicita-se que o(a) pesquisador(a) responsável retorne com o RELATÓRIO FINAL ao término do estudo, considerando o cronograma estabelecido e atendendo à Resolução CNS nº510/2016.

Att,

Elizabete Helbig

Coordenadora do CEP/ESEF/UFPEL

Este parecer foi elaborado baseado nos documentos abaixo relacionados:

Tipo Documento	Arquivo	Postagem	Autor	Situação
Informações Básicas do Projeto	PB_INFORMAÇÕES_BÁSICAS_DO_PROJETO_2218040.pdf	04/10/2023 15:35:18		Aceito
Outros	Anexo_consideracoeseticas.pdf	04/10/2023 15:32:03	Cristine Lima Alberon	Aceito
Outros	cartaresposta_cep.pdf	04/10/2023 15:31:39	Cristine Lima Alberon	Aceito
Outros	ApendiceD_calculoamostral.pdf	04/10/2023 15:30:16	Cristine Lima Alberon	Aceito
Outros	ApendiceC_fichadeavaliacao.pdf	04/10/2023 15:30:02	Cristine Lima Alberon	Aceito
Outros	ApendiceA_termodeanuencia.pdf	04/10/2023	Cristine Lima	Aceito

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Outros	ApendiceA_termodeanuencia.pdf	15:29:07	Alberton	Aceito
TCLE / Termos de Assentimento / Justificativa de Ausência	ApendiceB_TCLE.pdf	04/10/2023 15:28:51	Cristine Lima Alberton	Aceito
Projeto Detalhado / Brochura Investigador	projeto brochura.pdf	04/10/2023 15:27:43	Cristine Lima Alberton	Aceito
Folha de Rosto	folhaDeRosto_Mauricio_assinado_assinado.pdf	04/10/2023 15:25:17	Cristine Lima Alberton	Aceito
Cronograma	CRONOGRAMA.pdf	22/09/2023 13:08:43	Cristine Lima Alberton	Aceito
Outros	Anexo_E_indicequalidadedosono.pdf	22/09/2023 10:27:59	Cristine Lima Alberton	Aceito
Outros	Anexo_D_escalasintomasdedepressao.pdf	22/09/2023 10:25:04	Cristine Lima Alberton	Aceito
Outros	Anexo_C_escalapensamentoscatastroficos.pdf	22/09/2023 10:23:47	Cristine Lima Alberton	Aceito
Outros	Anexo_B_questionarioOA.pdf	22/09/2023 10:22:32	Cristine Lima Alberton	Aceito
Outros	Anexo_A_escalanumericadedor.pdf	22/09/2023 10:22:03	Cristine Lima Alberton	Aceito
Orçamento	ORCAMENTO.pdf	22/09/2023 10:11:07	Cristine Lima Alberton	Aceito

Situação do Parecer:

Aprovado

Necessita Apreciação da CONEP:

Não

PELOTAS, 10 de Outubro de 2023

Assinado por:
ELIZABETE HELBIG
(Coordenador(a))

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Anexo II – Registro do estudo RISE-KOA no Clinical Trials

Active, not recruiting ⓘ

Remote and In-person Supervised Exercise in Patients with Knee Osteoarthritis (RISE-KOA)

ClinicalTrials.gov ID ⓘ NCT06101797

Sponsor ⓘ Federal University of Pelotas

Information provided by ⓘ Cristine Lima Alberton, Federal University of Pelotas (Responsible Party)

Last Update Posted ⓘ 2025-02-18



+ Expand all content

– Collapse all content

Acesso pelo link: <https://clinicaltrials.gov/study/NCT06101797?intr=RISE-KOA&rank=1>

Anexo III - Normas do periódico *Physiotherapy Research International*

Author Guidelines

1. General

Effective with the 2014 volume, *Physiotherapy Research International* will be published in an online-only format. No printed edition will be published. All normal author benefits and services remain in place e.g. authors will continue to be able to order print reprints of articles if required. Furthermore, there will be no cost to authors for the publication of colour images in the online-only edition.

New submissions should be made via the Research Exchange submission portal <https://wiley.atyponrex.com/journal/PRI>. Should your manuscript proceed to the revision stage, you will be directed to make your revisions via the same submission portal. You may check the status of your submission at anytime by logging on to submission.wiley.com and clicking the “My Submissions” button. For technical help with the submission system, please review our [FAQs](#) or contact submissionhelp@wiley.com.

Transferable Review: *Health Science Reports*

This journal works together with Wiley's Open Access Journal, *Health Science Reports* to enable rapid publication of good quality research that is unable to be accepted for publication by our journal. Authors may be offered the option of having the paper, along with any related peer reviews, automatically transferred for consideration by the Editor of *Health Science Reports*. Authors will not need to reformat or rewrite their manuscript at this stage, and publication decisions will be made a short time after the transfer takes place. The Editor of *Health Science Reports* will accept submissions that report well-conducted research that reaches the standard acceptable for publication. *Health Science Reports* is indexed on PubMed/MEDLINE and Scopus. As *Health Science Reports* is a Wiley Open Access journal, authors of accepted papers pay an Article Publication Charge. Information on the Article Publication Charge for publishing in the journal is available [here](#).

We look forward to your submission.

Free Format Submission

Physiotherapy Research International now offers free format submission for a simplified and streamlined submission process.

Before you submit, you will need:

- Your manuscript: this can be a single file including text, figures, and tables, or separate files – whichever you prefer. All required sections should be contained in your manuscript, including abstract, introduction, methods, results, and conclusions. Figures and tables should have legends. References may be submitted in any style or format, as long as it is consistent throughout the manuscript. If the manuscript, figures or tables are difficult for you to read, they will also be difficult for the editors and reviewers. If your manuscript is difficult to read, the editorial office may send it back to you for revision.
- The title page of the manuscript, including statements relating to our ethics and integrity policies, some of which will apply to your article:

- data availability statement
- funding statement
- conflict of interest disclosure
- ethics approval statement
- patient consent statement
- permission to reproduce material from other sources
- study registration

(Why is this important? We need to uphold rigorous ethical standards for the research we consider for publication.)

- Your co-author details, including affiliation and email address. *(Why is this important? We need to keep all co-authors informed of the outcome of the peer review process.)*
- An ORCID ID, freely available at <https://orcid.org>. The ORCID iD is required for the corresponding/submitting author. *(Why is this important? Your article, if accepted and published, will be attached to your ORCID profile. Institutions and funders are increasingly requiring authors to have ORCID IDs.)*

To submit, login at <https://mc.manuscriptcentral.com/pri> and create a new submission. Follow the submission steps as required and submit the manuscript.

If you are invited to revise your manuscript after peer review, the journal will also request the revised manuscript to be formatted according to journal requirements as described below.

Equity, Diversity and Inclusion

Physiotherapy Research International aims to foster inclusive research that reflects the disciplinary, human, and geographic diversity of scientists, clinicians and other health professionals working in this area. Submissions are welcomed from authors of all ethnicities, races, colours, religions, sexes, sexual orientations, gender identities, national origins, disabilities, ages, or other individual status.

2. Article Types

Article Type	Description	Word Limit	Abstract / Structure	Other Requirements
Research Article	Reports of new research findings or conceptual analyses that make a significant contribution to knowledge	4000 limit	Yes, structured	Data Availability Statement IRB Statement Ethics Statement

Review	Critical reviews of the literature, including systematic reviews and meta-analyses	5000 limit	Yes, unstructured	Ethics Statement
Short Report	Preliminary findings of research in progress or a case report of particular interest	1500 limit	Yes, structured	Data Availability Statement IRB Statement
Case Report	Preliminary findings of research in progress or a case report of particular interest. The <u>CARE case report guidelines</u> should be followed.	1500 limit	Yes, unstructured	IRB Statement Ethics Statement
Letter to the Editor	Letters in response to a recently published article in <i>Physiotherapy Research International</i> . Please note, if accepted for publication, the author(s) of the referenced article will be invited to	1000 limit	No	

	submit a response.			
Editorial	Editorial is used to express a point of view on a specific topic.	2000 limit	No	

3. Content

Physiotherapy Research International welcomes scholarly papers including original research reports related to physiotherapy and other relevant professions. To expedite the reviewing process all manuscripts are all subject to a screening process by one of the Deputy Editors. Those judged to be of sufficient interest and methodologically robust will be reviewed by at least two experienced independent referees. Priority will be given to clinically relevant papers. The Editorial Board is committed to publishing excellent research and will consider the following types of papers:

- Research Articles – including quantitative, qualitative, and observational studies, clinical trials, and articles on methodological and statistical topics
- Reviews – including systematic
- Case Reports
- Short Reports
- Editorials

Submission of a manuscript to *Physiotherapy Research International* is limited to original work not previously published, nor being considered simultaneously elsewhere for publication. If accepted for publication it will not be published elsewhere in the same form, in any language, without the consent of the editor and once published is expected to conform to the usual ethical aspects of investigation and copyright.

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5. Presentation

If you require any information about the preparation of your manuscript, please contact submissionhelp@wiley.com or Gill.Arbane@sgul.kingston.ac.uk

Word Count

PRi operates a strict word count but has made allowances for the different methodological approaches.

Clinical trials: 2,500-3,000

Qualitative studies: 3,500-4,000

Observational studies: 2,500-3,000
 Articles on methodological and statistical topics: 2,500-3,000
 Systematic reviews: 3,500-4,000
 Case reports: 1,500-2,500

Main Text File

Manuscripts can be uploaded either as a single document (containing the main text, tables and figures), or with figures and tables provided as separate files. Should your manuscript reach revision stage, figures and tables must be provided as separate files. The main manuscript file can be submitted in Microsoft Word (.doc or .docx) or LaTeX (.tex) format.

If submitting your manuscript file in LaTeX format via Research Exchange, select the file designation “Main Document – LaTeX .tex File” on upload. When submitting a LaTeX Main Document, you must also provide a PDF version of the manuscript for Peer Review. Please upload this file as “Main Document - LaTeX PDF.” All supporting files that are referred to in the LaTeX Main Document should be uploaded as a “LaTeX Supplementary File.”

