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ANA ELLEN DO NASCIMENTO SANTOS

INTEGRAÇÃO DE PROGRAMA DE ATIVIDADE FÍSICA E TECNOLOGIA MÓVEL PARA REDUÇÃO DA DOR E INCAPACIDADE EM IDOSOS COM DOR LOMBAR NA ATENÇÃO PRIMÁRIA: ESTUDO DE VIABILIDADE DE ENSAIO CLÍNICO ALEATORIZADO

FORTALEZA

2022

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Dissertação apresentada ao Programa de Pós-Graduação em Fisioterapia e Funcionalidade da Universidade Federal do Ceará, com requisito parcial à obtenção do título de mestre.
Linha de pesquisa: Processos de avaliação e intervenção no sistema musculoesquelético nos diferentes ciclos da vida.

Orientação: Profª Drª Fabianna Resende de Jesus Moraleida
Co-orientação: Profª Drª Ana Carla Lima Nunes.

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“Como são grandes as tuas obras, Senhor, como são profundos os teus propósitos!”

(Salmos 92:5)

DESCRIÇÃO DA DISSERTAÇÃO PARA LEIGOS

A dor lombar incapacita muito os idosos, mas poucos estudos investigaram o papel do exercício físico para reduzir o impacto da dor lombar na população idosa. No Brasil, não existem informações sobre a viabilidade de tratamentos com exercícios e educação para idosos com dor lombar na atenção primária. Assim, a presente dissertação teve como objetivo responder à questão: é viável realizar um estudo que investigue o efeito de uma intervenção com exercícios, educação em dor e mensagens de texto motivacionais em idosos com dor lombar crônica no contexto da atenção primária à saúde brasileira?

A intervenção principal deste estudo teve oito atendimentos em grupo. Em todos os encontros, a fisioterapeuta dava orientações sobre enfrentamento da dor e treinava os exercícios com os idosos. Além disso, ao longo da semana, o fisioterapeuta enviava mensagens por celular de incentivo à prática de exercícios em casa. Já a intervenção controle foi uma sessão educativa individual, onde a fisioterapeuta entregava uma cartilha educativa e aconselhava sobre melhoras práticas para o cuidado da dor lombar crônica. A viabilidade do estudo foi avaliada por meio de diferentes taxas relacionadas ao interesse e participação no estudo, além da aceitação dos componentes das intervenções.

Nossos resultados mostraram que um grande número de idosos tinha interesse em participar do estudo e que poucos tiveram o perfil para participação. Considerando os idosos incluídos, a maioria aceitou participar das intervenções e da avaliação final. Com relação às intervenções, a maioria não teve dificuldade para entender as orientações educativas ou para realizar os exercícios em casa. No entanto, alguns idosos da intervenção principal relataram insegurança para realizar os exercícios em casa. Além disso, nós identificamos que as mensagens de texto motivaram a realização dos exercícios em casa e que grande parte dos idosos da intervenção principal seguiu as recomendações destes exercícios. Por outro lado, a participação semanal mínima na intervenção principal foi inferior ao esperado, indicando necessidade de mais estratégias para ampliar o envolvimento na intervenção.

Este estudo mostrou que é viável investigar o efeito das intervenções propostas para idoso com dor lombar na atenção primária. Destacamos a aplicabilidade de mensagens de texto junto à população idosa e reforçamos a necessidade de estratégias para aumentar a participação e a segurança de exercícios em casa. Além disso, este estudo traz as perspectivas dos idosos para o desenvolvimento de intervenções nas unidades de atenção primária.

RESUMO

A dor lombar (DL) é mais incapacitante em idosos. Embora seu impacto na funcionalidade seja grande, o manejo da DL nesta população tem sido pouco estudado. Estratégias que integrem exercícios, educação e tecnologias móveis podem reduzir o impacto da DL na população idosa. Entendendo que intervenções como esta ainda não foram investigadas no contexto da atenção primária à saúde brasileira, um estudo de viabilidade é necessário para futura condução de um estudo ampliado. Assim, o objetivo foi avaliar a viabilidade de um ensaio clínico controlado randomizado investigando a eficácia do programa de exercícios físicos e educação em dor, apoiado por tecnologia móvel de baixo custo, comparado a consulta única acompanhada de livreto educativo, na dor, incapacidade e capacidade funcional em idosos com dor lombar crônica na Atenção Primária. Foi desenvolvido um protocolo e um estudo de viabilidade de um ensaio clínico. Os desfechos primários foram: taxa de recrutamento, adesão, retenção, dificuldade de entendimento, segurança e dificuldade com os exercícios, percepção sobre mensagens e eventos adversos. Os desfechos secundários foram: intensidade de dor, incapacidade relacionada à DL, capacidade funcional, atividade física, sintomas depressivos, autoeficácia para dor e cuidados concomitante. Os participantes foram aleatorizados em dois grupos. O grupo intervenção (GI) consistiu de oito treinamentos em grupo. Cada treinamento contou com um bloco educacional seguido de exercícios físicos supervisionados por fisioterapeuta. Mensagens de texto motivacionais também foram enviadas visando a adesão aos exercícios. O grupo controle (GC) recebeu aconselhamento acompanhado de livreto educativo em consulta única. As taxas de viabilidade foram descritas em números absolutos e percentuais e os critérios foram definidos previamente para apontar a viabilidade. Nossos resultados mostram que 248 idosos foram recrutados, 46 foram elegíveis e 40 foram randomizados, indicando adequadas taxas de recrutamento e de consentimento. A taxa de adesão à intervenção foi de 60% e atendeu parcialmente ao critério de adesão. Já a taxa de adesão aos exercícios não supervisionados foi adequada (75%). A taxa de retenção foi alta em ambos os grupos (100% no GI e 95% no GC). Com relação às intervenções, tanto a dificuldade de entender o componente educativo como a dificuldade de realizar os exercícios em casa foram pequenas em ambos os grupos. A segurança para realizar exercícios foi parcialmente atendida no GI (70%) e totalmente atendida no GC (94,7%). Além disso, 95% dos idosos do GI relataram que as mensagens de texto motivaram a realização dos exercícios. Seis participantes relataram eventos adversos em cada grupo. Mudanças positivas nos desfechos secundários reforçam o uso de medidas específicas para idoso em ensaios clínicos. A maioria dos critérios de viabilidade foi atendida plenamente. A adesão ao programa e a

segurança para realizar os exercícios no GI atenderam parcialmente aos critérios de viabilidade, indicando a necessidade de ajustes menores na logística de intervenção e orientação dos exercícios domiciliares. Este estudo de viabilidade apoia a realização de um estudo completo que investigue o efeito do programa na Atenção Primária. Este estudo é o primeiro passo para que intervenções para idosos com DL estejam disponíveis na atenção primária.

Palavras-chave: Dor lombar; Idosos; Atenção primaria em saúde; Exercício Físico, Envio de Mensagens de Texto; Terapia Cognitivo-Comportamental; Estudos de viabilidade; Pessoas com deficiência.

ABSTRACT

Low back pain (LBP) is more disabling in older people. Although its impact on functioning is large, the management of LBP in the older adults has been little studied. Strategies that integrate exercise, education and mobile technologies can reduce the impact of LBP in the older population. Understanding that interventions like this have not yet been investigated in the Brazilian primary care, a feasibility study is necessary for the future conduct of a study. Thus, the aim was to evaluate the feasibility of a randomized controlled trial investigating the effectiveness of program of physical exercise and pain education, supported by low-cost mobile technology (PAT-Back), compared to best practice advice, on pain, disability, and functional capacity in older adults with chronic LBP in primary care. Protocol and feasibility study of a clinical trial were developed. Primary outcomes were: recruitment rate, adherence and retention rates, difficulty in understanding of the education, safety and difficulty in perform to exercise, perception of messages and adverse events. Secondary outcomes were: pain, LBP-related disability, functional capacity, physical activity, depressive symptoms, self-efficacy for pain and concomitant care seeking. Participants were randomized to two groups. The intervention group (IG) consists of eight group trainings. Each training had an educational block followed by a physical exercise block supervised by a physical therapist. In addition, motivational text messages were sent to adhere to the exercises. The control group (CG) received an educational booklet in a single consultation. Feasibility rates were described in percentages and absolute numbers. The criteria were defined a priori to set the feasibility. Our results show that 248 older people were recruited, 46 were eligible and 40 were randomized, indicating adequate rates of recruitment and consent. The rate of adherence to the intervention was 60% and partially met the adherence criterion. The rate of adherence to unsupervised exercises was adequate (75%). The retention rate was high in both groups (100% in the IG and 95% in the CG). Regarding the interventions, both the difficulty of understanding the educational component and the difficulty of performing the exercises were small in both groups. Safety to perform exercises was partially met in the IG (70%) and fully met in the CG (94.7%). In addition, 95% of the older adults in the IG reported that text messages motivated them to perform the exercises. Six participants reported adverse events in each group. Positive changes in secondary outcomes reinforce the use of specific measures for older people in clinical trials. Most of the feasibility criteria were fully met. Adherence to the program and the safety to perform the exercises in the IG partially met the feasibility criteria, indicating the need for minor adjustments in the intervention logistics and orientation of the exercises at home. This feasibility study supports the conduct of a full study investigating the

effect of the large-scale program on Primary Care. This study is the first step towards making interventions for older people with LBP available in primary care.

Key words: Low back pain; Aged, Disabled Persons; Primary health care; Physical exercise; text message; Cognitive behavior therapy; Feasibility studies.

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LISTA DE ABREVIATURAS

CAPES	Coordenação de Aperfeiçoamento de Pessoal de Nível Superior
CES-D	*Depression Scale of the Center for Epidemiological Studies*
CIF	Classificação Internacional de funcionalidade, incapacidade e saúde
CNPQ	Conselho Nacional de Desenvolvimento Científico e Tecnológico
CONSERVE	*Extension for RCTs Revised in Extenuating Circumstances*
CONSORT	*Consolidated Standards of Reporting Trials*
DLC	Dor lombar crônica
EARS	*Exercise Adherence Rating Scale*
IC	Intervalo de confiança
IL-6	Interleucina 6
IPAQ	*International Physical Activity Questionnaire*
IQR	*Interquartile range*
LPB	*Low back pain*
MD	Média de diferença
MET	*Metabolic equivalent of task*
PAT-Back	*Physical activity supported by mobile technology program*
PSFS	*Patient-specific functional Scale*
RCT	*Randomized controlled trial*
REBEC	Registro Brasileiro de estudos clínicos
REDCap	*Research Electronic Data Capture*
RPE	*Rating of perceived exertion*
SBST	*Start Back Screening Tool*
SD	*Standard deviation*
SMS	*Short message service*
SPIRIT	*Standard Protocol Items: Recommendations for Intervention Trials*
SPPB	*Short Physical Performance Battery*
SPSS	*Statistical Packages for the Social Sciences*
Tidier	*Template for Intervention Description and Replication*
TNF-α	Fator de necrose tumoral

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1 CONSIDERAÇÕES INICIAIS

1.1 Definições e epidemiologia da dor lombar no idoso

A dor lombar (DL) é a principal causa de incapacidade no mundo e um desafio urgente para saúde pública (VOS et al., 2016). Definida como queixa de dor, tensão ou rigidez na região entre as últimas costelas e a linha glútea, com ou sem irradiação da dor para os membros inferiores, a DL pode se apresentar como quadro agudo, subagudo ou crônico (superior a 3 meses) de acordo com a sua duração (DIONNE et al., 2008). Na maioria das vezes, a incapacidade relacionada a DL é resultante de fatores físicos específicos ou não, sofrendo também influência de componentes psicológicos e sociais (HARTVIGSEN et al., 2018).

Na população idosa mundial, a prevalência da DL varia de 21 a 75% (DE SOUZA et al., 2019). No Brasil, a DL é a segunda queixa mais reportada por idosos, com dados indicando uma prevalência pontual de 25% (LEOPOLDINO et al., 2016; NUNES et al., 2018). Recentes estimativas da região amazônica apontam prevalência pontual de 42% e anual de 93% na população idosa urbana, incluindo residentes de centros comunitários e hospitais (DE SOUZA et al., 2021). Os dados também apontam que a prevalência e a carga dessa condição aumentam com a idade, sendo o pico de prevalência aos 80 anos. (HOY et al., 2014). Com relação a DL crônica (DLC), uma revisão apontou prevalência pontual foi de 20,6% e anual de 36,1% em idosos. (WONG et al., 2021). Ademais, outro estudo revelou uma taxa de incidência acumulativa de 14,5% em 5 anos (SOLOVEV et al., 2020). Além das taxas de prevalência e incidência elevadas, existe forte evidência do aumento da gravidade dos sintomas e da incapacidade com o avançar dos anos (DIONNE; DUNN; CROFT, 2006). Em países de baixa e média renda, como China, Índia e África do Sul, os dados mostram um cenário semelhante com alta prevalência de DL e fatores associados em pessoas com mais de 60 anos, o que gera uma preocupação para os sistemas de saúde desses países (WILLIAMS et al., 2015).