Your main document file should include:

- A short informative title containing the major key words. The title should not contain abbreviations
- The full names of the authors with institutional affiliations where the work was conducted, with a footnote for the author's present address if different from where the work was conducted;
- Acknowledgments;
- Abstract structured (background and purpose/methods/results/discussion)
- Up to four keywords;
- Main body: formatted as abstract, introduction, methods, results/findings, discussion;
- References;
- Tables (each table complete with title and footnotes);
- Figures: Figure legends must be added beneath each individual image during upload AND as a complete list in the text.

Best Practices for Manuscript Transformation

- The main manuscript file must be submitted in Microsoft Word (.doc or .docx) or LaTeX (.tex) formats.
- Figures should be numbered in the order that they are cited in the text, and presented in that order after the text of the paper
- Full names (First, Middle, and Last) should be provided for all authors
- Authors should include the complete affiliation addresses in the manuscript. At minimum, authors should include the institution name and country, but a complete affiliation also includes department name and institution city. The institution postal code is optional.

Title page

The title page should be submitted separately and provide the title, the corresponding author's name and email address, and the names, titles and academic or other affiliations of all authors. No identifying details of the authors or their institutions must appear in the submitted manuscript. Please provide a shortened title to use as a header.

Abstract

An abstract of no more than 300 words is required on all submissions using the headings: Background and Purpose, Methods [giving design before participants], Results, Discussion. **All research papers** should consist of an Abstract; Introduction; Methods – to include design, subjects, procedure, ethical considerations; Results/Findings; Discussion (to include a section on limitations). All papers should end with a section on 'Implications for Physiotherapy Practice'.

Keywords

Please provide a list of four keywords or fewer. They should be listed alphabetically and on full without any abbreviations. Please ensure keywords are recognised MeSH terms from the master list of standardized **Medical Subject Headings**

Introduction

The introduction should justify the aims of the manuscript. Only include references that are essential to the understanding of the aims of the manuscript. Ideally this should be no longer than three to four paragraphs. Use the introduction to clearly define your research question or hypothesis, and justify the rationale for the study and choice of research methodology.

5.1 Main body

5.1.1 Quantitative studies

For clinical trials reporting please refer to guidance in the CONSORT statement: <http://www.consort-statement.org/resources/downloads/>

Methods

Study Design

Please provide a brief overview of the tests or experiments used to answer the research question(s). Include the independent variables manipulated, the dependent variables measured and all controls. Indicate the timing of the intervention and measurement. Include the committees that gave ethical approval and any informed consent procedures.

Subjects

Outline the recruitment procedures and the inclusion and exclusion criteria for their eligibility. Include details of any drop outs or missing data.

Materials

Indicate any materials used for the research including their validity and reliability. Provide manufacturer and manufacturers address for any equipment as necessary.

Procedure

Put as much detail as possible to allow others to evaluate or reproduce the test/experiments. Include outcome measures stating the impairment or activity or limitation or participation restriction being collected and its measurement with units. Mention any power analysis carried out to determine the number of subjects needed for the study. Explain how the research question(s) has been answered by the interpretive results (include details of statistical analysis). Include details of any statistical packages used.

Results

Pertinent results should be reported; results that help answer the question. Present the data in figures or tables within the body of the text. Do not duplicate data in tables and

figures. Only report a meaningful number of decimal places. All data reported as means should also be accompanied by the standard deviation (in brackets). When reporting the results of interpretive tests, report the size of the effect rather than its statistical difference. Avoid using abbreviations and reporting overly detailed statistics.

Discussion

This should initially summarise the main results and answer the research question asked in the introduction, if relevant. Emphasise the new and important aspects of the study. Data already presented in the Method and Results should not be repeated. The length of the Discussion should relate to the number of important findings, usually not less than 750 words.

5.1.2 Qualitative Studies

Qualitative studies explore complex phenomena and are less appropriate for strict guidance on reporting. However authors are advised to prepare manuscripts with attention to the following headings; Introduction: Method, to include study design (including theoretical framework); setting; sampling and recruitment; data collection, data analysis (whether software was used, data coding, participant checking); research team and reflexivity, ethical considerations. Results/Discussion- can be written together or separately and should include clarity and derivation of major and minor themes and identification of quotes (participant numbers) Authors are encouraged to consult checklists such as COREQ for further guidance: <http://www.equator-network.org/resource-centre/library-of-health-research-reporting/reporting-guidelines/qualitative-research/>

5.1.3 Observational studies

Cohort, case control and cross sectional studies will be considered for publication. Authors are encouraged to consult the Strengthening the Reporting of Observational Studies in Epidemiology (STROBE) recommendations quality of reporting of observational studies. The STROBE Statement consists of a checklist of 22 items, which relate to the title, abstract, introduction, methods, results and discussion sections of articles. See <http://www.strobe-statement.org/> for more details.

5.1.4 Articles on methodological and statistical topics should include study objective(s), design, data collection methods and source of subjects with selection methods and justifications. Indicate study procedure, data analysis and statistical methods used with appropriate references. Main results should be presented with confidence intervals. Indicate any study limitations.

5.2 Reviews

5.2.1 Systematic Reviews

A review of a clearly formulated question that uses systematic and explicit methods to identify, select, and critically appraise relevant research, and to collect and analyze data from the studies will be considered for publication. Statistical methods (meta-analysis) may or may not be used to analyze and summarize the results of the included studies. If the review finds that there is not enough good quality evidence or the literature is inconclusive, it is unlikely to be published. Authors of systematic reviews are encouraged to consult the PRISMA statement: <http://www.prisma-statement.org/statement.htm>

5.3 Case Studies

Single case studies that make a contribution to proof of concept for a clinical intervention

will be considered. The scope of the study should be justified with singular or multiple reports. The report must be systematic in process and collect multiple forms of data relevant to the report(s) and provide an avenue to express systematic trial of a new intervention. However, case reports should not draw conclusions about the effects of an intervention. To be accepted they should be of broad interest and should be more than just citing a case scenario to illustrate or justify opinion.

Acknowledgements

The Acknowledgments section details special thanks, personal assistance, and dedications. Contributions from individuals who do not qualify for authorship should also be acknowledged here. These should be grouped into one paragraph placed after the authorship.

References

The American Psychological Association style (APA Style 6th Edition) of referencing should be used. Bibliographical references in the text should strictly in chronological order.

1. Citations in Text

In-text citations include the author and date, either both inside parentheses or with the author names in running text and the date in parentheses.

- After the intervention, children increased in the number of books read per week (Smith & Wexwood, 2010).
- Smith and Wexwood (2010) reported that after the intervention, children increased in the number of books read per week.

*Note:

The use of "&" when both author and year are inside parentheses, while "and" is used when only the year is in parentheses.

For multiple citations within parentheses, alphabetize the studies as they would appear in the reference list and separate them by semicolons.

- Studies of reading in childhood have produced mixed results (Albright, Wayne, & Fortinbras, 2004; Gibson, 2011; Smith & Wexwood, 2010).

2. Use of "et al." – question: should et al. be in italics when used in references?

Below is a chart showing when to use *et al.*, which is determined by the number of authors and whether it is the first time a reference has been cited in the paper. Specifically, articles with one or two authors include all names in every in-text citation; articles with three, four, or five authors include all names in the first in-text citation but are abbreviated to the first author name plus *et al.* upon subsequent citations; and articles with six or more authors are abbreviated to the first author name plus *et al.* for all in-text citations.

Number of authors	First text citation (either parenthetical or narrative)	Subsequent text citations (all)
One or two	Palmer & Roy, 2008	Palmer & Roy, 2008

Three, four, or five	Sharp, Aarons, Wittenberg, & Gittens, 2007	Sharp et al., 2007
Six or more	Mendelsohn et al., 2010	Mendelsohn et al., 2010

3. Example of References

○ Journal Reference Type

- One Author:
Fawcett, T. (2006). An introduction to ROC analysis. *Pattern Recognition Letters*, 27(8), 861–874.
DOI: 10.1016/j.patrec.2005.10.010.
- Two to Seven Authors:
Daley, C. E., & Nagle, R. J. (1996). Relevance of WISC-III Indicators for assessment of learning disabilities. *Journal of Psychoeducational Assessment*, 14(4), 320–333.
Ramus, F., Rosen, S., Dakin, S. C. Day, B. L., Castellote, J. M., White, S., & Frith, U. (2003). Theories of developmental dyslexia: Insights from a multiple case study of dyslexic adults. *Brain*, 126(4), 841–865. DOI: 10.1093/brain/awg076
- More than Seven Authors:
Rutter, M., Caspi, A., Fergusson, D., Horwood, L. J., Goodman, R., Maughan, B., ...Carroll, J. (2004). Sex differences in developmental reading disability: New findings from 4 epidemiological studies. *Journal of the American Medical Association*, 291(16), 2007–2012. DOI: 10.1001/jama.291.16.2007
- In press or forthcoming:
van Bergen, E., de Jong, P. F., Maassen, B., Krikhaar, E., Plakas, A., & van der Leij, A. (in press). IQ of four-year-olds who go on to develop dyslexia. *Journal of Learning Disabilities*.
DOI: 10.1177/0022219413479673

Note:

Issue number is optional. Use issue only if each issue starts at page 1. If pagination is continuous within volume, use volume only. Do not add punctuation after DOIs and URLs.

4.

○ Book Reference Type

- Personal Authors:
Beck, I. (1989). *Reading today and tomorrow: Teachers edition for grades 1 and 2*. Austin, TX: Holt and Co.
Bradley, L., & Bryant, P. (1985). *Rhyme and reason in reading and spelling*. Ann Arbor: University of Michigan Press.
- Chapter in Book:
Borstrøm, I., & Elbro, C. (1997). Prevention of dyslexia in kindergarten: Effects of phoneme awareness training with children of dyslexic parents. In C. Hulme & M. Snowling (Eds.), *Dyslexia: Biology, cognition and intervention* (pp. 235–253). London, UK: Whurr.

○ **Conference Reference Type**

- Conference Paper:
Balakrishnan, R. (2006, March 25-26). Why aren't we using 3d user interfaces, and will we ever? Paper presented at the IEEE Symposium on 3D User Interfaces. doi:10.1109/VR.2006.148
- Fan, K. Y. (1986, September). Graphic symbol of the Chinese character. Paper presented at the meeting of the Symposium of Chinese Character Modernization, Beijing, China.
- Conference Proceedings:
Rapp, R. (1995). Automatic identification of word translations from unrelated English and German corpora. In *Proceedings of the 37th Annual Conference of the Association for the Computational Linguistics*, pp. 519–525.
- Argamon, S., & Levitan, S. (2005). Measuring the usefulness of function words for authorship attribution. In *Proceedings of the 2005 ACH/ALLC Conference*. Victoria: Canada. Retrieved from <http://citeseerx.ist.psu.edu/viewdoc/summary?doi=10.1.1.71.6935>

Note:

Use “Retrieved from” to indicate online sources.

○ **Other Reference Types**

- Scientific or Technical Reports:
NICHD. National Institute of Child Health and Human Development (2000). Report of the National Reading Panel. Teaching children to read: An evidence-based assessment of the scientific research literature on reading and its implications for reading instruction (NIH Publication No. 00-4769). Washington, DC: U.S. Government Printing Office.
- Dissertation:
van Otterloo, S. G. (2011). Early home-based intervention for children at familial risk of dyslexia. University of Amsterdam (unpublished doctoral dissertation).
- Eleveld, M. A. (2005). At risk for dyslexia. The role of phonological abilities, letter knowledge, and speed of serial naming in early intervention and diagnosis (PhD thesis). State University Groningen, The Netherlands. Leuven: Garant Publishers.

Note:

Personal Communication is not allowed in reference list. This should only be cited in text.

Tables and Figures and Illustrations

Tables (numbered in Arabic numerals) and diagrams or illustrations (also numbered in Arabic numerals) should be submitted separately from the main body of the text. For the reproduction of illustrations, only good line drawings or original photographs (black and white, not colour) can be accepted; negatives or photocopies cannot be used.

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This journal accepts artwork submissions for Cover Images. This is an optional service you can use to help increase article exposure and showcase your research. For more information, including artwork guidelines, pricing, and submission details, please visit the [Journal Cover Image page](#).

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You can refer to [Wiley's resources on ORCID iDs](#) or [visit the ORCID site to create or check your identifier number](#).

6. Ethical Considerations

Ethical Approval

Authors should always state that the study was approved by the relevant research ethics committee or institutional review board. Manuscripts must be accompanied by a statement that any experiments on participants were undertaken with the understanding and appropriate informed consent.

Patients' consent and permission to publish

Studies on patients or volunteers require ethics committee approval and informed consent, which should be documented in your paper. Where there is an unavoidable risk of breach of privacy - eg, in a clinical photograph or in case details - the patient's written consent, or that of the next of kin, to publication must be obtained. We will ask you to send a signed consent form before publication. Consent must be obtained for all Case Reports and Clinical Pictures.

Editors reserve the right to reject papers if there is doubt whether appropriate procedures have been followed. If a paper has been submitted from a country where there is no ethics committee, institutional review board, or similar review and approval, editors use their own experience to judge whether the paper should be published. If the decision is made to publish a paper under these circumstances a short statement should be included to explain the situation.

Authorship

Physiotherapy Research International conforms to uniform guidance from the International Committee of Medical Journal Editors: <http://www.icmje.org/about-icmje/faqs/icmje-recommendations/>

- Authorship credit should be based on 1) substantial contributions to 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. Authors should meet conditions 1, 2, and 3.

- When a large, multicenter group has conducted the work, the group should identify the individuals who accept direct responsibility for the manuscript (3). These individuals should fully meet the criteria for authorship/contributorship defined above, and editors will ask these individuals to complete journal-specific author and conflict-of-interest disclosure forms. When submitting a manuscript authored by a group, the corresponding author should clearly indicate the preferred citation and identify all individual authors as well as the group name. Other members of the group should be listed in the Acknowledgments. The NLM indexes the group name and the names of individuals the group has identified as being directly responsible for the manuscript; it also lists the names of collaborators if they are listed in Acknowledgments.
- Acquisition of funding, collection of data, or general supervision of the research group alone does not constitute authorship.
- All persons designated as authors should qualify for authorship, and all those who qualify should be listed.
- Each author should have participated sufficiently in the work to take public responsibility for appropriate portions of the content.

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All accepted manuscripts are required to publish a data availability statement to confirm the presence or absence of shared data. If you have shared data, this statement will describe how the data can be accessed, and include a persistent identifier (e.g., a DOI for the data, or an accession number) from the repository where you shared the data. Authors will be required to confirm adherence to the policy. If you cannot share the data described in your manuscript, for example for legal or ethical reasons, or do not intend to share the data then you must provide the appropriate data availability statement. *Physiotherapy Research International* notes that FAIR data sharing allows for access to shared data under restrictions (e.g., to protect confidential or proprietary information) but notes that the FAIR principles encourage you to share data in ways that are as open as possible (but that can be as closed as necessary).

Sample statements are available [here](#). Please note that the samples provided are examples of how the statements can be formatted – these can be modified accordingly depending on your requirements. If published, all statements will be placed in the heading of your manuscript.

7. Review Process

Authors will be notified within one month where the screening process identifies manuscripts appropriate for peer referral.

Once the comments are received from the reviewers these will be referred to the author when they will either be asked to make amendments as recommended or the paper is not considered suitable and will be rejected but comments will be given to enable the author to possibly take the paper forward for consideration by another journal.

Resubmission

When a paper is resubmitted authors are required to provide a detailed response to all points made by referees in a separate document. The amended paper will normally be reviewed again by one reviewer and designated Deputy Editor before a recommendation is made to the EIC to publish the paper.

8. Production

Once the paper has been through all reviewing processes it will be submitted to the publishers.

Amendments

When your paper has been accepted, it will be typeset and proofs will be sent to you for final scrutiny. Changes are expensive at this stage, and you are requested to keep these to an absolute minimum.

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Free access to the final PDF offprint of your article will be available via Author Services: <http://authorservices.wiley.com/bauthor/>. Please therefore sign up for Author Services if you would like to access your article PDF offprint and enjoy the many other benefits the service offers, such as Article Tracking, E-mail Publication Alerts and Customized Research Tools.

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Wiley Editing Services offers professional video, design, and writing services to create shareable video abstracts, infographics, conference posters, lay summaries, and research news stories for your research – so you can help your research get the attention it deserves.

Anexo IV – Normas do periódico *Annals of Physical and Rehabilitation Medicine*

Introduction

Annals of Physical and Rehabilitation Medicine (APRM) is a scientific journal created in 2009 from the existing *Annales de Réadaptation et de Médecine Physique*. It is published in English and covers all fields and aspects of Physical Medicine and Rehabilitation, from basic, to medical and social sciences related to rehabilitation.

Annals of Physical and Rehabilitation Medicine is published in association with the International Society of Physical and Rehabilitation Medicine (ISPRM). In addition, it is one of the Official journals of the Physical and Rehabilitation Medicine section of the European Union of Medical Specialists (UEMS) and is the official organ of the **Société Française de Médecine Physique et de Réadaptation (SOFMER)**.

The Journal is indexed in **MEDLINE** and **has one of the highest impact factors of the "Rehabilitation" category of the Journal Citation Report** (JCR, Clarivate Analytics), and **one of the highest CiteScore** (SCImago Journal Rank). The journal is also well-ranked in the "Orthopaedics" categories.

All papers are available with free access after 1 year. **The papers published in the Annals of PRM are increasingly popular**, as shown by the recent statistics of the ScienceDirect downloads. In 2020, the articles of the *Annals of PRM* were downloaded **1 000 000 times every month** worldwide.

Publication in the Annals of PRM is free of charge.

The Editorial policy of the Journal is to publish papers respecting the ethical principles of the Helsinki statement (1964). **Papers must deal with one of the following fields:**

- Assessment methods of motor, sensory, cognitive and visceral impairments
- Functional disabilities in children, adults, and older adults
- Clinical applications and research about handicap epidemiology and the International Classification of Functioning, Disability and Health
- Rehabilitation techniques and programs as well as technological innovations to reduce handicap in cardiovascular, neurological, orthopaedic, pulmonary, rheumatological, and urological diseases

- Evidence-based-medicine applied for non-pharmacological treatments, and drugs used in rehabilitation
- Elaboration of clinical recommendations in the field of rehabilitation
- Submission of papers dealing with interventions in rehabilitation is especially encouraged, as well as meta-analyses.

To ensure the quality of papers submitted for publication, the Annals of PRM require that the reporting follows guidelines: see Equator website <https://www.equator-network.org/>.

To ensure the quality of research published in the Annals of PRM, studies must be registered in international databases (WHO-labelled). This is mandatory for interventional studies and systematic reviews and strongly encouraged for observational studies. The registration reference must be given at the end of the abstract.

All manuscripts will be first subjected to a home reviewing possibly including an external expert. The editorial committee will do its best to decide whether or not a manuscript will go to standard reviewing. This decision should be made within the two weeks following the submission. Only a few manuscripts which have a chance to go through the reviewing process will be sent to reviewers. In that case, we will try to reach a decision within two months. Reviewing already done in previous high-standard journals can be added as additional materials. The editorial board can decide to consider this former reviewing to take a decision.

Types of article

This section describes the articles types for this journal.

Specifications for Manuscript Categories

- **Original articles:**
 - Word count (excluding abstract, tables, figure captions, references) $\leq$ 5000 + supplemental material
 - Abstract $\leq$ 300 words
 - References $\leq$ 50
 - Figures/Tables $\leq$ 6
 - Additional materials: what is required, sparingly
- **Reviews - Meta-analyses - Update papers - Position papers:**

- Word count (excluding abstract, tables, figure captions, references) ≤ 6000 + supplemental material
- Abstract ≤ 300 words
- References ≤ 80
- Figures/Tables ≤ 8
- Additional materials: what is required, sparingly
- **Letters to editor including outstanding single Case studies, short original research, Scientific Notes, etc.:**
- Word count (excluding abstract, tables, figure captions, references) ≤ 1800
- No Abstract
- References ≤ 20
- Figures/Tables ≤ 3
- Additional materials: what is required, sparingly
- **Editorials:**
- Word count (excluding abstract, tables, figure captions, references) ≤ 1500
- No Abstract
- References ≤ 12
- Figures/Tables ≤ 3
- **Correspondance: Comment on having a scientific scope**
- 1000 words
- References ≤ 5
- No figure/No table

The length of each manuscript must be given on the title page, including a word count for the abstract and main text, as well as number of tables, figures, references and additional materials.