Os fatores associados à alta prevalência também foram identificados na literatura (WONG et al., 2021). Esta revisão sistemática e meta-análise cita que evidências com alto nível de incerteza indicam sexo feminino, obesidade, ansiedade, depressão, transtornos mentais, pior auto expectativa de recuperação, pior autopercepção do estado de saúde, fatores do estilo de vida (como tabagismo, consumo diário de flúor), quedas anteriores ou lesão na parte inferior do corpo, aposentadoria devido a problemas de saúde, história familiar de dor no corpo, comorbidades, músculos abdominais fracos, presença de dor nas pernas, intensidade

da dor nas pernas, dor generalizada, interferência da dor na funcionalidade, uso de analgésicos, exposição ocupacional (condução por > 20 anos, ou trabalhos envolvendo flexão/torção por > 10 anos), estreitamento do espaço discal e osteoartrite facetária grave como fatores significativamente relacionados a uma maior prevalência de DLC em idosos (WONG et al., 2021).

Em relação ao curso da DL em idosos, a literatura sugere que, na comparação com adultos, a recuperação é menos favorável (RUNDELL et al., 2015). Um estudo de coorte prospectivo com 5239 indivíduos com 65 anos ou mais identificou que apenas 23% dos idosos americano com DL se recuperaram totalmente. A DL tem um curso favorável nos 3 primeiros meses, entretanto, aqueles com idade avançada, maior duração da dor, ansiedade e depressão, e expectativa negativa de recuperação apresentaram pior recuperação da incapacidade e limitação de atividades (RUNDELL et al., 2015).

Dados de um estudo com 542 idosos brasileiros com DL também apontam um cenário preocupante em relação à recuperação. Após 12 meses, apenas 6% e 13% dos idosos apresentaram recuperação completa da dor e da incapacidade, respectivamente (SILVA et al., 2022). Este mesmo estudo também mostrou que quadros mais severos e persistentes foram associadas ao pior estado biopsicossocial no início do estudo, a saber: baixo nível educacional, inatividade física, pouca mobilidade, quedas recentes, pior autoeficácia para quedas, presença de sintomas depressivos, mais cinesiofobia, maior número de comorbidades e presença de outras queixas associadas à DL (SILVA et al., 2022).

Ainda sobre prognóstico, recente síntese de estudos coorte apontou com forte evidência o papel dos sintomas depressivos como fator de risco para DL em idosos(FELÍCIO et al., 2021). Ademais, outro estudo identificou que após três meses de um episódio de DL, os idosos que apresentaram maiores pontuações no questionário de comorbidades auto administrado tem menos chances (-60%) de relatar melhora da dor e da incapacidade em comparação àqueles com menores escores, revelando o impacto de outras condições crônicas no curso da DL (LEOPOLDINO et al., 2019). Um possível fator protetor para DLC é o nível intermediário de atividade física no lazer, uma vez que este foi associado a uma baixa incidência de DLC moderada a grave em idosos (WONG et al., 2021).

Diante do exposto, a avaliação do idoso com dor crônica deve ser multifacetada e contemplar fatores biológicos (sexo, idade, comorbidades, distúrbios de sono, comportamentos, fadiga), psicológicos (depressão, ansiedade, estresse, enfrentamento da dor,

medo e evitação, autoeficácia) e sociais (raça, cultura, status socioeconômico, suporte social) como prevê o modelo biopsicossocial adaptado para idosos(MIASKOWSKI et al., 2020).

1.2 Fatores biopsicossociais associados à dor lombar crônica no idoso

As facetas biológicas, psicológicas, cognitivas e sociais da DL no contexto do envelhecimento podem ser diferentes e desafiadoras. Aspectos associados à senescência podem tornar o idoso mais suscetível a dor persistente e ao declínio da atividade física e da função (SIMON; HICKS, 2018). Sob a perspectiva biológica, o próprio processo de envelhecimento fisiológico induz a mudanças estruturais e fisiológicas, como a sarcopenia (CRUZ-JENTOFT et al., 2019), imunosenescência, *inflammaging* (FRANCESCHI et al., 2007, 2018), as alterações neuromusculares e processos degenerativos na coluna, que propiciam a dor (SIMON; HICKS, 2018). Os processos degenerativos na coluna lombar são prevalentes com o aumento da idade, sendo mais comuns osteoartrite de articulações facetárias e degenerações discais. Essas alterações levam a dor, má função articular e rigidez, e são causas comuns de DL nos idosos (FERREIRA; DE LUCA, 2017).

Um mecanismo de dor mais recente para o entendimento da DL em idosos leva em consideração os mediadores inflamatórios. Já foi descrito que idosos apresentam um processo inflamatório sublimiar crônico mesmo na ausência de patologias, no entanto, na ocorrência de dor lombar, mediadores inflamatórios como interleucina 6 (IL-6) e fator necrose tumoral alfa (TNF-α) estão aumentados, impactando no desempenho funcional e mediando sintomas depressivos (DA SILVA; SCAZUFCA; MENEZES, 2013; DE QUEIROZ et al., 2016; QUEIROZ et al., 2015; WANG et al., 2010). A inflamação parece estar envolvida na causa e consequência de processos degenerativos da coluna, assim como citocinas parecem contribuir para a geração da dor. Por outro lado, a dor também gera aumento das citocinas em idosos, ambos podendo levar a incapacidade, visto o papel catabólico na massa muscular. As citocinas podem levar a dor por propiciarem o aumento da eficácia de transmissão nervosa, redução do limiar e geração de atividade nociceptivas (QUEIROZ et al., 2016; WEBER et al., 2015). No cérebro, o estado de neuroinflamação oriundo da superativação de células da glia também tem se mostrado um mecanismo consistente para explicar a sensibilização central na DLC, sendo estresse crônico e baixa qualidade do sono, aspectos muitos presentes no envelhecimento, possíveis gatilhos para essa ativação glial(NIJS et al., 2017).

Com o envelhecimento, os idosos percebem e processam a dor de modo diferente. O sistema opioide alterado, a perda de fibras aferentes nociceptivas e a atividade alterada de neurotransmissores promove atraso na percepção da dor, facilitação da dor espinhal e supra-

espinhal, menor capacidade de inibição da dor e permite a liberação mais rápida e mais longa da substância P circulante, um neuropeptídeo associado à dor e inflamação (SIMON; HICKS, 2018). Evidências de neuroimagem apontam que o volume de regiões cerebrais responsáveis pelo processamento da dor (o cíngulo, a ínsula, o estriado, o hipocampo, o cerebelo e o córtex pré-frontal) reduz significativamente com o envelhecimento, este fato pode indicar que a maior sensibilidade a dor no idoso está relacionada a diminuição da inibição descendente. Outro indicativo é a diminuição da densidade de matéria cinzenta estriada, que pode comprometer a modulação endógena(WONG; KARPPINEN; SAMARTZIS, 2017).

O sistema muscular também sofre consequências deletérias com o avanço da idade. Estudos têm demonstrado que adultos mais velhos com DLC têm níveis mais elevados de gordura intramuscular em músculos multífidos que pares da mesma idade sem DL, bem como uma área transversal menor do músculo eretor da espinha(HICKS et al., 2005; SAKAI et al., 2017). Além disso, o aumento da gordura intramuscular (obesidade sarcopênica) nos músculos do tronco de idosos, que também contribui para inflamação e sobrecarga, foi associado a maior intensidade de dor e pior desempenho funcional(HICKS et al., 2005; SIONS et al., 2017). Os efeitos da inatividade física também agravam o problema. O tempo sentado e baixo nível de atividade se mostram fortemente associados à DL (PARK et al., 2018). Ademais, o baixo nível de atividade física aparece associado a história recente de DL incapacitante, assim como o diagnóstico de depressão, fadiga, frequente recorrência de DL e sobrepeso (MACHADO et al., 2018).

Um estudo transversal avaliando uma ampla gama de variáveis em 100 idosos com DLC indicou por modelos de regressão que variáveis relacionadas a dor (intensidade, duração, dor induzida pelo movimento lombar), variáveis clínicas (idade, comorbidades, sintomas depressivos, amplitude de movimento das costas, índice de massa corporal e gravidade da patologia radiográfica) influenciam na função e incapacidade (WEINER et al., 2004). No entanto, após ajuste individual, apenas a duração da dor e intensidade foram associados significativamente à incapacidade, mensurada pelo Questionário Roland Morris e testes físicos. Este estudo demonstra a necessidade de compreensão de múltiplos aspectos, no entanto reforça que alguns aspectos como alterações radiográficas são limitadas para predizer o nível de incapacidade, sendo aspectos da dor mais importantes (WEINER et al., 2004). Ainda sobre o impacto de fatores físicos, um estudo verificou que o desempenho de membros inferiores também interferiu estatisticamente na relação entre DL e incapacidade em atividade básicas e instrumentais de vida diária (DI IORIO et al., 2007).

A contribuição de fatores psicossociais e comportamentais tem sido amplamente estudada. Condições do sistema nervoso central como ansiedade, depressão, insônia, enfrentamento mal-adaptativo; e condições periféricas como dor sacroíliaca estão associadas à incapacidade (WEINER et al., 2019). Além disso, a presença de sintomas depressivos diminui a contribuição da atividade física para menores índices de incapacidade (DE JESUS-MORALEIDA et al., 2020). Estudos apontam que a crença de medo e evitação são significantemente associados à incapacidade e desempenho, com impacto inclusive na velocidade de marcha (CAMACHO-SOTO et al., 2012; SIONS; HICKS, 2011). Outro aspecto que influencia negativamente na DL em idosos é a má qualidade do sono. Um estudo longitudinal aponta relação bidirecional entre qualidade do sono e intensidade de dor, sendo estes fatores prognósticos (MORELHÃO et al., 2021).

Outros aspectos psicológicos relevantes podem influenciar no enfrentamento da DLC. A autoeficácia também pode ser fator protetor em idosos. Um estudo apontou que a autoeficácia em níveis crescentes reduz o efeito direto da intensidade da dor nos sintomas depressivos e o efeito indireto nos sintomas depressivos por catastrofização em idosos com dor crônica(CHENG et al., 2018). Nessa mesma perspectiva, a resiliência para a dor (capacidade percebida de regular pensamentos e emoções e manter um funcionamento adaptativo positivo) parece ser outra característica moderadora da relação entre dor e incapacidade. Um estudo recente apontou que maior resiliência à dor foi associada a menor medo-evitação e catastrofização da dor. As análises também destacaram que, após o controle de variáveis demográficas, participantes idosos com alta resiliência tem menor dor evocada ao movimento que aqueles com baixa resiliência (PALIT; FILLINGIM; BARTLEY, 2019).

Sob ótica social, alguns estudos já têm indicado haver associação entre fatores socioeconômicos e a DL em idosos. No Brasil, um estudo transversal caracterizou o perfil de 602 idosos com novo episódio de DL(DE JESUS-MORALEIDA et al., 2018). Os dados apontaram que os idosos com menor nível educacional e renda têm mais incapacidade. De modo semelhante, outro estudo brasileiro com 363 indivíduos destacou maior prevalência de idosos com baixo status socioeconômico e associação da DL com tarefas de carregamento de peso e número de comorbidades referida(QUINTINO et al., 2017). Comparado a idosos holandeses, idosos brasileiros apresentam sintomas mais severos quanto a dor, incapacidade, sintomas depressivos e catastrofização(JESUS-MORALEIDA et al., 2017). Um levantamento amplo realizado em seis países de média e baixa renda que observou 30.146 adultos, a partir de 50 anos de idade, apontou alguns fatores como: baixa renda e baixa escolaridade foram

associados a maior incapacidade relacionada DL, quando a dor era constante(WILLIAMS et al., 2015).

O impacto da DL na funcionalidade do idoso é amplo e integra sofrimento e limitação em atividades diária(MAKRIS et al., 2017). No Brasil, dados transversais de um estudo com 386 idosos com DL apontaram que maior intensidade de dor, ocorrência de rigidez matinal, pior mobilidade funcional, maiores índices de massa corporal, pior saúde física e mental, dificuldade de dormir, cinesiofobia, baixa autoeficácia para quedas e sexo feminino foram associados à incapacidade (SILVA et al., 2019). Um estudo qualitativo sobre o impacto físico, emocional e social revelou que, na visão dos idosos, a DL afetou a execução de tarefas rotineiras, interrupção do sono e exercícios, o que mostra que diferentes domínios são afetados. Os prejuízos psicossociais foram sentimentos de tristeza, irritabilidade, medo sobre o agravamento da saúde, perda de esperança de recuperação ou alívio da dor, experiências de isolamento e incapacidade de seguir hobbies (MAKRIS et al., 2017).

Pelo olhar do core set abrangente da Classificação internacional de funcionalidade, incapacidade e saúde (CIF), um estudo com 244 participantes destacou a influência da idade e do sexo nessa classificação. Na comparação com jovens, idosos com DL tem mais limitação no autocuidado, mobilidade e caminhada, que reforça o grande impacto na funcionalidade(atividades e participação social)(FEHRMANN et al., 2019). Este fato reforça a necessidade de considerar cuidados com foco nas diferentes fases do ciclo de vida. Assim, o corpo de evidências atual sobre DL em idosos já demonstra a relevância de um olhar multidimensional como ponto de partida para o enfrentamento da carga global e pessoal dessa condição em diversos contextos(FEHRMANN et al., 2019)

1.3 Intervenções por exercícios para manejo da dor lombar crônica em idosos

Exercício terapêutico é a recomendação com mais evidência para o manejo da DL em adultos, comparado a cuidados usuais, lista de espera ou placebo(HAYDEN et al., 2021). Associado à educação e terapia cognitivo-comportamental, o exercício faz parte da primeira linha cuidado da DLC em adultos(FOSTER et al., 2018). Neste sentido, priorizar a investigação do efeito de terapias que já provaram ser eficazes em adultos é recomendado, principalmente quando há evidências de que maioria dos estudos no campo da DL não inclui idosos(CARVALHO DO NASCIMENTO et al., 2019; PAECK et al., 2014).