Original articles

Articles are full-length reports of original research. These include large-scale pivotal trials of new therapies (randomized clinical trials). According to

ClinicalTrials.gov, clinical trials "are generally considered to be biomedical or health-related research studies in human beings that follow a pre-defined protocol". ClinicalTrials.gov includes both interventional and observational types of studies. Interventional studies are those in which the research subjects are assigned by the investigator to a treatment or other intervention, and their outcomes are measured. Observational studies are those in which individuals are observed and their outcomes are measured by the investigators.

Original articles report new and original work that has not been published elsewhere (except as an abstract at a conference). The last paragraph of the introduction should state the question(s) of the study, whose answers are found in the results section. The results should be described concisely, with no redundancies between the text and the tables or figures. The discussion should start with a brief summary of the results and an explanation of how the results contribute to answer the study question(s). The discussion should be brief; in general, one-third of the total manuscript length is appropriate.

Specifications:

- No more than 5000 words excluding Abstract, Figures, Tables, References, Additional material.
- Structured Abstract, maximum 300 words.
- Ideally, the introduction should not exceed 350 words.
- A maximum of 50 References. The best references should be included rather than duplicative citations for single points. Citations to non-peer-reviewed work should be avoided. If additional references are deemed important, they can be published as supplemental data.
- No more than of 6 Figures and/or Tables. Tables should not repeat data in the text. Figure legends must explain what is represented in the figure rather than repeat results, methods, and conclusions. °
- If Methods contain widely available, detailed protocols, appropriate portions may be posted online only at the Editor's discretion.

Reviews, Meta-analyses, Update papers, Position papers

Reviews and Position papers are either a review or an opinion statement that provides a summary of the most important recent information on a topic. Update papers present an update of recent data about a specific topic. Methodologies of review papers must follow some rules regarding the bibliography selection, reading and presentation (PRISMA reporting guidelines). If a review summarizes recommendations for practice, use the word "Recommendations" in the title rather than "Guidelines", unless they have been established by a process involving learned societies. The structure of Update articles and position papers may be more flexible.

Specifications:

- No more than 6000 words, excluding Abstract, Figures, Tables, References, Additional material
- Abstract (structured optional), maximum 300 words
- Ideally, the introduction should not exceed 350 words.
- A maximum of 80 References (additional references may be added as Additional material). They should cite the most important papers in the field.
- No more than 8 Tables and/or Figures.

Letters to editors

Letters to the editor are Clinical/Scientific notes, or comments on a paper published in the Annals of PRM. The writing may be organized in sections, must be fluid without any chapter heading. The introduction and the discussion should be brief and should point out the originality of the study or the case(s) description and its contribution to scientific knowledge. No attempt should be made to write a review of the topic. Manuscripts reporting a case with a review of the literature will not be considered.

Specifications:

- No more than 1800 words, excluding Abstract, Figures, Tables, References
- No abstract (the title serves as abstract)
- No more than 20 References.
- No more than 3 Tables and/or Figures.

In some cases, the length of a letter to the editor may exceed that mentioned in the Table above, but only with the agreement of the editors.

Editorial

Editorials expound opinions, describe noteworthy facts, summarize prominent studies, report news, or provide perspective. The authors are free to choose the outline. There is no abstract. Although editorials are often commissioned by the Editorial Committee, spontaneous submissions are welcome, with or without a pre-submission inquiry to the editors. In some cases, the length of the editorial can be longer than the one mentioned in the specifications below, with the agreement of the editors.

Specifications:

- No more than 1500 words, excluding Figures, Tables, References

- No abstract
- No more than 20 References.
- No more than 3 Tables and/or Figures.

Submission checklist

You can use the list at the bottom of the page for a final check of your submission before sending it to the journal for review.

Before you begin

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Please see our information on [Ethics in publishing](#).

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If the work involves the use of human subjects, the author should ensure that the work described has been carried out in accordance with [The Code of Ethics of the World Medical Association](#) (Declaration of Helsinki) for experiments involving humans. The manuscript should be in line with the [Recommendations for the Conduct, Reporting, Editing and Publication of Scholarly Work in Medical Journals](#) and aim for the inclusion of representative human populations (sex, age and ethnicity) as per those recommendations. The terms [sex](#) and [gender](#) should be used correctly.

The author should ensure that the manuscript contains a statement that all procedures were performed in compliance with relevant laws and institutional guidelines and have been approved by the appropriate institutional committee(s). This statement should contain the date and reference number of the ethical approval(s) obtained. Authors should also include a statement in the manuscript that informed consent was obtained for experimentation with human subjects. The privacy rights of human subjects must always be observed.

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1. that autonomous consent free from coercion was obtained from the donor(s) or their next of kin; and
2. that organs/tissues were not sourced from executed prisoners or prisoners of conscience.

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Declaration of interest

All authors must disclose any financial and personal relationships with other people or organizations that could inappropriately influence (bias) their work. Examples of potential competing interests include employment, consultancies, stock ownership, honoraria, paid expert testimony, patent applications/registrations, and grants or other funding. Authors must disclose any interests in two places: 1. A summary declaration of interest statement in the title page file. If there are no interests to declare then please state this: 'Declarations of interest: none'. 2. Detailed disclosures as part of a separate Declaration of Interest form, which forms part of the journal's official records. It is important for potential interests to be declared in both places and that the information matches. [More information](#).

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"he, she," or "he/she." We recommend avoiding the use of descriptors that refer to personal attributes such as age, gender, race, ethnicity, culture, sexual orientation, disability or health condition unless they are relevant and valid. When coding terminology is used, we recommend to avoid offensive or exclusionary terms such as "master", "slave", "blacklist" and "whitelist". We suggest using alternatives that are more appropriate and (self-) explanatory such as "primary", "secondary", "blocklist" and "allowlist". These guidelines are meant as a point of reference to help identify appropriate language but are by no means exhaustive or definitive.

Reporting sex- and gender-based analyses

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For research involving or pertaining to humans, animals or eukaryotic cells, investigators should integrate sex and gender-based analyses (SGBA) into their research design according to funder/sponsor requirements and best practices within a field. Authors should address the sex and/or gender dimensions of their research in their article. In cases where they cannot, they should discuss this as a limitation to their research's generalizability. Importantly, authors should explicitly state what definitions of sex and/or gender they are applying to enhance the precision, rigor and reproducibility of their research and to avoid ambiguity or conflation of terms and the constructs to which they refer (see Definitions section below). Authors can refer to the [Sex and Gender Equity in Research \(SAGER\) guidelines](#) and the [SAGER guidelines checklist](#). These offer systematic approaches to the use and editorial review of sex and gender information in study design, data analysis, outcome reporting and research interpretation - however, please note there is no single, universally agreed-upon set of guidelines for defining sex and gender.

Definitions

Sex generally refers to a set of biological attributes that are associated with physical and physiological features (e.g., chromosomal genotype, hormonal levels, internal and external anatomy). A binary sex categorization (male/female) is usually designated at birth ("sex assigned at birth"), most often based solely on the visible external anatomy of a newborn. Gender generally refers to socially constructed roles, behaviors, and identities of women, men and gender-diverse people that occur in a historical and cultural context and may vary across societies and over time. Gender influences how people view themselves and each other, how they behave and interact and how power is distributed in society. Sex and gender are often incorrectly portrayed as binary (female/male or woman/man) and unchanging whereas these constructs actually exist along a spectrum and include additional sex categorizations and gender identities such as people who are intersex/have differences of sex development (DSD) or identify as non-binary. Moreover, the terms "sex" and "gender" can be ambiguous--thus it is important for authors to define the manner in which they are used. In addition to this definition guidance and the [SAGER guidelines](#), the [resources on this page](#) offer further insight around sex and gender in research studies.

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General considerations

- Manuscript has been spell checked and grammar checked
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This section describes the article structure for this journal.

Subdivision_unnumbered sections

Divide your article into clearly defined sections. Each subsection is given a brief heading (H1, H2, H3 formats). Each heading should appear on its own separate line. Subsections should be used as much as possible when cross-referencing text: refer to the subsection by heading as opposed to simply 'the text'.

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State the objectives of the work and provide an adequate background, avoiding a detailed literature survey or a summary of the results.

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Results should be clear and concise.

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The main conclusions of the study may be presented in a short Conclusions section, which may stand alone or form a subsection of a Discussion or Results and Discussion section.

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If there is more than one appendix, they should be identified as A, B, etc. Formulae and equations in appendices should be given separate numbering: Eq. (A.1), Eq. (A.2), etc.; in a subsequent appendix, Eq. (B.1) and so on. Similarly for tables and figures: Table A.1; Fig. A.1, etc.

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A concise and factual structured abstract (Background, Objectives, Methods, Results, and Conclusion[s]) is required for Original articles. The abstract should state briefly the purpose of the research, the principal results and major conclusions. An abstract is often presented separately from the article, so it must be able to stand alone. For this reason, References should be avoided, but if essential, then cite the author(s) and year(s). Also, non-standard or uncommon abbreviations should be avoided, but if essential they must be defined at their first mention in the abstract itself.

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Immediately after the abstract, provide a maximum of 6 keywords, using British or American spelling, depending on what is used in the rest of the paper, and avoiding general and plural terms and multiple concepts (avoid, for example, 'and', 'of'). Be sparing with abbreviations: only abbreviations firmly established in the field may be eligible. These keywords will be used for indexing purposes.

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Provide abbreviations meaning list on the first page of the article. Each abbreviation must be defined at its first mention there. Ensure consistency of abbreviations throughout the article.

Acknowledgements

Collate acknowledgements in a separate section at the end of the article before the references and do not, therefore, include them on the title page, as a footnote to the title or otherwise. List here those individuals who provided help during the research (e.g., providing language help, writing assistance or proof reading the article, etc.).

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Follow internationally accepted rules and conventions: use the international system of units (SI). If other units are mentioned, please give their equivalent in SI.

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This section describes the artwork for this journal.

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Where a preprint has subsequently become available as a peer-reviewed publication, the formal publication should be used as the reference. If there are preprints that are central to your work or that cover crucial developments in the topic, but are not yet formally published, these may be referenced. Preprints should be clearly marked as such, for example by including the word preprint, or the name of the preprint server, as part of the reference. The preprint DOI should also be provided.

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[1] Van der Geer J, Hanraads JAJ, Lupton RA. The art of writing a scientific article. *J Sci Commun* 2010;163:51-9. <https://doi.org/10.1016/j.Sc.2010.00372>.

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Reference to a book:

[3] Strunk Jr W, White EB. The elements of style. 4th ed. New York: Longman; 2000.

Reference to a chapter in an edited book:

[4] Mettam GR, Adams LB. How to prepare an electronic version of your article. In: Jones BS, Smith RZ, editors. Introduction to the electronic age, New York: E-Publishing Inc; 2009, p. 281-304.

Reference to a website:

[5] Cancer Research UK. Cancer statistics reports for the UK, <http://www.cancerresearchuk.org/aboutcancer/statistics/cancerstatsreport/>; 2003 [accessed 13 March 2003].

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[dataset] [6] Oguro M, Imahiro S, Saito S, Nakashizuka T. Mortality data for Japanese oak wilt disease and surrounding forest compositions, Mendeley Data, v1; 2015. <https://doi.org/10.17632/xwj98nb39r.1>.

Note shortened form for last page number. e.g., 51-9, and that for more than 6 authors the first 6 should be listed followed by 'et al.' For further details you are referred to 'Uniform Requirements for Manuscripts submitted to Biomedical Journals' (J Am Med Assoc 1997;277:927-34) (see also [Samples of Formatted References](#)).

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After acceptance

Online proof correction

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Criteria

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All submitted protocols must have ethical approval. If the study has undergone full external peer review as part of the funding process, the study protocol will usually only undergo editorial peer review by a Protocol Editor. Study protocols without major external funding will undergo full, external peer review. Study protocols without ethical approval will generally not be considered. To support efficient handling of your study protocol, the Editors advise that prospective authors familiarize themselves with this [Editorial on what is expected in a study protocol submission](#).

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Statistical Analysis Plans can be directly integrated into the study protocol being submitted for publication (for uncomplicated RCTs this might be sufficient) or included as an additional file to the submission. For more information, read our Editorial: [Prospective](#)

reporting of statistical analysis plans for randomised controlled trials. Standalone statistical analysis plans submitted separately to a study protocol should be submitted as an Update. These should be submitted before data lock.

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On submission, the following documentation should be uploaded as Additional Files. If the original documents are not in English, an English translation of each is mandatory.

- Ethical approval document
- Copy of the original funding documentation
- A completed SPIRIT checklist (unless the structured study protocol template has been used), or checklist for another appropriate reporting guideline

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1. By following the guidance set out in our structured study protocol template. This is the preferred option if you have not yet started writing your manuscript.
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The information below details the section headings that you should include in your manuscript and what information should be within each section.

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The Abstract should not exceed 350 words. Please minimize the use of abbreviations and do not cite references in the abstract. The abstract must include the following separate sections:

- **Background:** the context and purpose of the study
- **Methods:** how the study will be performed
- **Discussion:** a brief summary and potential implications
- **Trial registration:** If your article reports the results of a health care intervention on human participants, it must be registered in a WHO IC RTP registry. The name of the registry, registration number and date of registration should all be stated in this section. If it was not registered prospectively (before enrollment of the first participant), you should include the words 'retrospectively registered'. See our editorial policies for more information on trial registration. If your article reports the results of research on research and you have registered your work with the Research on Research (RoR) registry, please include the registry record URL.

Keywords

Three to ten keywords representing the main content of the article.

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The Background section should explain the background to the study, its aims, a summary of the existing literature and why this study is necessary or its contribution to the field.

Methods/Design

The methods section should include:

- the aim, design and setting of the study
- the characteristics of participants or description of materials
- a clear description of all processes, interventions, comparisons and details of the randomization process. Generic drug names should

generally be used. When proprietary brands are used in research, include the brand names in parentheses

- the type of statistical analysis used, including a power calculation if appropriate.

Discussion

This should include a discussion of any practical or operational issues involved in performing the study and any issues not covered in other sections.

Trial status

Authors should report the protocol version number and date, the date recruitment began, and the approximate date when recruitment will be completed.

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If abbreviations are used in the text they should be defined in the text at first use, and a list of abbreviations should be provided. Please try not to include too many unnecessary acronyms and abbreviations within the text. If this hinders the legibility of the manuscript, you may be asked to remove these by the Editor.

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All manuscripts **must** contain the following sections under the heading 'Declarations':

- Ethics approval and consent to participate
- Consent for publication
- Availability of data and materials
- Competing interests
- Funding
- Authors' contributions
- Acknowledgements
- Authors' information (optional)

Please see below for details on the information to be included in these sections. If any of the sections are not relevant to your manuscript, please include the heading and write 'Not applicable' for that section.

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Acknowledgements

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References

Examples of the Vancouver reference style are shown below.

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Example reference style:

Article within a journal

Smith JJ. The world of science. Am J Sci. 1999;36:234-5.

Article within a journal (no page numbers)

Rohrmann S, Overvad K, Bueno-de-Mesquita HB, Jakobsen MU, Egeberg R, Tjønneland A, et al. Meat consumption and mortality - results from the European Prospective Investigation into Cancer and Nutrition. BMC Medicine. 2013;11:63.

Article within a journal by DOI

Slifka MK, Whitton JL. Clinical implications of dysregulated cytokine production. Dig J Mol Med. 2000; doi:10.1007/s801090000086.

Article within a journal supplement

Frumin AM, Nussbaum J, Esposito M. Functional asplenia: demonstration of splenic activity by bone marrow scan. Blood 1979;59 Suppl 1:26-32.

Book chapter, or an article within a book

Wyllie AH, Kerr JFR, Currie AR. Cell death: the significance of apoptosis. In: Bourne GH, Danielli JF, Jeon KW, editors. International review of cytology. London: Academic; 1980. p. 251-306.

OnlineFirst chapter in a series (without a volume designation but with a DOI)

Saito Y, Hyuga H. Rate equation approaches to amplification of enantiomeric excess and chiral symmetry breaking. Top Curr Chem. 2007. doi:10.1007/128_2006_108.

Complete book, authored

Blenkinsopp A, Paxton P. Symptoms in the pharmacy: a guide to the management of common illness. 3rd ed. Oxford: Blackwell Science; 1998.

Online document

Doe J. Title of subordinate document. In: The dictionary of substances and their effects. Royal Society of Chemistry. 1999. <http://www.rsc.org/dose/title of subordinate document>. Accessed 15 Jan 1999.

Online database

Healthwise Knowledgebase. US Pharmacopeia, Rockville. 1998. <http://www.healthwise.org>. Accessed 21 Sept 1998.

Supplementary material/private homepage

Doe J. Title of supplementary material. 2000.

<http://www.privatehomepage.com>. Accessed 22 Feb 2000.

University site

Doe, J: Title of preprint. <http://www.uni-heidelberg.de/mydata.html>

(1999). Accessed 25 Dec 1999.

FTP site

Doe, J: Trivial HTTP, RFC2169. <ftp://ftp.isi.edu/in-notes/rfc2169.txt>

(1999). Accessed 12 Nov 1999.

Organization site

ISSN International Centre: The ISSN register. <http://www.issn.org>

(2006). Accessed 20 Feb 2007.

Dataset with persistent identifier

Zheng L-Y, Guo X-S, He B, Sun L-J, Peng Y, Dong S-S, et al. Genome data from sweet and grain sorghum (*Sorghum bicolor*). GigaScience Database. 2011. <http://dx.doi.org/10.5524/100012>.

Figures, tables and additional files

See [General formatting guidelines](#) for information on how to format figures, tables and additional files.

Anexo VI – Normas do periódico *Archives of Physical Medicine and Rehabilitation*

Introduction

Introduction

Archives of Physical Medicine and Rehabilitation publishes original articles that report on important trends and developments in physical medicine and rehabilitation and in the wider interdisciplinary field of rehabilitation. *Archives of Physical Medicine and Rehabilitation* brings readers authoritative information on the therapeutic utilization of physical and pharmaceutical agents in providing comprehensive care for persons with disabilities and for chronically ill individuals. *Archives* began publication in 1920, publishes monthly, and is the official journal of the ACRM | American Congress of Rehabilitation Medicine. Its content is cited more often than any other rehabilitation journal.

A steadily increasing rate of submissions has forced the *Archives* to adopt a policy of restricting its manuscripts to topics that proved new information that may alter clinical practice or represent influential advances in the research. *Archives* will not review studies involving animal models, healthy normal samples, or small case reports, except in unusual circumstances. We may make exceptions when the clinical implications for populations of persons with chronic illness or disability are compelling. In addition, we will not review studies that report psychometric information of well-established instruments for language-specific applications.

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Original Research: Present new and important basic and clinical information, extend existing studies, or provide a new approach to a traditional subject. Manuscripts should be limited to 3000 words of text (Introduction through Conclusions). Figures, tables, and references should be limited to the number needed to clarify, amplify, or document the text. This paper requires a structured abstract. Please view the rules on abstracts in these instructions.

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When submitting an invited commentary please select Editorial as your manuscript type and note the word limit of 2,000 in your cover letter. This paper requires an unstructured abstract. Please view the rules on abstracts in these instructions.

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Authors are invited to submit Information/Education Page manuscripts or proposals to the *Archives*' Editorial Office (ArchivesMail@archives.acrm.org). The ACRM Communications Committee will assess subject matter, content, and target reading level then provide feedback on suitability and instructions on how to proceed directly to the author. Note that this should not be considered an official peer review of the content. For more information go to <http://www.acrm.org/publications/archives-of-pm-r/information-education-pages/>.