Quando consideramos o público idoso, a literatura aponta o mesmo caminho, no entanto as evidências são limitadas. Uma revisão sistemática com meta-analise mostrou, através de evidência moderada, que o exercício físico resultou em pequeno efeito da

incapacidade a curto prazo (MD = 1,7 [IC 95% 0,3–3,0] em escala de 25 pontos)(AMARAL et al., 2020). Outra revisão com foco na investigação da atividade física no tratamento da DLC em idosos mostra uma tendência de melhora para incapacidade e dor, porém, a evidência é limitada com poucos ensaios clínicos aleatorizados (VADALÀ et al., 2020). Considerando que pacotes combinando tratamentos físicos e psicológicos são promissores em adultos, uma revisão sistemática recente mostrou que intervenções multimodais que incluem exercícios para idosos com dor musculoesquelética crônica, comparadas aos grupos controle e de cuidados habituais, têm um efeito positivo na dor (MD = -0,71 [IC 95% -1,08 a -0,34] em uma escala de 10 pontos) e incapacidade (MD = -0,47 [IC 95% -0,81 a -0,12]), com tamanhos de efeito pequenos a moderados apenas para incapacidade (KECHICHIAN et al., 2022). No entanto, os dados específicos para DL em idosos são limitados.

Este cenário de evidência limitada reforça a necessidade de estudos de alta qualidade com estratégias específicas para população idosa e que também considerem a problemática da adesão ao exercício nesta população. Dados de um levantamento americano mostram que apenas 16% dos idosos com dor crônica relataram uso de exercícios para o controle da dor(AUSTRIAN; KERNS; CARRINGTON REID, 2005). Neste sentido, outro estudo sobre adesão de idosos a exercícios apontou taxas de adesão de 50 a 80% para programas supervisionados, valores considerados de baixo a moderado.(PICORELLI et al., 2014).

1.4 Por que uma intervenção multifacetada pode funcionar?

O programa de treinamento multifacetado incluindo exercícios físicos, educação em dor e exposição gradativa pode funcionar com base na inferência de alguns achados da literatura. De acordo com estudos anteriores, o exercício físico parece um caminho promissor para manejo da dor lombar em idosos(AMARAL et al., 2020). O papel do exercício foi descrito de forma mais ampla diante dos diversos mecanismos de dor. Pela via nociceptiva, nociplástica e neuropática, o exercício físico pode diminuir a excitabilidade de receptores locais, reduzir citocinas inflamatórias e ativar sistemas inibitórios descendentes com opioides endógenos. O mecanismo neuromuscular visa atuação nas disfunções de movimentos encontradas que interferem na dor como mobilidade e força (CHIMENTI; FREY-LAW; SLUKA, 2018).

A via dos mediadores inflamatórios também pode ser sinalizadora de efeitos positivos(PEREIRA et al., 2013). A IL-6 pode ter ação anti-inflamatória quando liberada pela contração muscular em uma cascata independente de TNF-α, sendo chamada de miocina. Em resposta ao exercício, a IL-6/miocina estimula a produção de proteínas e outras citocinas anti-

inflamatória (MATHUR; PEDERSEN, 2008). Neste contexto, evidências clínicas observaram a associação da atividade física com menores concentrações de mediadores pró-inflamatórios e que idosos ativos sem dor também são contemplados por essa relação(COLBERT et al., 2004; KAWI et al., 2016; PEREIRA et al., 2013).

O papel da atividade física na modulação central da dor também é um potencial mecanismo. Um estudo com idosos saudáveis mostrou que maior comportamento sedentário e níveis mais baixos de atividade física foram associados a menos modulação da dor condicionada ao calor, sugerindo que níveis de atividade maiores podem modular a excitabilidade e inibição central. No entanto, esta relação ainda não foi esclarecida para indivíduos idosos com dor e nem se a atividade física poderia modificar a modulação central(NAUGLE et al., 2017). Embora não demonstre relação causal, um estudo de base populacional com pessoas acima de 50 anos apontou que caminhada regular está fortemente associada a menor presença de DL na população geral (PARK et al., 2019).

Por fim, a dor parece ser modulada também por fatores psicossociais. O mecanismo psicossocial parece estar associado ao aumento da expressão de receptores opioides e de fator derivado do cérebro, uma neurotrofina chave na modulação da dor(CHIMENTI; FREY-LAW; SLUKA, 2018). Assim, os estudos apontam que o exercício reduz fatores psicológicos negativos associados à dor, como a depressão, e podem melhorar fatores cognitivos e sociais(COONEY et al., 2013). A principal hipótese para aumento do bem-estar psicossocial relacionado ao exercício é o aumento da interação social com os pares, o incentivo, além da aliança terapêutica e a instrução profissional(FRANCO et al., 2015).

Tendo em vista a natureza biopsicossocial da DLC, abordagens educativas com foco em aspectos psicossocias e comportamentais também podem ser aliadas, uma vez que crenças disfuncionais podem impactar na recuperação(CAMACHO-SOTO et al., 2012; VLAEYEN; CROMBEZ; LINTON, 2016). Partindo das teorias cognitivo social e da auto-regulação, o conhecimento acerca da condição de saúde é o primeiro passo para a mudança de comportamento (BANDURA, 1989; LEVENTHAL, HOWARD BRISSETTE, 2012). O uso de abordagens educativas baseadas em neurofisiologia da dor, autogestão e terapia cognitivo-comportamental foram investigadas em idosos com dor crônica musculoesquelética e apontam resultados positivos, principalmente no formato de grupo (HIRASE et al., 2018; NICHOLAS et al., 2017; NIKNEJAD et al., 2018; REID et al., 2003). A investigação de abordagens educativas em idosos com DL ainda é incipiente e apresenta grande risco de viés (GOODE et al., 2018; RUFA; BEISSNER; DOLPHIN, 2019; ZAHARI; ISHAK; JUSTINE, 2020).

Intervenções multifacetadas que envolvem estratégias de adesão por meio do uso de tecnologia móvel podem estimular a motivação para o engajamento em exercício físico(FRITSCH et al., 2020; SÖDERLUND; VON HEIDEKEN WÅGERT, 2021). Uma revisão de escopo identificou que componentes relacionados a capacidade, motivação e oportunidade podem ser guias para mudança de comportamento em idosos com dor musculoesquelética. Visando melhorar a adesão, os componentes de capacidade destacados foram: educação e supervisão, classificação e domínio do exercício para aumentar a autoeficácia. Os componentes de motivação incluíram a prontidão para mudar, automonitoramento e estabelecimento de metas; e os componentes de oportunidade incluíram sessões de reforço, feedback e apoio social(SÖDERLUND; VON HEIDEKEN WÅGERT, 2021).

Entendendo esse contexto, uma revisão sistemática apontou que o uso de estratégias motivacionais foi positivo para adesão a exercícios(NICOLSON et al., 2017). Comparação de comportamento, apoio social, consequências naturais, identidade, objetivos e planejamento foram outras estratégias encontradas(NICOLSON et al., 2017; ROOM et al., 2017). Uma das formas acessíveis de promover a adesão a partir da literatura atual, é o uso de tecnologia móvel, principalmente de baixo custo. Um estudo piloto em indivíduos com dor crônica que utilizou Short Message Service (SMS) com a finalidade de apoio social mostrou efeitos positivos na intensidade de dor e interferência da dor(GUILLORY et al., 2015). Adicionalmente, as mensagens de texto lembrete mostraram ser um ferramenta útil para empoderamento e facilitar a memorização dos exercícios em idosos com DL recorrente(LILJE et al., 2017). Com foco no suporte à atividade física em domicílio, intervenções digitais baseadas em chamadas telefônicas demonstraram viabilidade (GOODE et al., 2018). Estratégias como ligações e mensagens de texto também podem ser favoráveis porque são ferramentas inclusivas, sem grandes exigências de letramento digital como aplicativos ou sites.

1.5 Implicações para um estudo de viabilidade

Ensaios de viabilidade são estudos exploratórios que visam avaliar se um ensaio clínico randomizado maior ou definitivo de uma intervenção deve ser realizado no futuro em um ambiente específico. Este tipo de estudo preliminar também informa se os componentes cruciais de intervenções complexas serão viáveis, bem como, se os procedimentos internos do estudo (ex. recrutamento, retenção, cegamento, randomização) serão aplicáveis no cenário de realização (ELDRIDGE et al., 2016).

Em geral, estudos de viabilidade são indicados quando: há poucos estudos publicados anteriormente numa área, a população ou alvo de intervenção demonstra que precisa de consideração exclusiva, intervenções anteriores tiveram resultados positivos, mas em cenários diferentes do de interesse (BOWEN et al., 2009). Estudos de viabilidade ou piloto podem ser considerados em diferentes momentos do desenvolvimento de intervenções, mas geralmente na primeira etapa, eles respondem à questão: esta intervenção pode funcionar? Assim, os principais aspectos investigados são: aceitabilidade, demanda, implementação, praticidade, integração, expansão e eficácia limitada (BOWEN et al., 2009). Estudos de viabilidade não podem inferir sobre a eficácia de intervenções e seus critérios devem ser estabelecidos a priori (ABBOTT, 2014).

Quando consideramos a abordagem da atividade física em ensaios clínicos, os desafios são ainda maiores e estudos de viabilidade são altamente recomendados para melhorar as chances de sucesso de um ensaio em larga escala. Nesse contexto, além dos motivos anteriores, estudos de viabilidade também pode ser úteis para avançar na investigação científica, aprimorando critérios de elegibilidade, a intervenção principal, a intervenção comparadora, identificando segurança da intervenção, dose apropriada, aprimorando a adesão ao exercício não supervisionado e suas medidas. Além disso, a retenção pode ser mais desafiadora, uma vez que os desfechos incluem medidas de desempenho exigindo *follow-up* presencial (EL-KOTOB; GIANGREGORIO, 2018). Assim, as principais contribuições de estudos de viabilidade visam favorecer o delineamento de estudos posteriores mais eficientes, e de trazer a perspectiva do público-alvo como parâmetro para aprimoramento das intervenções.

1.6 Justificativa

Considerando as rápidas taxas de envelhecimento da população e os fatores biopsicossociais relacionados à senescência e senilidade, o impacto da DL na população idosa tenderá a aumentar. Em prol desta demanda, a busca por intervenções eficazes para o manejo da DLC em idosos tornou-se imprescindível, principalmente no cenário da atenção primária em contextos socioeconômicos desfavoráveis como o Nordeste brasileiro.

Atualmente, a literatura sobre intervenções para DL em idosos é limitada, baseada majoritariamente em estudos de moderada a baixa qualidade metodológica, apresentando efeitos de pequenos a médios para redução de dor e incapacidade a curto prazo(AMARAL et al., 2020). Por outro lado, embora o corpo de evidência para dor lombar seja grande, poucos estudos clínicos incluem pessoas acima de 60 anos (CARVALHO DO NASCIMENTO et al.,

2019). Estes fatos reforçam a necessidade de estudos que investiguem abordagens estruturadas sob a luz do envelhecimento para promover a autonomia e independência da população idosa.

Estratégias integradas baseadas em exercícios, educação e tecnologia móvel têm mecanismos potenciais para alcançar de modo mais abrangente os aspectos biopsicossociais complexos relacionados a DL na população idosa. Mesmo escassas, algumas informações de estudo clínicos sugerem que educação em dor, exercícios de fortalecimento, atividade física graduada e exposição gradativa são viáveis e tem efeitos preliminares na dor e função de idosos com DLC (ISHAK; ZAHARI; JUSTINE, 2016; KUSS et al., 2016; LEONHARDT et al., 2017; ZAHARI; ISHAK; JUSTINE, 2020). Embora existam algumas iniciativas multifacetadas que usem tecnologia móvel na literatura (GOODE et al., 2018), para o melhor conhecimento dos autores, não há ensaios clínicos com esta proposta em idosos com DL em contextos socioeconômicos desfavoráveis.

A iniciativa de delinear o programa de intervenção no âmbito da atenção primária considera que 75% dos idosos brasileiros dependem do sistema público de saúde e que a atenção primária é porta de entrada para este sistema (MACINKO et al., 2018). Adicionalmente, diretrizes internacionais também recomendam o manejo da DL neste nível de atenção (ALMEIDA et al., 2018). Este estudo atende ao chamado da série de estudos da Lancet que orienta desenvolver e replicar intervenções no contexto de países em desenvolvimento para reduzir a carga global da DL recorrente (BUCHBINDER et al., 2018). Do ponto de vista da saúde pública de um país de média renda, pesquisas que adotam o formação de grupos (O'KEEFFE et al., 2017) e tecnologias de baixo custo podem trazer respostas preliminares para investigações futuras que guiarão a tomada de decisão de profissionais e gestores no sistema de saúde com a redução do impacto da DL em idosos.