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Special Communications: Provide information or an objective analysis of issues in physical medicine and rehabilitation that does not qualify as a research or clinical paper or commentary. Manuscripts are peer reviewed and should be limited to 5000 words of text, exclusive of references. This paper requires an unstructured abstract. Please view the rules on abstracts in these instructions. This paper requires an unstructured abstract. Please view the rules on abstracts in these instructions.

Before you begin

Ethics in Publishing

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Reporting sex- and gender-based analyses

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For research involving or pertaining to humans, animals or eukaryotic cells, investigators should integrate sex and gender-based analyses (SGBA) into their research design according to funder/sponsor requirements and best practices

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Definitions

Sex generally refers to a set of biological attributes that are associated with physical and physiological features (e.g., chromosomal genotype, hormonal levels, internal and external anatomy). A binary sex categorization (male/female) is usually designated at birth ("sex assigned at birth"), most often based solely on the visible external anatomy of a newborn. Gender generally refers to socially constructed roles, behaviors, and identities of women, men and gender-diverse people that occur in a historical and cultural context and may vary across societies and over time. Gender influences how people view themselves and each other, how they behave and interact and how power is distributed in society. Sex and gender are often incorrectly portrayed as binary (female/male or woman/man) and unchanging whereas these constructs actually exist along a spectrum and include additional sex categorizations and gender identities such as people who are intersex/have differences of sex development (DSD) or identify as non-binary. Moreover, the terms "sex" and "gender" can be ambiguous--thus it is important for authors to define the manner in which they are used. In addition to this definition guidance and the SAGER guidelines, the [resources on this page](#) offer further insight around sex and gender in research studies.

Authorship

Authors have read the submitted manuscript and vouch for its accuracy. All authors have participated sufficiently in the conception and design of this work and the analysis of the data (where applicable), as well as the writing of the manuscript to take public responsibility for its content. If any author (or group of authors) listed cannot verify substantial contribution, the author's name should be moved to the acknowledgment section. If requested, authors shall produce the data on which the manuscript is based for examination by *Archives* or its assignees.

Authors warrant the manuscript is original and its essential substance, tables, or figures have not been previously published in part or in whole. The manuscript or one with substantially similar content under declared authorship or the data within it has not been accepted for publication elsewhere and it is not presently under review by any other publisher. The manuscript will not be submitted for

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Clinical trial

While there may be occasional exceptions, the *Archives* is committed to the need for clinical trial reports to be accompanied by adequate periods of follow-up. A lack of sufficient follow-up may be detrimental to a paper's acceptance.

As of January 1, 2017 the *Archives* will **only** consider clinical trials that have been registered before the first patient is enrolled.

For our purposes, a clinical trial is defined as "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" (<http://www.who.int/ictcp/en>). Thus, cohort and retrospective studies without an intervention do not require registration, and neither do observational studies of clinical care. However, studies of human subjects with prospective assignment of an intervention by the investigators, regardless of the size of the trial or method of assignment, must be registered.

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Beginning January 2021 *Archives* encourages prospective registration of systematic reviews. The goal of systematic review registration is to avoid duplication of effort and reduce reporting bias by allowing comparison of the completed review with what authors planned in advance. Authors may register reviews through the International Prospective Register of Systematic Reviews (PROSPERO) or the Open Science Framework (OSF) Center for Open Science. Please see the editors guidance on this subject [here](#).

Reporting Guidelines and Checklists

To ensure a high and consistent quality of research reporting, original research articles, including brief reports, must contain sufficient information to allow readers to understand how a study was designed and conducted. For review articles, systematic or narrative, readers should be informed of the rationale and details behind the literature search strategy.

To achieve this goal, *Archives* requires that authors upload a completed checklist for the appropriate reporting guideline during original submission. Taking the time to ensure your manuscript addresses basic reporting prerequisites will greatly improve your manuscript, and enhance the likelihood of publication. These checklists serve as a guide for the editors and reviewers as they evaluate your paper.

The EQUATOR Network (<http://www.equator-network.org>) is an excellent resource for key reporting guidelines, checklists, and flow diagrams. These guidelines should be especially useful for *Archives'* authors.

Click on the checklist that applies to your manuscript, download it to your computer, fill it out electronically, "save as," and upload it with your manuscript when you submit. Links to mandatory flow diagrams also are provided. Below are the most commonly used checklists but please note that the Equator Network provides many others (e.g. TRIPOD, SRQR, etc.) and it is up to the authors to select the one most appropriate for their study.

- Randomized Controlled Trials — [CONSORT](#) — Consolidated Standards of Reporting Trials
- Observational Studies — [STROBE](#) — Strengthening the Reporting of Observational studies in Epidemiology
- Systematic Review of Controlled Trials — [PRISMA](#) — Preferred Reporting Items for Systematic Reviews and Meta-Analyses
- Study of Diagnostic accuracy/assessment scale — [STARD](#) — Standards for the Reporting of Diagnostic Accuracy Studies
- For psychometric studies the editors recommend either the [COSMIN](#) or [GRRAS](#) guideline, though the final choice is up to the author.

During the submission process when you are prompted to state which checklist is needed please check the appropriate box for your manuscript or check Not Applicable if your paper is a Commentary, Letter to the Editor, etc. Then the system will allow you to select the file type and upload the appropriate checklist and flow diagram. IT IS PERMISSIBLE TO ADD A COLUMN OR SPACE TO THE CHECKLIST THAT SPECIFIES WHERE IN THE MANUSCRIPT EACH COMPONENT HAS BEEN FOLLOWED AND USE THAT FOR YOUR UPLOAD. YOU MAY NEED TO DO THIS FOR STROBE AS WELL AS OTHERS. A MODIFIED STROBE FORM IS AVAILABLE [HERE](#).

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Please write your text in good English (American or British usage is accepted, but not a mixture of these). Authors who feel their English language manuscript may require editing to eliminate possible grammatical or spelling errors and to conform to correct scientific English may wish to use the [Language Editing service](#) available from Elsevier's Language Services.

Submission

Manuscripts must be submitted through the journal's online system at <https://www.editorialmanager.com/ARCHIVES-PMR/default.aspx>. The review process will not begin until authors have complied completely with the submission requirements. Compliance includes submission of separate documents in the following order: (1) cover letter; (2) title page, including acknowledgments and explanation of any conflicts of interest; (3) main text file (manuscript without author identifiers) including a structured or standard abstract, keywords, list of abbreviations, body of the text, suppliers' list, references, figure legends; (4) figures; (5) tables; (6) appendices; (7) supplementary files; (8) checklist; and (9) ICMJE Form for Disclosure of Potential Conflicts of Interest.

Referees

All submissions will be screened by editors to determine their suitability for further review. Manuscripts that are approved for review will be evaluated by at least one recognized expert in the particular subject matter. Biostatistical review may be obtained. Peer reviewers' assessments are referred to a member of the Editorial Board, who may also critique the manuscript. The assigned Editorial Board Member will then make a final decision and communicate with the corresponding author via e-mail. Decisions are typically communicated within 60 days after the manuscript has been approved for peer review. All reviews are conducted in a double-blind fashion.

Letters to the Editors and Editorials are generally evaluated by an editorial committee, however, external reviews may also be sought.

Published annually without peer review are the ACRM | American Congress of Rehabilitation Medicine presidential address and the John Stanley Coulter Lecture. The Editorial Board does not peer review the published abstracts of posters, platform presentations of scientific papers, or audiovisual materials presented at the ACRM annual meeting. *Archives* also publishes the official documents of ACRM. These documents are not peer reviewed by *Archives* and include position papers and other materials approved by the ACRM.

Revisions

When submitting your revised manuscript, at the request of the Editorial Board, please include a document, separate from your cover letter, itemizing your response to each of the suggested revisions and any other changes you have made. Use consecutive line numbering in the text and cite line numbers for each change. In addition, highlight each change in the revised manuscript. You will upload this document in the file upload step as the "Detailed Response to Reviewers." Please note that this file should be blinded and should not include author names or institutional letterhead.

If revisions are not received within the time specified in the decision e-mail, the manuscript file will be closed. A revision received after a file has been closed will be handled as a new submission. An extension beyond the deadline may be granted at the Editorial Board's discretion, but only in extenuating circumstances, given the editors' commitment to prompt publication.

Submission of a revised manuscript includes submission of separate documents in the following order: (1) cover letter; (2) title page, including acknowledgments and explanation of any conflicts of interest; (3) main text file with highlighted changes, including an appropriate (structured or standard) abstract, keywords, list of abbreviations, body of the text, suppliers' list, references, figure legends; (4) a clean copy of the main text file with no highlighted changes, including an appropriate abstract, keywords, list of abbreviations, body of the text, suppliers' list, references, figure legends; (5) figures; (6) tables; (7) appendices; (8) supplementary files; (9) checklist; and

(10) ICMJE Form for Disclosure of Potential Conflicts of Interest for each author.

Resubmissions

From time to time an author may receive a decision of "Reject-Resubmit" on their original submission. This is a reject but grants the author the opportunity to revise and resubmit their work under a new manuscript number at any time. The resubmission will be linked to the original submission but there will be no expectation of acceptance. The resubmission will be treated as new.

To submit a resubmission authors should note the following:

1. Select RESUBMISSION as the article type.
2. In your cover letter, please 1) reference this manuscript ID number and include an itemized list of the revisions. 2) Use line numbering in the text and reference the revisions made by page and line number in the cover letter. 3) Highlight changes made in one copy of the manuscript text. Submit another copy with all changes accepted and not highlighted. Please add "marked copy" to the file name of the highlighted version and "clean copy" to the file name of the clean version. Submit both clean and highlighted copies under the category titled Manuscript without author identifiers. Both should remain blinded for the review process.

Additional information

Unless author(s) notify the Editorial Office of alternate preferences, all accepted articles are posted online within 5 business days of release to production. Author(s) should notify the Editorial Office immediately with any requests to delay posting. This posted version will include a fully citable PDF of the author's accepted files, and will be submitted to PubMed. Supplementary material(s), such as raw data, videos, etc., will not be included. Supplementary materials will be included when the article is typeset and published on the Articles in Press platform or in the monthly print/online issue of the journal.