Tendo em vista que estamos diante de uma proposta inovadora direcionada para uma população específica pouco estudada e dentro de um contexto pouco explorado, um estudo de viabilidade se faz necessário para evitar o desperdício e reduzir o risco de investimentos de financiamento em ensaios completos mais caros (MORGAN et al., 2018). Entendendo que nossa proposta integra educação e atividade física numa abordagem em grupo adicionadas do uso de tecnologia móvel é preciso entender a perspectiva dos idosos brasileiros para participação e aceitação do programa. Para pesquisadores, este estudo pode ajudar no estabelecimento do conjunto básico de desfechos relevantes a ser medido antes de verificação de efeito em larga escala (WILLIAMSON et al., 2020).

Este estudo é o primeiro passo para vislumbrar o impacto dessas estratégias na funcionalidade, nos custos diretos e indiretos ao sistema de saúde, na inclusão de uma linha de cuidado para saúde musculoesquelética de idosos na rede de saúde e no entendimento de barreiras e facilitadores desse modelo de atendimento. Ademais, este estudo permitirá vislumbrar o potencial de aplicações digitais para cuidado na terceira idade. Desse modo, a proposta desta dissertação é um estudo que investigue a viabilidade de uma intervenção multifacetada para idosos com DL na atenção primária, visando oferecer suporte à condução de um estudo ampliado no futuro.

2 PRODUTO 1

09-Dec-2021

Dear Dr. Jesus-Moraleida:

Your manuscript entitled "Physical activity supported by low-cost mobile technology for back pain (PAT-Back) program to reduce disability in older adults with low back pain at Primary Care: a feasibility study protocol" has been successfully submitted online and is presently being given full consideration for publication in the Motriz, Journal of Physical Education.

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Physical activity supported by mobile technology program (PAT-Back) for older adults with back pain at Primary Care: a feasibility study protocol

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Abstract - Aims: Low back pain (LBP) is disabling in older adults. Although physical activity interventions positively affect LBP, older adults are underrepresented in the literature. We aim to investigate the feasibility of conducting a study to evaluate a primary care program of exercise therapy and pain education, supported by mobile technology, for older adults with chronic LBP (compared to best practice advice). **Methods:** In this parallel, two-arm randomized pilot trial, we will recruit adults aged 60 years and older with chronic LBP. The experimental group (Physical Activity supported by low-cost mobile technology for Back pain-PAT-Back) will consist of a 8-week group exercise program based on pain education, exercises, graded activities, and in-home physical activity. Text messages will be sent to promote adherence to home exercises. The control group will receive an evidence-based educational booklet given during one individual consultation. Outcomes will include: recruitment rate, adherence and retention rates, level of understanding of the intervention content, perception of utility of mobile technology, compliance with the accelerometer in a sub-sample of patients, and adverse events. **Discussion:** The results of this study will form the basis for a large randomized controlled trial. This innovative approach to managing LBP in the primary care setting for older adults, if proven to be effective, can bring an important advance in the knowledge of chronic LBP management to this population.

Keywords: low back pain; aged; feasibility studies; physical exercise; mobile health;

Trial registration: Brazilian Registry of Clinical Trials (RBR-653xcn)

1. Introduction

Low back pain (LBP) is the leading cause of disability worldwide[1,2]. One in four older adults in Brazil suffers from LBP[3], and there is evidence that pain and disability levels worsen with age[4]. Considering the aging of the population primarily in low and middle-income countries, LBP will continue to grow as a significant public health concern[5,6].

Therapeutic approaches that involve physical exercise in primary health care are recommended within clinical practice guidelines[7]. Evidence shows that exercise reduces symptoms of pain and disability in adults with chronic LBP[8,9]. However, most studies do not include older adults, limiting the generalizability of their results to this population[10]. A recent individual participant data analysis from high-quality randomized clinical trials of adults have demonstrated that older individuals might benefit less from exercise, although age does not interact significantly with the effect of this therapy[11]. Evidence about the effectiveness of exercise-based LBP interventions in this population is limited[12]. Some isolated approaches of education targeting self-efficacy[13] and exercise have[14–16] shown little effects for older adults, but they are mainly based on small sample studies with heterogeneous methods and high risk of bias[13–16]. Chronic LBP in older adults occurs within a context of vulnerabilities in body structure and function (e.g. degenerative changes, systemic diseases, depressive symptoms, lack of social support, polypharmacy, history of falls) that are interrelated and contribute to the negative impact of LBP in this population[17–20]. Thus, the therapeutic effects of exercise seen on adults with LBP may not be directly translated for the older adult population.

Clinical practice guidelines often recommend a combination of education, exercises that may include graded activity/exposure that together have the potential to address the biopsychosocial nature of LBP. Some proposed mechanisms of action of these interventions include changes in central pain modulation, positive changes in inflammatory cytokines levels[21,22], improvement in muscle function, and psychosocial factors. These interventions also reinforce self-management while addressing negative beliefs and attitudes towards pain[23]. A multimodal program of care of this nature in older adults with chronic LBP is promising, yet, adherence has been found to be challenging[24,25] especially

in unfavorable contexts(e.g.areas of poverty and scarce resources). Adherence can be even worse when considering older adults that have difficulties in access, physical limitations, misbeliefs, and competing priorities that can present as barriers to exercise programs. Thus, strategies to tackle adherence such as mobile technology and motivational strategies are recommended[26–28]. In this context, the use of multifaceted exercise programs coupled with the use of low-cost technology that can enhance engagement with self-management strategies may lead to improved chronic LBP outcomes in older adults within a primary health care setting.

Although there are some interventions supported by mobile technology in the literature[29], there are no clinical trials for chronic LBP in older adults at a primary health care setting, especially in socioeconomically disadvantaged scenarios. Thus, the primary aim of the study is evaluate the feasibility of 1) an eight-week program of physical exercise and pain education, supported by low-cost mobile technology 2) conducting a randomized controlled trial (RCT) to evaluate the intervention on disability and functional capacity in older adults with chronic LBP in a primary care setting. The results of this study will inform the planning and design of a future pragmatic randomized controlled trial.

2. Methods

2.1. Design

We will conduct a pilot parallel RCT comparing the effectiveness of an intervention involving physical activity and pain education, supported by low-cost mobile technology to best practice advice at eight weeks follow-up (Figure 1). This trial has been designed and reported according to the Consolidated Standards of Reporting Trials (CONSORT) statement for pilot and feasibility trials and the Standard Protocol Items: Recommendations for Interventional Trials (SPIRIT) statement[30,31]. This protocol was registered at the Clinical Trials Registry (REBEC RBR-653xcn) and was approved by the Human Research Ethics Committee from the Federal University of Ceará (5.187.327/2021).

***Insert Figure 1**. Study flowchart according to CONSORT recommendations.

2.2. Participants

We will recruit community dwelling older adults with non-specific LBP who are users of primary health centers from a low-income area in Fortaleza, Brazil.

2.3. Recruitment method

Patients will be identified through advertisement or referral. The project will be advertised at local primary health care units, that is, public units registered at the Brazilian Unified Health System, media, and local senior centers. Potential participants will be referred to the study by health care professionals (e.g., family physicians, public health care nurses, physiotherapists) or will be able to contact the research team directly. The enrollment period will extend over 12 months. On the completion of the eligibility assessment, the researcher will ask those who are eligible to provide written informed consent prior to enrolling in the trial.

2.3.1. Inclusion criteria

- Community-dwelling older adults aged 60 years and older,
- chronic non-specific LBP (i.e. LBP pain unrelated to specific causes, with a duration of at least 12 weeks, with or without associated leg pain);
- residents in Fortaleza,
- mobile phone users,
- at least medium(minimum score of three points) in Start Back Screening Tool (SBST), which suggests referral for rehabilitation[32].

2.3.2. Exclusion criteria

- specific LBP (e.g. history of malignancy, recent history of trauma to the spine or a fracture, vertebral stenosis),
- acute or decompensated systemic or neurological disease, rheumatic diseases, thoracic/abdominal surgeries or those who underwent physical therapy treatments in the previous 12 months, with a history of spine surgery.

- serious visual deficits, or with severe cognitive deficits detected by the Mini-Mental State Examination that won't be able to fill in questionnaires will be excluded from the trial[33].
- contraindications or limitations that prevent walking for a minimum of ten continuous minutes will be excluded from the study.

Those using analgesic medication will not be excluded from the study, but dosage, frequency and type of medication used will be recorded in the pre and post-intervention periods. Additionally, comorbidities associated with the aging process (e.g knee osteoarthritis) will not be a reason for exclusion, but they will be recorded.

2.4. Procedures

At baseline, a blinded assessor will interview participants on demographic and anthropometric information, study outcomes, as well as about the state of health in general, the presence of comorbidities associated with treatments, the number of falls in the previous six week. After providing consent, participants will be randomized either to intervention or control groups. Participants will receive an individual consultation (up to one hour) to establish the initial exercise dosage for the program, for those allocated to the intervention group, or to receive an educational booklet during an individual consultation. All participants will be invited to attend a face-to-face follow-up visit with a blinded assessor at eight weeks post-randomization. If participants are unable to attend the follow-up visit we will either mail a follow-up package or complete the questionnaires over the phone with our primary outcome measures. To assure assessor blinding we will ask the blinded assessor to guess each patient allocation. Data analysis will also be conducted by a blinded statistician.

2.5. Group allocation

Eligible participants will be randomly allocated (1:1) to either a multifaceted program or to a standard care group that will receive an educational booklet. Randomization will occur after confirmation of eligibility and baseline assessment, prior to the first consultation with a physiotherapist. Allocation will be blinded and performed using a computer-generated random allocation schedule (using permuted blocks) operated by a remote researcher not involved in the study.

Neither physical therapist nor participants will be blinded to allocation due to the nature of the proposed intervention.

2.5.1. Intervention group: The PAT-Back program

The Physical Activity supported by low-cost mobile technology for Back pain (PAT-Back) program is described according to the Template for Intervention Description and Replication (Tidier) guidance [34]. Participants will be invited to join one weekly 90 minute group sessions for 8 weeks. The PAT-Back program will consist of patient education and supervised and home exercises and will be based on the biopsychosocial model of pain. All sessions will be conducted using cognitive-behavioral principles.

Prior to initiating PAT-Back, each participant will undergo an individual session for both baseline assessment and identification of exercise targets. The format of all sessions will include 20 minutes of physiotherapist-delivered education plus 60 minutes of supervised exercise therapy (see Table 1). Participants will also be asked to perform home exercises three to five times per week for the duration of the intervention. The education component will target pain self-management and will be focused on the role of exercise on the management of chronic LBP such as pain neurophysiology, behavior changes, and strategies for coping with pain. Group exercises will involve the modalities of relaxation, mobility, strengthening of large muscle groups in a closed-kinetic chain and progression towards functional positions and tasks, plus a home walking program. Details of the intervention are described in Table 2.

Supervised and home exercises will be individualized. Exercises will be delivered using principles of graded activity. Physiotherapists will use the modified 0-10 BORG rating of perceived exertion (RPE) for the progression after each exercise, and the target area will be exercises performed at moderate intensity[35,36]. Home exercises will be progressed over 8 weeks according to participants' progression. In addition, during session four participants will develop with the therapist an action plan, which will include the organization of daily tasks, activity pacing, and the home exercise program (see Table 2). Exercise sessions will start with a 10 minutes warm-up walking program

aiming at an intensity of 5-6/10 BORG RPE. In sequence, participants complete pelvic mobility exercises, stretching, and strengthening large muscle groups of the lower limb and pelvis. We will include progressive training of activities in which they said they were limited due to their LBP (using the Patient-Specific Functional Scale (PSFS). Finally, the session will end with breathing diaphragmatic exercises and progressive muscle relaxation exercises for relaxation. We will measure participants' vital signs (blood pressure and heart rate) at the beginning and at the end of each session.

Exercise progression will be set at varying positioning, frequency, and intensity, and will be registered using a printed spreadsheet for monitoring purposes. We will give performance feedback to encourage gradual improvement and positive reinforcement. The exercises will be proposed gradually so that they are incorporated into a home program throughout the following week. An exercise booklet will be delivered for home training of the program. The team will monitor progress or the need to interrupt or modify the exercise in the case of pain worsening persists after a session (for at least 48 hours), or in the presence of an acute systemic change. The last treatment session will be focused on the transition to independence and progression of exercises at home, work (if applicable), and leisure time. Home exercise training and exercise progression will be tracked using printed diaries for monitoring purposes. Additionally, participants will receive text messages via mobile phone messages (via Whatsapp® or SMS, depending on the participant's preference) three times a week, at their preferred day period (morning or afternoon) with texts directed to support and encourage the engagement on home exercises in between-sessions. The messages were developed through a process involving evidence review, development and draft by researchers and pre-tested to solicit elderly's feedback. The text messages will be semi-personalised including their preferred contact name and preferred shift.

2.5.2. Control group

The control group will have access to an evidence-based educational booklet in either printed formats provided during a one-to-one consultation with a physiotherapist (up to one hour). The booklet includes best information on chronic LBP natural history and general self-management

strategies for this condition, and it will be made available to all participants during the initial consultation. The booklet was previously designed by researchers from the present research team through the consultation of experts and patients with chronic LBP. Participants from the control group will also receive a phone call four weeks after initial consultation with the objective of solving booklet-related questions and reinforcing its related topics. Both in seventh and eighth weeks, weekly text messages will be sent as reminders to attend follow-up sessions.

3. Outcomes

3.1. Primary outcomes

3.1.1. Feasibility

Feasibility outcomes will include recruitment, adherence and retention rates, level of understanding of the education and intervention content, perception of utility of mobile technology, and adverse events. We will also measure compliance with using a wearable accelerometer in a sub-sample of patients. Table 3 describes the details of both feasibility outcomes and criteria for the next steps for the full RCT.

3.2. Secondary outcomes

The self-reported outcomes will be collected to allow for an investigation of the burden of data collection as well as to observe trends in outcomes. LBP related disability, pain intensity and functional capacity measured at baseline and at immediate follow-up (8 weeks). Data collection will be conducted face to face interviews as online data collection may not be feasible given the low social economical and education status of the target population group in this study.

3.2.1. Disability

The Roland Morris Disability Questionnaire will be used to assess LBP related disability. It is composed of 24 questions that verify disability as a result of low back pain, relating it to activities of daily living, pain, and function (0-24). The higher the score, the greater the individual's disability. Roland Morris's questionnaire was properly translated and adapted to Brazilian Portuguese[39].

3.2.2. Pain intensity

We will measure pain intensity using the Numerical Rating scale Scale (0-10 points), 0 being no pain and 10 unbearable or the worst pain you have ever felt in the last week, the pain region being identified by schematic body drawing. This scale has been used internationally, having adequate psychometric properties[40].

3.2.3. Functional capacity

The Short Physical Performance Battery measure (SPPB) uses of three tasks to evaluate static balance in the standing position, speed of normal and habitual gait and the estimated muscular strength of the limbs lower by lifting and sitting on the chair for five consecutive times, without the aid of upper limbs. The results of the SPPB allow the indication of four categories for the participants, depending on their performance: 0 to 3 points indicate disability or very poor performance; 4 to 6 points, low performance; 7 to 9 points moderate performance; whereas 10 to 12 points indicate good performance, and the test has been proved to predict disability[41].

The Patient-Specific Functional Scale, in which the individual reports three daily activities relevant to them and that they have difficulty in performing due to LBP. This scale is rated from 0 to 10 points where greater activity limitation the higher the scores[42,43].

3.2.4. Physical activity level

The level of physical activity of the participants will be reported using the short version of the International Physical Activity - IPAQ, which estimates the time spent, week, on vigorous, light, and moderate activities. The questionnaire has a format that allows the participant to self-report their activities during the week preceding data collection. It allows categorizing patients on categories of low, moderate or high level of physical activity, according to combinations of activities and corresponding calculation of METminutes/week[44].

3.2.5. Self-efficacy to cope with low back pain

The Self-Efficacy Scale for Chronic Pain (Likert scale, 30-300) measures the perception of self-efficacy and the ability to deal with pain and its repercussions. The higher the score, the greater the perceived self-efficiency. The scale was adapted to Brazilian Portuguese[45].

3.2.6. Depressive symptoms

Depressive symptoms will be assessed using the Depression Scale of the Center for Epidemiological Studies (CES-D) (0-60 points) [46]. This consists of 20 questions associated with the senses perceived and experienced in the last week experienced by the participant, and the responses are associated with the frequency at which the participant perceives the feelings described. The higher the score, the higher the presence of these symptoms. Batistone et al. identified that the cutoff point of the instrument with a value above 11 points was associated with the presence of symptoms of depression. In addition, all participants will be asked about the presence of clinically diagnosed depression, for descriptive purposes[47].

3.3. Additional measures

We will collect anthropometric (e.g. body mass index), demographic (e.g. years of schooling and gender), and clinical data (e.g. comorbidities and the use of medication for pain). We will also collect information on concurrent care seeking during the program at follow-up.

3.4. Implementation and Monitoring plan

The research team will be composed of physiotherapists experienced in the field of aging and pain and physiotherapists in training, who will undergo two 4-hour training sessions covering all protocol-related procedures under the supervision of coauthors of this protocol. Coauthors FJM and AN will regularly observe researchers implementing supervision to ensure quality of the protocol.

3.5. Data Management

This study will use Research Electronic Data (REDCap) for data capture, management, and storage. Each participant will receive a trial identification number, and any identifiers will be masked for the purpose of the confidentiality of identity. Using REDCap will also allow us to monitor data

collection in terms of completeness and accuracy of data, and also for ongoing quality of data procedures.

3.6. Sample size calculation

A sample size calculation was not performed given the feasibility nature of this study. We estimated that a total of 40 participants (20 per group) would be adequate for the purpose of this study[48].

3.7. Statistical analysis

The description of the characteristics of the participants and feasibility outcomes will be reported using frequency, mean and standard deviations or median and interquartile ranges when appropriate. The feasibility rates will be described in absolute numbers and percentages (details in Table 3). We will present mean and 95% confidence intervals of clinical outcomes to observe trends. The analyses will be processed in the program Statistical Package for Social Sciences, 22.0 (SPSS Inc., Chicago, IL), considering an alpha value of 0.05.

4. Discussion

The results of this study will add to the limited available evidence for the management of non-specific chronic LBP in older adults. Findings will support the potential modification of the program as well as improvement on the methods of the RCT. The results of this study will form the foundation for the conduct of a large RCT to evaluate the effectiveness of the intervention. The results of this study will be the first necessary step to investigate the effectiveness of this intervention for the management of LBP in older adults within a primary care setting.

Potential limitations of this study include the differences in intervention frequency between the two treatment groups, meaning that individuals in the control group will have poorer therapeutic alliance leading to potentially lower non-specific intervention effects as well as potentially higher dropout rates. We intend to minimize the risk by addressing personal motivations and the relevance for contributing to the study prior to randomization, and by conducting a telephone call at 4 weeks in

order to clarify the information about the booklet for the control group only. Another limitation is that older patients who do not have access to mobile phone will be excluded from this study.

Our assessment protocols for primary outcomes accommodate both in-person and telephone assessments and flexible assessment times if needed, and we will monitor absences and repeated attempts to reschedule during the intervention period to adapt procedures (e.g. offer opportunities for flexible reschedule) to facilitate continued participation for those at risk of dropout. Other strengths of this study include the feasible infrastructure required for implementing the intervention protocol (weekly supervised therapy, home exercises, plus mobile text messages for adherence) and the selected secondary outcome measures that are relevant for the older population. Thus, this innovative intervention was conceived to be easily implemented in Primary Health Care units for the ageing population if its effectiveness turns to be favorable during the future course of investigations. As literature is scarce and brings inconsistent findings for the management of chronic low back pain in older adults, the results of this study have the potential to contribute with the discussion of specifically targeting this population in low back pain investigations including the use of adjunctive low cost support strategies (i.e. mobile messages and booklet) aiming to reduce the burden and increase autonomy in them.

Conflicts of interest

The authors declare that they have no competing interests

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This protocol was registered at the Clinical Trials Registry (REBEC RBR-653xcn) and was approved by the Human Research Ethics Committee from the Federal University of Ceará (3.836.257/2020).

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Figure 1. Study flowchart according to CONSORT recommendations.

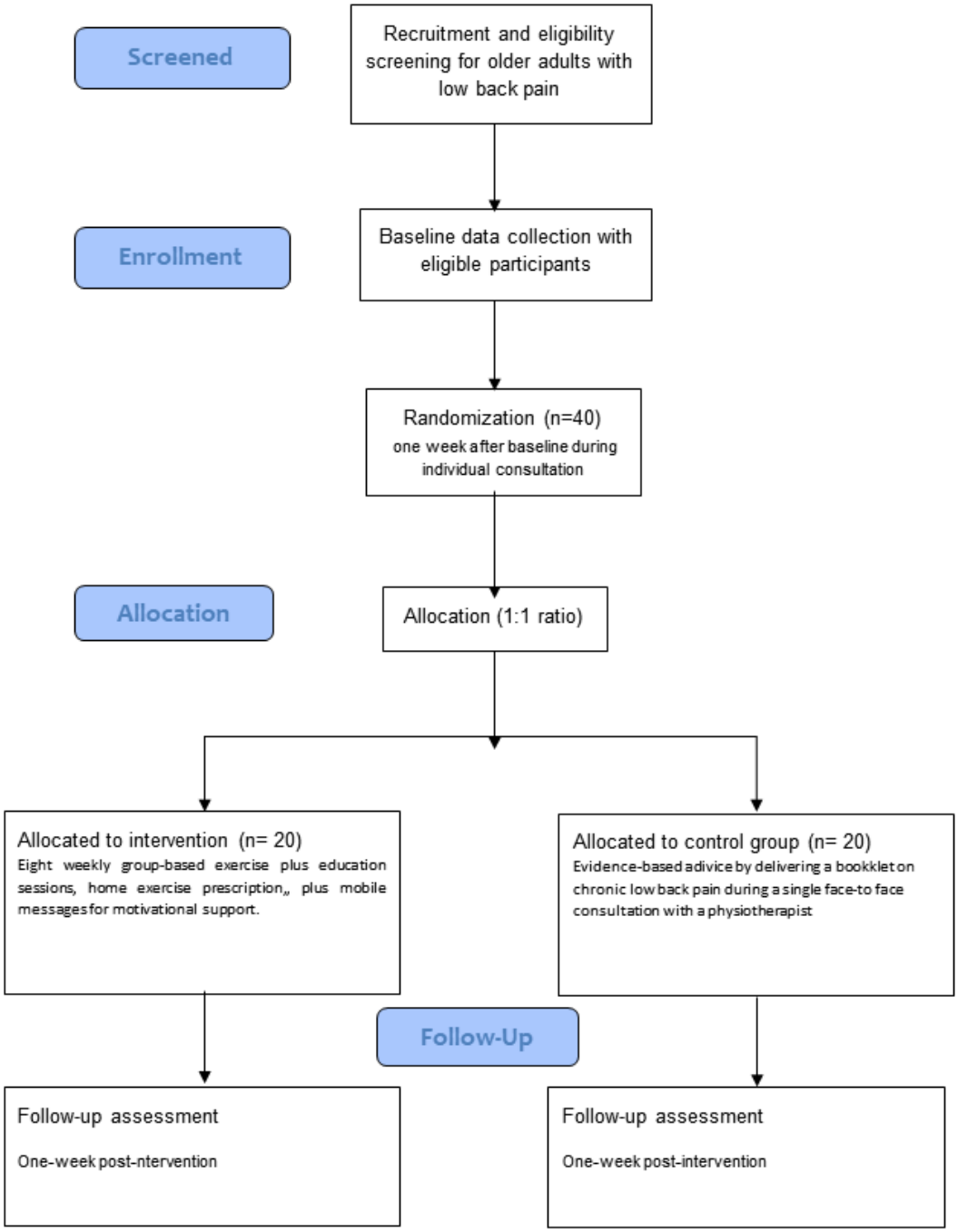

Table 1. Details of the program components.

Week	Educational componente	Exercise component	Mobile technology component
1	Theme: Understanding low back pain; Objective: To clarify the patient about his condition; Topics: Definition of pain, factors that influence pain, types of pain and transition, neurophysiology of chronic pain, pain ≠ injury, prognosis in the older adults, myths about low back pain. Exercise booklet delivery.	Group training: diaphragmatic breathing, lumbar-pelvic mobility exercise, global stretching and progressive muscle relaxation; Home exercises: group-trained exercises.	Messages: reminder for attitudes of relaxation and pain relief techniques;
2	Theme: The importance of moving Objective: Highlight exercise as a remedy for low back pain and encourage engagement in physical activity. Topics: Definition of movement, body repercussions, ways of moving, cycle of pain - fear avoidance , effects of inactivity, benefits of physical exercise for pain, walking program, 1st line of care for LBP;	Group training: exercises from week 1 , bridge and walking circuit; Home exercises: group-trained exercises	Messages: Reminder for benefits of becoming active and effects of inactivity, and incentive to exercise.
3	Theme: Gradual exposure to the activity; Objective: To present gradual exposure as a resource to overcome fear, dysfunctional beliefs of movement or dysfunctional behaviors. Topics: Belief in fear and behavioral avoidance, pain effects, the impact of LBP in daily activities, definition, aim s and strategies of gradual exposure.	Group training: exercises for week 2 , gradual exposure to the specific activity indicated and exercise of sitting and standing; Home exercises: group-trained exercises	Messages: Reminder for personalized gradual exposure strategies.
4	Theme: Management of biopsychosocial factors in low back pain and aging; Objective: To promote an understanding of the contribution of relevant biopsychosocial factors that impact LBP and how to control them. Topics: Common comorbidities and the importance of their management in the care of LBP; sleep quality and measures for restful sleep, measures for reducing stress and distraction,	Group training: exercises for week 3 , abduction of lower limbs, truck extension;	Messages: reminder to control biopsychosocial factors.

	leisure.	Home exercises: group-trained exercises	
5	Theme: importance of planning; Objective: Organize the exercise routine at home, guide rhythm, micro pause and division of tasks. Topics: What is and why to plan, strategies for organizing activities and exercises, balance between activity and rest, respect for the appropriate limit and pace, definition of goals and action plan based on the SMART system.	Group training: week 4 exercises and, partial curl exercise; Home exercises: group-trained exercises	Messages: Reminder and incentive to set goals and achieve objectives.
6	Theme: How to do self-management in pain? Objective: To reinforce LBP self-management skills and strategies for implementation; Topics: Problems of implementation and solutions in acute exacerbation of pain through the principles of resolution problems, decision-making, use of resources, goal setting and action planning and self-adaptation, therapist-patient partnership.	Group training: progression of week 5 exercises and step up and down exercises; Home exercises: group-trained exercises	Messages: Reminder for self-management implementation strategies.
7	Theme: What have we learned so far? Objective: To establish important intervention. Topics for the confrontation and continuous management of DLC; Topics: Exercise benefits and impairment of inactivity, reinforcement of planning and importance of progressing exercises	Group training: progression of week 6 exercises and plantar flexion exercise; Home exercises: group-trained exercises	Messages: Encouraging exercises and monitoring them to achieve objectives.
8	Theme: You are in control, but you are not alone! Objective: Obtain feedback on changes, help resolve doubts and problems, provide positive reinforcement of advances and assist in facing barriers.	Group training: progression of exercises for week 7 ; Home exercises: group-trained exercises	Messages: Encouraging exercises and monitoring them.