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Preparation

NEW- Submission checklist

Archives requires the completion and upload of a checklist with each manuscript. Please follow the instructions on the checklist to ensure all required manuscript elements are included with your submission. Please note that this submission checklist is NOT the same as a reporting guideline checklist or form noted above. This is a separate item specific to the *Archives*.

THE SUBMISSION CHECKLIST CAN BE DOWNLOADED [[HERE](#)]

For any further information please visit our customer support site at <https://service.elsevier.com>.

Authors should prepare manuscripts according to the "Recommendations for the Conduct, Reporting, Editing, and Publication of Scholarly Work in Medical Journals" [undefined](#) as developed by the International Committee of Medical Journal Editors. The Requirements are available at <https://www.icmje.org>.

Document Formatting

Manuscripts must be double-spaced throughout, including the title page, abstract, text, acknowledgments, references, individual tables, and legends. Use only standard 12-point type and spacing. Use unjustified, flush-left margins. Number the pages of the text consecutively. Put the page number in the upper or lower right-hand corner of each page. Number each line on each page of the text to facilitate peer review.

Authors should format manuscripts for specific attributes such as italics, superscripts/subscripts, and Greek letters. **The coding scheme for each such element must be consistent throughout the file.**

Text Style: Enter only 1 space between words and sentences. Leave 1 blank line between paragraphs. Leave 2 blank lines between headings and text.

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As part of the Your Paper Your Way service, at initial submission you may choose to submit your new manuscript as a single file to be used in the refereeing process. This can be a PDF file or a Word document, in any format or lay-out that can be used by referees to evaluate your manuscript. It should contain high enough quality figures for refereeing. If you prefer to do so, you may still provide all or some of the source files at the initial submission. Please note that individual figure files larger than 10 MB must be uploaded separately. **If your paper is accepted, you will be requested, at the revision stage, to put your paper in the correct format by supplying individual files for the manuscript, tables, figures, etc. and any other items required for the publication of your article. To find out more, please read the rest of the Preparation section.**

New Submissions

Submission to this journal proceeds totally online and you will be guided stepwise through the creation and uploading of your files. The system automatically converts your files to a single PDF file, which is used in the peer-review process.

References

There are no strict requirements on reference formatting at submission. References can be in any style or format as long as the style is consistent. Where applicable, author(s) name(s), journal title/book title, chapter title/article title, year of publication, volume number/book chapter and the article number or pagination must be present. Use of DOI is highly encouraged. The reference style used by the journal will be applied to the accepted article by Elsevier at the proof stage. Note that missing data will be highlighted at proof stage for the author to correct.

Formatting requirements

There are no strict formatting requirements for articles at initial submission (for requirements for revised submissions, please see REVISED SUBMISSIONS section below) but all manuscripts must contain the essential elements needed to convey your manuscript, for example Abstract, Keywords, Introduction, Methods, Results, Conclusions, Artwork and Tables with Captions.

If your article includes any Videos and/or other Supplementary material, this should be included in your initial submission for peer review purposes.

Divide the article into clearly defined sections.

Please ensure the text of your paper is double-spaced — this is an essential peer review requirement.

Figures and tables embedded in text - Your Paper Your Way

If you choose the Your Paper Your Way option when submitting your manuscript for the first time, please ensure the figures and the tables included in the single file are placed next to the relevant text in the manuscript, rather than at the bottom or the top of the file.

NEW- Peer Review

Archives uses a double-blind peer-review process. The blinded submission should be submitted in a word document and should begin with a **title** followed by the **abstract**, **keywords**, list of **abbreviations**, **body of the text**, **references**, **figure legends**, and any relevant **suppliers' list**.

The entire main body of text should be blinded as well including obvious references to institutions and names in the methods section, etc.

Revised submissions

This section describes the revised submissions process for this journal.

Please note if you submitted your original manuscript following the Your Paper Your Way format you will now need to put the paper in the correct format by supplying individual files for the manuscript, tables, figures, etc. and any other items required for the publication of your article.

Use of word processing software

Regardless of the file format of the original submission, at revision you must provide us with an editable file of the entire article. Keep the layout of the text as simple as possible. Most formatting codes will be removed and replaced on processing the article. The electronic text should be prepared in a way very similar to that of conventional manuscripts (see also the [Guide to Publishing with Elsevier](#)). See also the section on Electronic artwork.

To avoid unnecessary errors you are strongly advised to use the 'spell-check' and 'grammar-check' functions of your word processor.

Subdivision

Manuscript files should be structured as follows: (1) Title page, including Disclosure of interest and Acknowledgments, etc.; (2) Manuscript file including Abstract, Keywords, Abbreviations, Main text, References, Legends of figures

and tables; (3) Table files; (4) Figure files; (5) Supplementary files; (6) ICMJE forms.

Manuscript Headings

Original Article level 1 headings are: Methods, Results, Discussion, and Conclusions. Articles should include the level 2 subsection heading Study Limitations at the end of the Discussion section. Longer articles may need other level 2 and/or level 3 subsection headings to clarify their content, especially the Results and Discussion sections.

Other types of articles such as Commentaries and Special Communications do not require this format.

Title Page

Include these elements in the title page in the following sequence, double-spaced: (1) Running head of no more than 40 character spaces (no abbreviations); (2) Title (no abbreviations); (3) Author(s) full name(s) and highest academic degree(s); (4) The name(s) of the institution(s), section(s), division(s), and department(s) where the study was performed and the institutional affiliation(s) of the author(s) at the time of the study. An asterisk after an author's name and a footnote may indicate a change in affiliation; (5) Acknowledgment of any presentation of this material, to whom, when, and where; (6) Acknowledgment of financial support, including grant numbers and any other needed acknowledgments. Explanations of any conflicts of interest; (7) Name, address, business telephone number, and e-mail address of corresponding author; and (8) Clinical trial registration number, if applicable. Please note that clinical trial registration will now be required as of January 1, 2016. The grace period will end January 1, 2017 when registration will be mandatory.

Abstract

For articles reporting original data (Original Articles, Brief Reports) and Review Articles (including Meta-Analyses), a structured abstract is required (see the [Instructions for Structured Abstracts](#)). Authors should make sure the key elements from the Reporting Guideline (eg. CONSORT, PRISMA, etc.) they followed for their manuscript are included in the abstract as well as the body of the paper.

Structured abstracts for Original Research and for Systematic Reviews/Meta-Analyses should be no more than 300 words in length.

For other manuscripts (e.g., Commentaries, Editorials and Special Communications), include a conventional, unstructured abstract of no more than 250 words.

Keywords

All abstracts must include provide 1 to 10 Keywords identified by the author. Keywords must be selected from the US National Library of Medicine's (NLM) *Medical Subject Headings*, which is available at <http://www.nlm.nih.gov/mesh/MBrowser.html>.

Abbreviations

Archives' editorial policy is to **minimize the use of abbreviations**. Fewer abbreviations make it easier for the multidisciplinary readership to follow the text. Authors should include a list of abbreviations in their manuscript file directly following the keywords (just above the introduction). *Archives* uses only standard abbreviations with Davis's and Dorland's as our guides. Abbreviations that are used only in tables, appendices, or figures are not included in the list and should be defined in the table, appendix, or figure legend. However, abbreviations that are in the list need not be re-defined in a table footnote or figure legend. All abbreviation lists **must** be alphabetized. All abbreviations must be defined upon first mention in the body of the manuscript. The abbreviations SD (standard deviation) and SE (standard error) require no definition in *Archives*.

Main Manuscript

The main manuscript includes the following sections:

Introduction

State the purpose of the article. Summarize the rationale for the study or observation. Give only pertinent references, and do not review the subject extensively. Do not include data or conclusions from the work being reported. Do not include a heading for this section.

Methods

Describe the selection of the observational or experimental subjects (patients or experimental animals, including controls) clearly. Discuss eligibility of experimental subjects. Give details about randomization. Describe the methods for any blinding of observations. Identify the methods, equipment and materials, and procedures in sufficient detail to allow others to reproduce the results.

Reference established methods, including statistical methods (see below); provide very brief descriptions for methods that have been published but are not well known; describe new or substantially modified methods, give reasons for using them, and evaluate their limitations. Identify precisely all drugs and chemicals used, including generic name(s), dose(s), and route(s) of administration.

While there may be occasional exceptions, *Archives* is committed to the need for clinical trial reports to be accompanied by adequate periods of follow-up. A lack of sufficient follow-up may be detrimental to a paper's acceptance.

When reporting work with human subjects, indicate whether the procedures followed protocol and accord with the ethical standards of the responsible institutional review board, ethics committee or with the Helsinki Declaration of 1975, as revised in 2013, as appropriate for the country where the research took place. [undefined](#)

Do not use patients' names, initials, or hospital numbers, especially in any illustrative material. When reporting experiments on animals, indicate whether the procedures followed accord with the institution's committee on animal experimentation or with the National Research Council's guide on the care and use of laboratory animals. *Archives* may require authors to verify the above procedures.

Describe statistical methods in enough detail to enable knowledgeable readers with access to the original data to verify the reported results. When possible, quantify findings and present them with appropriate indicators of measurement error or uncertainty (eg, confidence intervals [CIs]). Avoid sole reliance on statistical hypothesis testing, such as *P* values, which fails to convey important quantitative information.

Researchers should report and identify the specific statistical test used and the obtained statistical value. Researchers should supplement the results of any statistical value. Researchers should supplement the results of any statistical significance test with the use of effect size values or CIs. Measures of effect size or CIs should be routinely included in quantitative clinical trials reported in rehabilitation research. The statistical power values and the corresponding type II error probability should always be reported for statistically nonsignificant results.

The investigator should ensure that there is sufficient power to detect, as statistically significant, a clinically meaningful treatment effect of an *a priori* specified size [undefined](#). References for study design and statistical methods should be to standard works (with pages stated) rather than to papers in which designs or methods were originally reported.

Specify any general use computer programs used. Avoid nontechnical uses of technical terms in statistics, such as "random" (which implies a randomizing device), "normal," "significant," "correlation," or "sample." Define statistical terms, abbreviations, and symbols.

When submitting manuscripts on randomized controlled trials (RCTs), authors must include the CONSORT (Consolidated Standards for Reporting Trials) flow diagram. See the [Reporting Guidelines](#).