Table 2. Description of the physical exercise component

Exercise	Initial approach	Progression
Diaphragmatic breathing	Starting position: supine position with bent knees Description: inhalation / exhalation with abdominal movement. (5 minutes)	After performing the pattern properly, the participant evolves to a sitting, standing and double task. Home frequency recommendation: 7x/ week , 1x/day
Pelvic Tilt	Starting position: sitting in comfortable position Avel Description: Execution of retroversion before pelvis version within non-painful range (2 minutes)	The participant can evolve to standing and four supports, with the addition of repetitions. Home frequency recommendation : 3x / week, 1x / day
Progressive muscle relaxation	Starting position: supine position Description: With his eyes closed, the participant is guided to think about pleasant situations and to breathe calmly. Contract, maintain muscle contraction for a few moments and relax areas of the face, arms, hands, legs and feet (10 minutes).	No progression Home frequency recommendation: 7x / week , 1x / day
Overall stretch	Position: Standing or sitting Description: stretching of the posterior and anterior trunk chair, upper and lower limbs (30 s each muscle group). (5 minutes)	The participant is oriented to reach greater amplitudes Home frequency recommendation : 7x / week , 1x / day
Bridge	Initial position: Participant in supine position , knee and arm flexion in pronation extended to the side of the body . Description: And hip lift and return to the initial position, associated with diaphragmatic breathing (repetitions in 1 minute)	The participant will evolve, in order, with number of repetitions, lift, load and unipodal support according to perceived effort on the BORG scale. Target recommendation: 2x10 repetitions Home frequency recommendation: 3x / week , 1x / day

Sit and stand	Starting position: Participant sitting in a firm chair Description: Get up and sit again without using your arms (repetitions in 1 minute)	The participant will evolve, in order, with number of repetitions, series and speed according to the perception of effort on the BORG scale. Target recommendation: 3x10 repetitions with speed increase. Home frequency recommendation: 3x/week, 1x/day
Gradual exposure	Activity dependent, guided by the principles of reinforcement, rhythm. Safely repeats in 1 minute	The participant will evolve to a more challenging position and / or range. Target: Complete the task safely. Home target recommendation: 3x/week , 1x/day
Abduction of lower limbs	Starting position: Standing participant, positioned in front of a firm support surface. Description: Request that you lift one leg to the side and return to the center, slowly. The same is done on the contralateral leg after the initial leg series. (repetitions per member in 1 minute)	The participant will evolve, in order, with number of repetitions, series, change to lateral decubitus and speed according to the perception of effort on the BORG scale. Target recommendation: 3x10 repetitions with speed increase. Home frequency recommendation: 3x / week, 1x/day
Step up and down	Starting position: Participant standing, with a close support surface. Description: ask to go up a step and go down , alternating legs (repetitions in 1 minute).	The participant will evolve, in order, with number of repetitions, series and speed according to the perception of effort on the BORG scale. Target recommendation: 3x10 repetitions with increased speed. Home frequency recommendation: 3x/ week , 1x/day
Partial Curl	Initial position: Patient supine, knees bent, feet flat on the surface Description: trunk partial flexion , raising the scapular waist to its limit.	The participant will evolve, in order, with number of repetitions, amplitude, series, load according to the perception of effort on the BORG scale. Target recommendation: 3x10 repetitions with increased load and speed. Home frequency recommendation: 3x/ week , 1x/ day
Tiptoe (plantar flexion)	Initial position: The participant is standing, positioned in front of a support surface. Description: ask him to lift his heel and stand on his toes,	The participant will evolve, in order, with number of repetitions , support , series according to the perception of effort on the BORG scale. Target recommendation: 3x10 repetitions. Home frequency

	then request the return, slowly (repetitions in 1 minute)	recommendation: 3x / week , 1x / day
Trunk extension	Initial position: Participant in prone position, with the support of the elbows, extends the trunk, up to its limit. Description: Raise the trunk and return.	The participant will evolve, in order, with a number of repetitions, support, series according to the perception of effort. Home frequency recommendation: 3x/week , 1x/day
Walking circuit	Make sure that the participant has adequate footwear, HR and PA in normal parameters. Pay attention to the effort and complaints to stop at any time. Description: The participant will walk on a circuit that will involve free walking, with speed obstacles to perceive moderate effort for 10 minutes. Training at home: Free walk for minimum 10 minutes.	The participant will be instructed to increase the walking pace to perform a greater number of walking cycles when the perceived exertion is less than moderate. Home target recommendation: 90 min/week. Progressing time and walking pace for moderate perceived effort.

Table 3. Details of outcomes and feasibility measures.

Outcomes	Instruments / measures	Analyze	Feasibility criteria
Recruitment rate	Electronic registration of participants recruited in 12 months.	Number of participants recruited	Proceed $x \geq 100$ Proceed with change $60 < x < 100$ Proceed with significant changes $x \leq 60$
	Electronic registration of eligible participants who agreed to participate in 12 months.	Percentage of eligible people who consented to participate and were randomized	Proceed $x \geq 50\%$ Proceed with change $50 < x < 25\%$ Proceed with significant changes $x \leq 25\%$
Retention rate	Registrations allocated participants and who completed follow-up action immediately	Percentage of participants who completed follow-up measures after randomization.	Proceed $x \geq 85\ \%$ Proceed with change $60\% < x < 85\ \%$ Proceed with significant changes $x \leq 60\%$
Adherence rate to program	Electronic weekly attendance record	Percentage of individuals who completed 75% of attendance in 8 weeks	Proceed $x \geq 75\ \%$ Proceed with change $50\% < x < 75\ \%$ Proceed with significant changes $x \leq 50\%$
Adherence to unsupervised exercises	Brazilian Portuguese version of the Exercise Adherence Rating Scale (EARS-Br) [37]	Percentage of participants who score 17 points or more	Proceed $x \geq 70\%$ Proceed with change $50\% < x < 70\%$

			Proceed with significant changes x ≤ 50%
	Written journal of frequency of execution of the prescribed exercises completed by the participant himself	Percentage of participants who performed 75% of training in group	-
Difficulty understanding the intervention	Feasibility form through the question: How much difficulty did you have to understand any content / instruction at the time of training?	Percentage of participants with a mean response s on a likert scale (0-10) equal to or less than 5	Proceed x ≤ 50% Proceed with change 50% < x <75% Proceed with many changes x ≥ 75%
Difficulty performing exercises at home	Feasibility form through the question: How much difficulty did you have to perform the exercises at home?	Percentage of participants with a mean response on a Likert scale (0-10) equal to or less than 5	Proceed x≤ 50% Proceed with change 50% < x <75% Proceed with significant changes x ≥ 75%
Safety to perform exercises at home	Feasibility form through the question: How safe did you feel to perform the exercises at home?	Percentage of participants with an average of responses on a Likert scale (0-10) equal to or greater than 5	Proceed x ≥ 75% Proceed with change 50% < x <75% Proceed with significant changes x ≤ 50%
Perception on the use of mobile technology	Feasibility form through the question: How much do you believe that text messages will motivate you to perform the exercises?	Percentage of participants with an average of responses on a Likert scale (0-10) equal to or greater than 5	Proceed x ≥ 75% Proceed with change 50% < x <75% Proceed with significant changes x ≤ 50%

Compliance with the accelerometer protocol	Use of the accelerometer on the right side of participants' waist (Actigraph, model wGT3X-BT) for at least 10 hours a day for at least four days (removing the first and last days and disregarding days with less than 600 minutes, and periods of less than 90 minutes of no activity record)[38].	Percentage of participants using it according to the minimum established period of time.	-
Adverse events	Electronic registration of event reporting by patients	-	-

3 PRODUTO 2

Physical Activity supported by Low-cost Mobile Technology for Back pain (PAT-Back) Program to Reduce Disability in Older Adults with Low Back Pain at Primary Care: Results of a Feasibility Study

Article submitted to journal: The Journal of Geriatric Physical Therapy

Abstract

Background and Purpose: Low back pain (LBP) is disabling in older adults. The management of LBP in older people has been overlooked. Primary care-based interventions for this population are needed to reduce chronic LBP impact. Thus, we aimed to evaluate the feasibility of a randomized controlled trial investigating the effectiveness of program of physical exercise and pain education, supported by low-cost mobile technology (PAT-Back) compared to best practice advice on pain, disability, and functional capacity in older adults with chronic LBP in primary care.

Methods: This feasibility study took place in Fortaleza, Brazil. We recruited adults aged 60 years and older with chronic LBP. PAT-Back group consisted of a program with exercises, pain education, and motivational text messages. The control group received an evidence-based educational booklet given during one individual consultation. Outcomes included: recruitment rate, adherence and retention rates, level of understanding of the education and intervention content, perception of utility of mobile technology, and adverse events. *A priori* feasibility criteria for these outcomes were set. Pain intensity, disability, functional capacity, physical activity, depressive symptoms, and self-efficacy for pain were evaluated. Descriptive statistics were used.

Results and discussion: Most feasibility criteria were met. 248 people were recruited, 46 older adults were eligible. The retention rate was high (100% in the PAT-back group and 95% in the control group). The adherence rate to intervention was partially met (60%) in the PAT-back group. The adherence rate to unsupervised exercises was adequate (75%) in the PAT-group. Difficulty in understanding and performing the intervention were small in both groups. Safety to perform home exercise was partially acceptable in the PAT-back group. In addition, 95% of older adults reported which text messages motivated them to perform the exercises in the PAT-back group. Six participants reported adverse events in each group.

Conclusion: The majority of older adults accepted both interventions and their components. Strategies to increase adherence to intervention and safety to perform home exercise are needed.

Keywords: low back pain; aged; feasibility studies; physical exercise; mobile health;

Clinical implications

1. The PAT-Back program is likely feasible in a primary care setting.
2. Treatment adherence and safety performing home exercise are challenging for older adults.
3. Motivational text messages and pain education are well accepted by older people.

Introduction

Older adults are commonly impacted by LBP[1], with symptoms and prognosis worsening with age[2,3], resulting in reduced functioning and increased psychological suffering.[4] Among Brazilian older adults, LBP is the second most often reported health problem[5], with prevalence ranging from 25% to 42%[6,7] Due to the rapid aging of the population, LBP-associated burden in older adults is increasing and challenging healthcare system, mainly in low-income and middle-income countries.[8]

Current evidence shows that exercise reduces symptoms of pain and disability in adults with chronic LBP compared to no treatment, usual care or placebo.[9] Internationally, clinical guidelines recommend the management of LBP mostly at primary care.[10] The guidelines also highlight the use of multifaceted approaches combining exercises, education, and cognitive behavioral therapy as the first line of treatment.[10] Unfortunately, management of LBP in older people has been overlooked. In general, studies participants have a mean age of 43.7 years.[9] Evidence about the effectiveness of conservative therapy (eg. education, exercise, drugs, electrotherapy, among others) for LBP in older population is uncertain and scarce, with exercise-based interventions showing small effects on disability compared to placebo, sham, waiting list or no intervention.[11] Moreover, older adults are significantly underrepresented in randomized controlled trials in the LBP field.[12] This finding has important implications because creates uncertainty about applicability and generalizability of results of first line of treatment for LBP in older people, in particular due to the specific characteristics of the geriatric population.

Considering chronic LBP in older adults often coexists with comorbidities, degenerative changes, history of falls, depressive symptoms, and sleep disturbances[13], there is an urgent need to develop multidimensional interventions age-specific to reduce chronic LBP impact. In this direction, a review showed that multimodal interventions including exercise therapy are promising for older patients with chronic musculoskeletal pain when compared to control and usual care groups.[14] Yet, LPB specific data are limited.

Additionally, understanding that treatment adherence could be a key contributor to clinical effects of multimodal interventions with exercise, efforts are required to increase adherence in older adults.[15] A relevant trend to tackle poor adherence to exercise is use of accessible mobile technology with motivational strategies[16,17] In this context, a combination of education, exercises and low-cost mobile technology have the potential to address the biopsychosocial nature of LBP, improving chronic LBP outcomes in older adults within a primary health care setting.

As there are no clinical trials for chronic LBP in older adults at a primary care setting in developing countries, especially in socioeconomically disadvantaged scenarios, a feasibility study is needed before embarking on a full trial. Thus, the primary aim of the study is to evaluate the feasibility of a

randomized controlled trial investigating the effectiveness of program of physical exercise and pain education, supported by low-cost mobile technology, compared best practice advice, on pain, disability and, functional capacity in older adults with chronic LBP in a primary care setting.

Methods

Study design

We conducted a two-arm, assessor-blinded, feasibility RCT. This study was approved by the Human Research Ethics Committee from the Federal University of Ceará (5.187.327/2022), and prospectively registered at the Clinical Trials Registry (REBEC RBR-653xcn). The study protocol has been submitted previously. We followed the Consolidated Standards of Reporting Trials (CONSORT) statement extension for pilot and feasibility randomized trials for reporting.[18] We also used Extension for RCTs Revised in Extenuating Circumstances (CONSERVE) for reporting some modifications due to the COVID-19 Pandemic.[19]

Participants

We recruited community dwelling older adults with non-specific LBP in Fortaleza, Brazil. Initially, recruitment methods were used to identify potentially eligible participants, including: print and web-based advertising (at 14 public units registered at the Brazilian Unified Health System), referral, social media posts (Facebook and Instagram and word of mouth). Due to the COVID 19 pandemic, few people were seeking care for back pain at health units, thus we added other strategies to expand recruitment: sponsored posts on social media during one week and print advertising in fleet buses. This was a protocol deviation.

Potential participants registered their interest through contacting the research team and were then screened for eligibility by a researcher via telephone according to the specified eligibility criteria. Inclusion criteria were: community-dwelling older adults aged 60 years and older, reported chronic non-specific LBP (i.e. LBP pain unrelated to specific causes, with a duration of at least 12 weeks, with or without associated leg pain), residents in Fortaleza, mobile phone users, at least medium(minimum score of three points) in Start Back Screening Tool (SBST), which suggests the need to referral for rehabilitation.[20] Exclusion criteria included: specific LBP (e.g. history of malignancy, recent history of trauma to the spine or a fracture, vertebral stenosis), acute or decompensated systemic or neurological disease, rheumatic diseases(fibromyalgia, or rheumatic arthritis), thoracic/abdominal surgeries or those who underwent physical therapy treatments in the previous 12 months, with a history of spine surgery, serious visual deficits, or with severe cognitive deficits detected (cut-off point of less than 13 for illiterate participants, 18 for participants with elementary education, and 26 for participants with secondary and/or higher education) by the Mini-Mental State Examination [21], contraindications or limitations that limited walking for a minimum of ten continuous minutes.

Eligible participants were randomly allocated (1:1) to groups through a computer-generated random allocation schedule (using permuted blocks of 8) operated by a remote researcher not involved in the study. Allocation was concealed in sequentially numbered, sealed, opaque envelopes created by investigators not involved in study. Participants were allocated to the group by an investigator who coordinated treatment. Neither physical therapist nor participants were blinded to allocation due to the nature of the proposed intervention. Data collection was conducted in-person by an independent researcher, blinded to groups assignment. This study used Research Electronic Data (REDCap) for data capture, management, and storage.

Procedures

At baseline, a blinded assessor interviewed participants on demographic and anthropometric information, study outcomes, as well as about the state of health in general, and the presence of comorbidities. After the assessment, participants were invited for an individual consultation with a physical therapist (± one week post-assessment). At this moment, participants were immediately randomized either to intervention or control group. Participants received an individual consultation (up to one hour) to establish the initial exercise dosage for the program, for those allocated to the intervention group, or to receive an educational booklet during an individual consultation. All participants were invited to attend a face-to-face follow-up visit at one week post-intervention. If participants were unable to attend the follow-up visit we complete the questionnaires over the phone with our primary outcome measures. To evaluate assessor blinding we asked the assessor if he knew each patient allocation before reassessment. Six assessors and three therapists received extensive training in measures and interventions, respectively

Intervention group: The PAT-Back program

The Physical Activity supported by low-cost mobile technology for Back pain (PAT-Back) program is a physiotherapist-delivered intervention weekly 90-minute group sessions for 8 weeks. The PAT-Back program combined patient education and supervised and home exercises. All sessions were conducted using cognitive-behavioral principles[22]. This program is described according to the Template for Intervention Description and Replication (Tidier) guidance[23] and was also described at the protocol in detail.

Prior to initiating PAT-Back, each participant underwent an individual session for both baseline assessment and identification of exercise baseline targets. The format of the group included 20 minutes of physiotherapist-delivered pain education plus 60 minutes of supervised exercise therapy. Participants were asked to perform in-home exercises three to five times per week for the duration of

the intervention. The education component targeted pain self-management and was focused on the role of exercise on the management of chronic LBP. Group exercises involved the modalities of relaxation, mobility, strengthening of large muscle groups in a closed-kinetic chain, walking circuit and progression towards functional positions and tasks, plus a home walking program.

Supervised and home exercises had individualized prescription. Exercises were delivered using principles of graded activity, such as quotas, pacing, and self-reinforcemen[24]. Physiotherapists used the modified 0-10 BORG rating of perceived exertion (RPE) for the progression after each exercise, and the target area were exercises performed at moderate intensity. [25] An exercise booklet was delivered for home training of the program. Home exercise training and exercise progression were tracked using printed diaries. Additionally, participants received text messages via mobile phone messages (via Whatsapp ® or SMS) three times a week with texts to support and encourage the engagement on home exercises in between-sessions. See original messages in the supplementary material 1. All participants could have two absences during the sessions. To help participants to complete the program, we offered an only extra session after three absences during eight weeks. See details in Figure 1.

Control group

The control group had access to an evidence-based educational booklet in printed formats provided during a one-to-one consultation with a physiotherapist (up to one hour). The booklet includes pieces of information described in Figure 1. The booklet was previously designed by researchers from the present research team through the consultation of experts and patients with chronic LBP. Participants from the control group also received a phone call four weeks after initial consultation with the objective of solving booklet-related questions and reinforcing its related topics. Both in seventh and eighth weeks, weekly text messages were sent as reminders to attend to follow-up sessions.

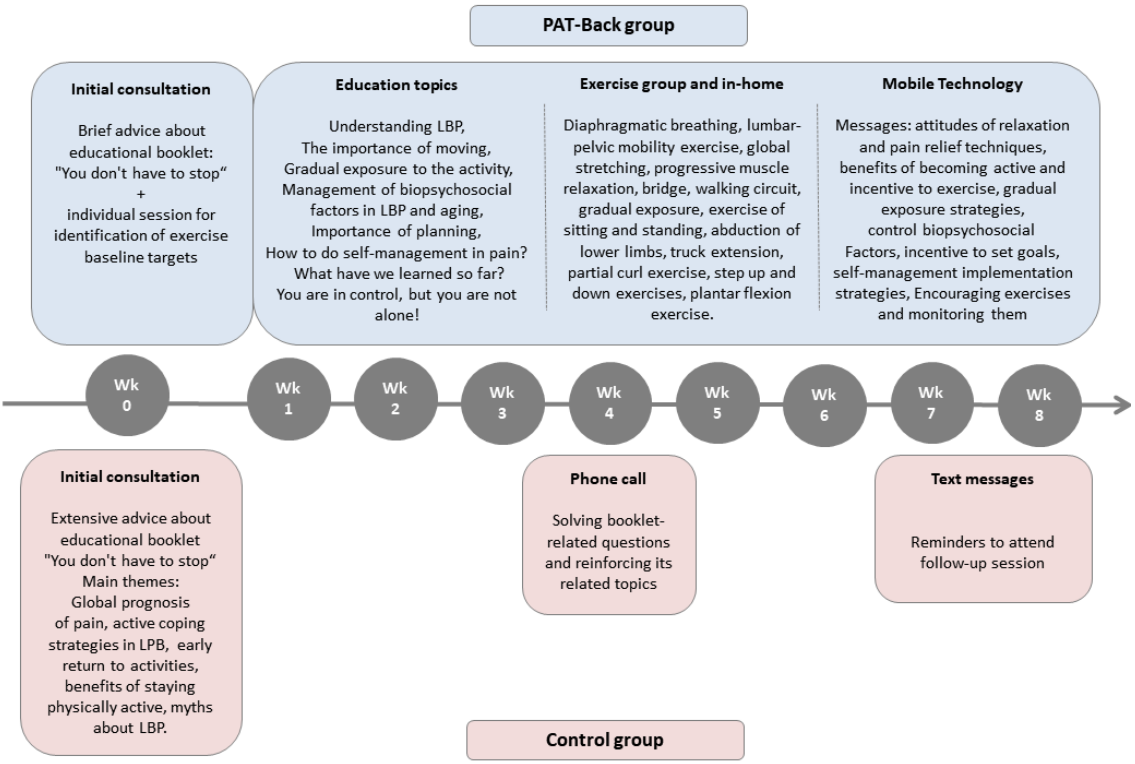

Figura1. Details of the PAT-back and control interventions.

Primary outcomes

Feasibility outcomes were recruitment, adherence and retention rates, level of difficulty of the education and intervention content, perception of utility of mobile technology, and adverse events. Compliance with the accelerometer in a subsample of patients was not collected because costs of devices were impacted due in COVID 19 pandemic. This was a deviation of the protocol. Adherence to unsupervised exercise and non-adherence reasons were assessed using the Brazilian version of the Exercise Adherence Rating Scale - EARS-Br (0-24 points)[26]. In addition, we used exercise diaries to describe the percentage of participants who performed 75% of training in group. The return rate of diaries was reported (number of diaries received/number of diaries delivered). Feasibility measures were collected one-week post-intervention using a form developed for the survey. Items related to mobile technology and adherence to the exercise protocol were measured only in the intervention group. Adverse events were also counted and described. Details of feasibility outcomes and them criteria (See Table 1).

Table 1. Details of outcomes and feasibility measures.

Outcomes	**Feasibility criteria**		
	Proceed	**Proceed with change**	**Proceed with significant changes**
Recruitment rate	100 or more participants recruited in 12 months	99-61 participants recruited in 12 months	60 or less participants recruited in 12 months
	50% or more of eligible people were randomized in 12 months	49-26% of eligible people were randomized	25% or less of eligible people were randomized
Retention rate	85% or more of participants completed follow-up	84-61% of participants completed follow-up	60% or less of participants completed follow-up
Adherence rate to program	75% or more of individuals who completed 75% of attendance	74-51% of individuals who completed 75% of attendance	50% or less of individuals who completed 75% of attendance
Adherence to unsupervised exercises	70% or more of participants who score 17 points or more(cut-off for acceptable adherence behavior) in Brazilian Portuguese version of the Exercise Adherence Rating Scale (EARS-Br) [26]	69-51% of participants who score 17 or more in EARS-Br	50% or less of participants who score 17 or more in EARS-Br
Difficulty understanding the intervention	50% or less of participants with responses equal to or greater than 5 on a likert scale (0-10). Question: How much difficulty did you have to understand any instruction at the time of training?	74-51% of participants with responses equal to or greater than 5	75% or more of participants with responses equal to or greater than 5
Difficulty performing exercises at home	50% or less of participants with responses equal to or greater than 5 on a likert scale (0-10). Question: How much difficulty did you have to perform the exercises at home?	74-51% of participants with responses equal to or greater than 5	75% or more of participants with responses equal to or greater than 5
Safety to perform exercises at home	75% or more of participants with responses equal to or greater than 5 on a Likert scale (0-10). Question: How safe did you feel to perform the exercises at home?	74-51% of participants with responses equal to or greater than 5	50% or less of participants with responses equal to or greater than 5
Perception on the use of mobile technology	75% or more of participants with responses equal to or greater than 5 on a Likert scale (0-10). Question: How much do you believe that text messages will motivate you to perform the exercises?	74-51% of participants with responses equal to or greater than 5	50% or less of participants with responses equal to or greater than 5

Secondary outcomes

The secondary outcomes were LBP related disability, pain intensity, functional capacity, self-reported physical activity level, self-efficacy for pain and depressive symptoms measured at 8 weeks after randomization. We assessed disability using Roland Morris Disability Questionnaire, which contains 24 questions related to activities of daily living, pain, and function (0-24). The higher the score is, the greater the disability.[27] We measured pain intensity using the Numerical Rating scale Scale (0-10 points), 0 being no pain and 10 unbearable or the worst pain you have ever felt in the last week.[28] The specific disability was assessed with the Patient Specific Functional Scale, in which the participants identified until three daily activities relevant to them and that they have difficulty in performing due to LBP. This scale is rated from 0 to 10 points where greater activity limitation the higher the scores. The final score is the mean of up to 3 ratings [29] We assessed Functional capacity using The Short Physical Performance Battery measure (SPPB). The results of the SPPB test allow the indication of four categories for the participants: 0 to 3 points indicate disability or very poor performance; 4 to 6 points, low performance; 7 to 9 points moderate performance; whereas 10 to 12 points indicate good performance.[30,31]

The level of physical activity of the participants was reported using the short version of the International Physical Activity - IPAQ, which estimates the time spent, per week, on vigorous, light, and moderate activities. The questionnaire allows categorizing patients on categories of low, moderate or high level of physical activity, according to combinations of activities and corresponding calculation of METminutes/week. [32] The Self-Efficacy Scale for Chronic Pain (Likert scale, 30-300) measured the perception of self-efficacy and the ability to deal with pain and its repercussions. The higher the score, the greater the perceived self-efficiency.[33] Depressive symptoms were assessed using the Depression Scale of the Center for Epidemiological Studies (CES-D) (0-60 points). This consists of 20 questions associated with the senses perceived and experienced in the last week experienced by the participant. The higher the score, the higher the presence of these symptoms. The cutoff point of the instrument was a value above 11 points.[34]

Additional measures

We collected anthropometric (e.g. body mass index), demographic (e.g. education level, income, and gender), and clinical data (e.g. comorbidities, sleep quality (good/bad) and the use of medication for pain). The history of falls was not assessed. This was derivation of protocol. We also collected information on concurrent care seeking during the program at follow-up.