Results

When data are summarized in the Results section, specify the statistical methods used to analyze them. Describe the success of any blinding of observations. Report treatment complications. Give numbers of observations. Report losses to observation (ie, dropouts from a clinical trial). Present results in logical sequence in the text, tables, and illustrations. *Archives* aims to publish no more than 5 figures per manuscript so restrict tables and figures to those needed to explain arguments and to assess their support. Use graphs as an alternative to tables with many entries; do not duplicate data in graphs and tables. Do not repeat in the text all the data in the tables, illustrations, or both; emphasize or summarize only important observations.

While there may be occasional exceptions, *Archives* is committed to the need for clinical trial reports to be accompanied by adequate periods of follow-up. A lack of sufficient follow-up may be detrimental to a paper's acceptance.

Discussion

Emphasize the new and important aspects of the study and the conclusions that follow from them. Do not repeat in detail data or other material given in the introduction or the Results section. Include in the Discussion section the implications of the findings and their limitations, including implications for future research. Authors should address the issue of effect magnitude, in terms of both the statistics reported and the implications of the research. Relate the observations to other relevant studies.

Study Limitations

Include the subsection (Level 2 heading), "Study Limitations" to discuss the limitations of the study.

Conclusions

Link the conclusions with the study's goals but avoid unqualified statements not supported by the data. Avoid claiming priority and alluding to work that is incomplete. State new hypotheses when warranted, but clearly label them as such. Recommendations, when appropriate, may be included.

Highlights

Highlights are optional yet highly encouraged for this journal, as they increase the discoverability of your article via search engines. They consist of a short collection of bullet points that capture the novel results of your research as well as new methods that were used during the study (if any). Please have a look at the [example Highlights](#).

Highlights should be submitted in a separate editable file in the online submission system. Please use 'Highlights' in the file name and include 3 to 5 bullet points (maximum 85 characters, including spaces, per bullet point).

Graphical abstract

Although a graphical abstract is optional, its use is encouraged as it draws more attention to the online article. The graphical abstract should summarize the contents of the article in a concise, pictorial form designed to capture the attention of a wide readership. Graphical abstracts should be submitted as a separate file in the online submission system. Image size: Please provide an image with a minimum of 531 x 1328 pixels (h x w) or proportionally more. The image should be readable at a size of 5 x 13 cm using a regular screen resolution of 96 dpi. Preferred file types: TIFF, EPS, PDF or MS Office files. You can view [Example Graphical Abstracts](#) on our information site.

Acknowledgments

One or more statements should specify: (1) contributions that do not justify authorship (ie, third-party statistical analysis, writing/editing); and (2) acknowledgments of technical help.

Persons who have contributed intellectually to the manuscript but whose contributions do not justify authorship must be named and their function or contribution described, e.g., "scientific adviser," "critical review of study proposal," "data collection," or "participation in clinical trial." Clerical, administrative, laboratory staff, and participants/subjects in the study should not be acknowledged unless they have contributed significantly to the research, writing, or intellectual quality of the article. Such persons must give permission to be named. Authors are responsible for obtaining written permission from persons acknowledged by name because readers may infer their endorsement of the data and conclusions.

Formatting of funding sources

List funding sources in this standard way to facilitate compliance to funder's requirements:

Funding: This work was supported by the National Institutes of Health [grant numbers xxxx, yyyy]; the Bill & Melinda Gates Foundation, Seattle, WA [grant number zzzz]; and the United States Institutes of Peace [grant number aaaa].

It is not necessary to include detailed descriptions on the program or type of grants and awards. When funding is from a block grant or other resources available to a university, college, or other research institution, submit the name of the institute or organization that provided the funding.

If no funding has been provided for the research, it is recommended to include the following sentence:

This research did not receive any specific grant from funding agencies in the public, commercial, or not-for-profit sectors.

Units

Metric units are required. Blood pressures in millimeters of mercury (mmHg) and all hematologic and clinical chemistry measurements using the International System of Units (SI).

Footnotes

Footnotes other than for references are not allowed in the manuscript body.

Artwork

Preferred file formats are TIFF, EPS, JPEG, and PDF.

300 dpi is minimum resolution to achieve high quality images. Typical desired resolutions are 300 dpi for black and white and color figures; 500 dpi for combination art (combined photo with line art); and 1000 dpi for line art.

Figures should be numbered consecutively in the order they are first cited in the text. If a figure has been published, acknowledge the original source in the reference list and the figure legend, and submit written permission from the copyright holder to reproduce the material. Permission is required, irrespective of authorship or publisher, except for documents in the public domain.

Letters, numbers, and symbols should be clear and even throughout, and of sufficient size that when reduced for publication each item will still be legible. Titles and detailed explanations belong in the legends for figures, not on the figures themselves. For multi-part figures, please label each component separately with A, B, C, etc. both in the figure itself and in the legend.

Consistency in size within the article is strongly preferred. Any special instructions regarding sizing should be clearly noted.

Photomicrographs must have internal scale markers. Symbols, arrows, or letters used in the photomicrographs should contrast with the background.

If photographs of persons are used, either the subjects must not be identifiable or the author must obtain and archive permission to publish the pictures and attest that permission has been granted in the cover letter that accompanies the manuscript submission.

The Editorial Board reserves the right to determine which figures are appropriate for publication. There is no charge for publication of black and white illustrations.

Electronic artwork

General points

- Make sure you use uniform lettering and sizing of your original artwork.
- Preferred fonts: Arial (or Helvetica), Times New Roman (or Times), Symbol, Courier.
- Number the illustrations according to their sequence in the text.
- Use a logical naming convention for your artwork files.
- Indicate per figure if it is a single, 1.5 or 2-column fitting image.
- For Word submissions only, you may still provide figures and their captions, and tables within a single file at the revision stage.
- Please note that individual figure files larger than 10 MB must be provided in separate source files.

A detailed [guide on electronic artwork](#) is available.

You are urged to visit this site; some excerpts from the detailed information are given here.

Formats

Regardless of the application used, when your electronic artwork is finalized, please 'save as' or convert the images to one of the following formats (note the resolution requirements for line drawings, halftones, and line/halftone combinations given below):

EPS (or PDF): Vector drawings. Embed the font or save the text as 'graphics'.

TIFF (or JPG): Color or grayscale photographs (halftones): always use a minimum of 300 dpi.

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TIFF (or JPG): Combinations bitmapped line/half-tone (color or grayscale): a minimum of 500 dpi is required.

Please do not:

- Supply files that are optimized for screen use (e.g., GIF, BMP, PICT, WPG); the resolution is too low.
- Supply files that are too low in resolution.
- Submit graphics that are disproportionately large for the content.

Color artwork

Color figures (minimum 300dpi) will be published without charge when color reproduction is essential to understanding of the material presented.

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A list of figure legends should be provided after the reference list, listing each figure in order by number. Legends/captions should not be embedded in the figure files themselves.

Figure captions

Ensure that each illustration has a caption. A caption should comprise a brief title (**not** on the figure itself) and a description of the illustration. Keep text in the illustrations themselves to a minimum but explain all symbols and abbreviations used.

Tables

Submit each table as a separate file. Accepted file formats are PDF and Word (Please do not upload Excel files). If needed, Excel files will be requested from the authors upon a final editorial decision of accept. Number tables consecutively in the order of their first citation in the text. Include a brief title for each table, include a short or abbreviated heading for each column. Place explanatory matter in footnotes, not in the title or column headings. Explain in footnotes all nonstandard abbreviations that are used in each table. For footnotes, use the following symbols, in this sequence: *, †, ‡, §, ||, ¶, #, **, ††, ‡‡

Identify statistical measures of variations such as standard deviation and standard error of the mean. Do not use internal horizontal and vertical rules. Be sure that each table is cited in the text in order. Using too many tables in relation to the length of the text may produce typesetting difficulties.

Data from another published or unpublished source may only be used with permission and must be acknowledged fully. It is the author's responsibility to obtain such permission.

Supplementary data

Archives accepts electronic supplementary material to support and enhance your scientific research. Supplementary files offer the author additional possibilities to publish supporting applications, high-resolution images, background datasets, sound clips, and more. Supplementary files supplied will be published online alongside the electronic version of your article in Elsevier Web products, including ScienceDirect: <https://www.sciencedirect.com>.

Suppliers

Before the References section, provide a Suppliers list with contact information (names and complete mailing addresses) for manufacturers of devices and other non-drug products used directly in a study (ie, do not provide such

information for products not directly used in your research but mentioned in studies you cite). Identify equipment and/or materials in text, tables, and legends by superscript lower case letters. List suppliers consecutively in the order they are mentioned in the text.

Manufacturer names and locations should **not** be listed in the text where the product is introduced. Do not list Suppliers in the References list. Do not list drug manufacturers in the Suppliers list.

References

References in manuscripts accepted by *Archives* shall include only material that is retrievable through standard literature searches. Number references consecutively in the order in which they first appear in the text. Identify references in text, tables, and legends by superscript Arabic numerals. References cited only in tables or in legends to figures should be numbered in accordance with a sequence established by the first identification in the text of the particular table or figure.

Try to avoid using abstracts as references; "unpublished observations" and "personal communications" may not be used as references, although references to written, not oral, communications may be inserted (in parentheses) in the text. Avoid "personal communication" unless it provides essential information not available from a public source. In this case, cite the name of the person and date of communication in parentheses in the text. For scientific articles, authors should obtain written permission and confirmation of accuracy from the source of personal communication.

Include among the references those papers **accepted** but not yet published; designate the journal and add "In press." Authors must obtain written permission to cite such papers as well as verification that they have been accepted for publication. Editors will request from the author(s) a copy of the letter from the journal accepting the "in press" article if the manuscript in which it is cited is accepted by *Archives*. Information from manuscripts **submitted** but not yet accepted should be cited in the text as "(unpublished observations)" with written permission from the source.

The references must be verified by the author(s) against the original documents. List all authors and/or editors for each reference, up to 6 authors. If there are 7 or more authors, truncate the list to the first 3 names and add "et al."

Citations in the running text

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Updated November 5, 2015