Sample size calculation

We aimed for total of 40 participants (20 per group). This sample size was adequate for the purpose of this study.

Statistical analysis

The description of the characteristics of the participants was reported. We also reported data for feasibility outcomes using frequency, mean and standard deviations (SD), or median and interquartile range. The feasibility rates were described in absolute numbers and percentages (details in Table 1). We calculated within-group change scores in the secondary outcome measures. We presented mean and 95% confidence intervals of clinical outcomes to observe trends. The analyses were processed in the Jamovi (version 1.6.22), considering an alpha value of 0.05.

Results

Figure 2 illustrates the CONSORT flow chart of participants from screening to follow-up. Two hundred forty-eight patients were recruited between September 2020 and October 2022 after reaching the 40th participant. Data were collected until January 2022, with median (IQR; range) duration to follow-up of 4 (13.5; -15 to 183) days. Reasons for withdrawal are presented in Fig 2. Final sample of 40 participants were randomized to groups. Table 2 describes the baseline demographic and clinical characteristics of the older adult participants randomized in the study. The groups were composed mainly of women, retired, physically sedentary, living with up to 2 Brazilian minimum wages. Baseline characteristics and outcomes were comparable between the groups. However, baseline scores of LBP-related disability were somewhat higher in the PAT-back than the control group. In addition, more older adults in the control group reported being more physically active. We conducted five groups with 2-5 older adults in this period. The delay between randomization and initiation of PAT-back group had a median (IQR; range) of 12.5 (11.8, 1 to 52) days. There is no delay in control group.

Missing data

Follow-up data measures were missing. In the PAT-back group, one participant did not complete the self-efficacy questionnaire, whereas two did not complete the functional capacity test. In the control group, one participant did not respond to any questionnaire (lost to follow-up). Furthermore, one participant did not respond to the self-efficacy questionnaire and self-reported exercise practice, and two did not complete the Patient-specific disability scale and functional capacity test.

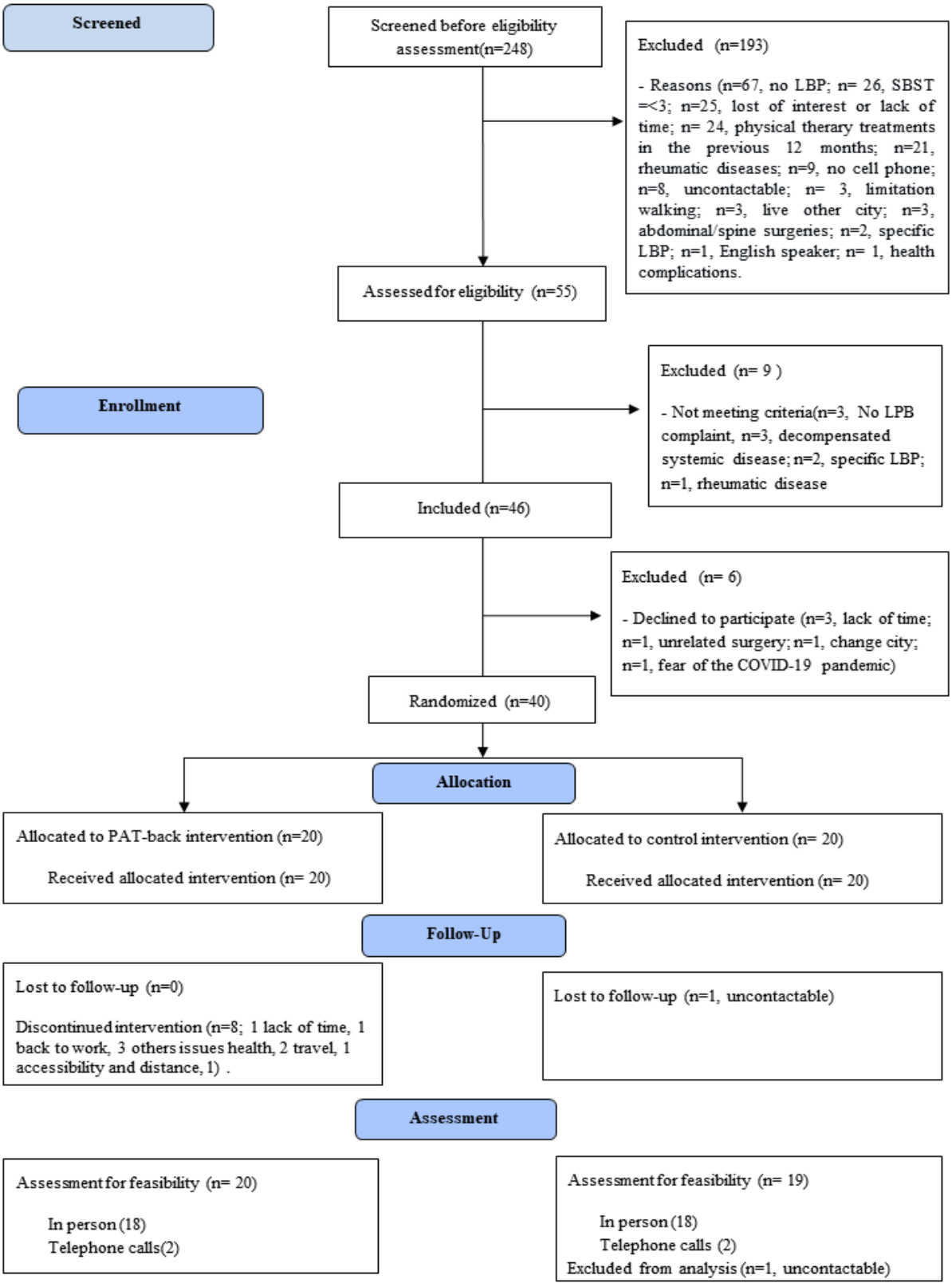

Figure 2. Flow chart of study.

Table 2. Participant demographics and baseline measures

Measures	PAT-back (n=20) Mean (SD) or N(%)	Control (n=20) Mean (SD) or N(%)
Age(years)	68.2(7.21)	67.3(6.65)
Gender(female)	18(90)	15(75)
Marital status		
Married	7(35)	9(45)
Single	4(20)	5(25)
Separated	3(15)	2(10)
Widowed	6(30)	4(20)
BMI(kg/m^2)	31.1(5.79)	27.3(4.89)
Education		
Primary school(5-9 years)	8(40)	9(45)
Secondary school(10-12 years)	7(35)	5(25)
Graduation or post graduation	5(25)	6(30)
Primary occupation		
Retired	14(70)	14(70)
Unemployed	4(20)	3(15)
Paid job or freelance	2(10)	3(15)
Income		
Less to wage[a]	3(15)	0(0)
1 wages	4(20)	8(40)
1-2 wages	6(30)	6(30)
3 wages or more	7(35)	6(30)
Smoking (yes)	1(5)	0(0)
Practice exercise(yes)	3(15)	6(30)
Comorbidities(1-7)	3.80(1.99)	3.45(2.21)
Up to 2	5(25)	9(45)
3 or more	15(75)	11(55)
Sleep quality(bad)	11(55)	12(60)
Use of medication for pain (yes)	9(45)	7(35)
Pain duration(years)	11.2(9.38)	11.6(13.1)
Leg pain(yes)	17(85)	15(75)
Pain intensity(0-10 points)[b]	6.55(2.37)	6.50(1.88)
Disability(0-24 points)[c]	16.7(5.63)	14.4(3.44)
Patient-specific disability(0-10 points)[d]	3.41(2.18)	3.87(1.95)
Depressive symptoms(0-60 points)[e]	19.4(9.58)	18.1(9.07)
Self-efficacy(30-300 points)[f]	161(46.5)	176(48.8)
Self-reported physical activity[g]		
Physical Activity (MET[h])	3119(7820)	3863(4044)
Low level	11(55)	7(35)
Moderate level	5(25)	4(20)
High level	4(20)	9(45)
Functional capacity[i]		
Total score (0-12 points)	7.95(2.19)	7.90(2.00)
Low (4-6)	7(35)	4(20)
Moderate(7-9)	8(40)	13(65)
High(10-12)	5(25)	3(15)

[a] One Brazilian wage = $ 230.8 [b] Pain intensity measured with the numerical rating scale (0–10), [c]Disability measured with the Rolland-Morris Disability Questionnaire (0–24), [d] , Specific disability measured with the Patient Specific Functional Scale(0-10), [e] Depressive symptoms measured with the Depression Scale of the Center for Epidemiological Studies (CES-D)

(0-60), [f]Self-efficacy measured with the Self-Efficacy Scale for Chronic Pain (30-300), [g]Physical activity per week measured with the International Physical Activity Questionnaire (IPAQ), [h]MET = metabolic equivalent of task, [i]Functional capacity measured with The Short Physical Performance Battery(0-12)

Feasibility outcomes

Recruitment rate

248 older adults were recruited. Of these, 46 older adults were eligible. When considering the percentage of eligible participants who consent and were randomized, a rate of 86.95% (40/46) was fully met, indicating feasibility based on our pre-specified criteria. During thirteen months, various methods were implemented (in person and online) due to COVID pandemic. In this period, seven months had less than ten participants recruited. In month August, it was observed greater number of older adults after sponsored post on social media (110 contacts). Due to the second wave of COVID pandemic in Brazil, the research team did not recruit at any primary care units from February to May 2021.

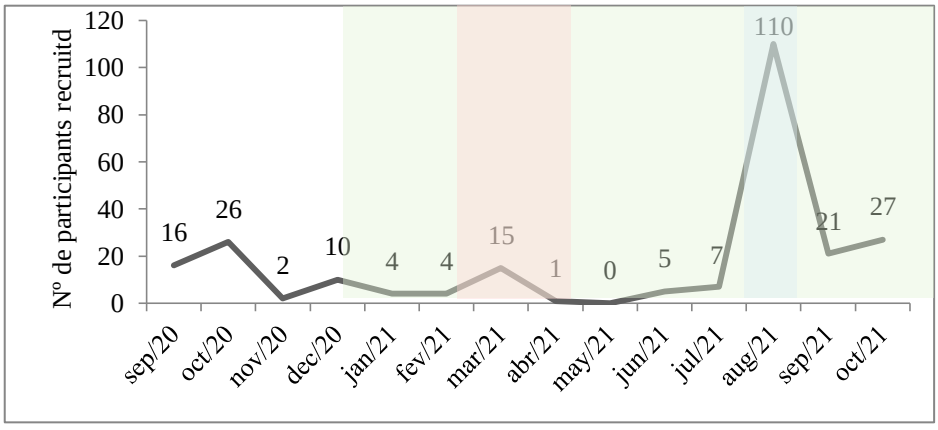

Figura 3. Monthly recruitment rate throughout the study. The green zone indicates the beginning and progress of vaccination of older people in Brazil. The red zone indicates a lockdown period in Fortaleza. The blue zone indicates the advertising period of sponsored posts on social media.

Retention rate

This feasibility criteria of >85% was fully met. At one week post-intervention, The PAT-back group had 100% follow-up and the control group had 95% (n=19/20, 1 lost to follow-up). In the PAT-back group, duration to follow-up had a median (IQR, range) of 1.5 (10; -15 to 91) days and the control group had a median of 9 (44.1, 1 to 183) days. Variations in the duration of follow-up greater than 15 days were mainly due to competing demands (n=3), lockdown periods (n=2), another health problem (n=2), lack of response to contacts (n= 1), travel (n=1), and Covid infection (n=1), with 60% of cases in the control group. In this period, both groups had two follow-ups by telephone calls. Depressive symptoms and self-efficacy questionnaires data were missing because participants reported lack of time or difficulty of listening. Data of functional capacity test were also missing due to the format of the follow-up.

Adherence rate

The adherence rate to program partially met the criteria. In the PAT-back group, 60% (12/20) of older adults attended at least six intervention sessions. Of the eight participants who did not adhere to the intervention, three did not attend any session (n= 3, competing demands). Main reasons to discontinued intervention were: others issues such as health (n=3), travel (n=1), and distance from home (n=1). See all the reasons in figure 1. Only 4 participants booked an extra session.

The adherence rate to unsupervised exercises fully met the criteria. 75% (15/20) of older adults reported acceptable adherence behavior through the EARS. The mean(SD) EARS-B scores were 19.1 (4.93). Of the five older adults who did not adhere to exercise, one adhered to intervention and four did not adhere. The main barriers to adhering to exercise were worsening of pain (47.4%) and other personal demands(31.6%).

The adherence to unsupervised exercise through exercise diary was conducted for descriptive purposes. We obtained a return rate of 77.5% (69/89) of exercise diaries. Of older adults who adhere to intervention, 33.3% (4/12) registered 75-100% adherence to all unsupervised exercise, 25% (3/12) registered between 40 to 70% adherence over the weeks, and (3/12) registered less than 40% of adherence.

Difficulty in understanding and performing intervention and safety to performed home exercise

The criteria for difficulty in understanding the intervention and difficulty performing exercise were fully met in both groups. In the PAT-back group, safety feasibility criteria partially met the criteria (70%). Of the six older adults who feel unsafe three did not adhere to intervention and three adhered. Only two did not adhere to exercise home based on EARS score. In the control group, this criteria was also met.

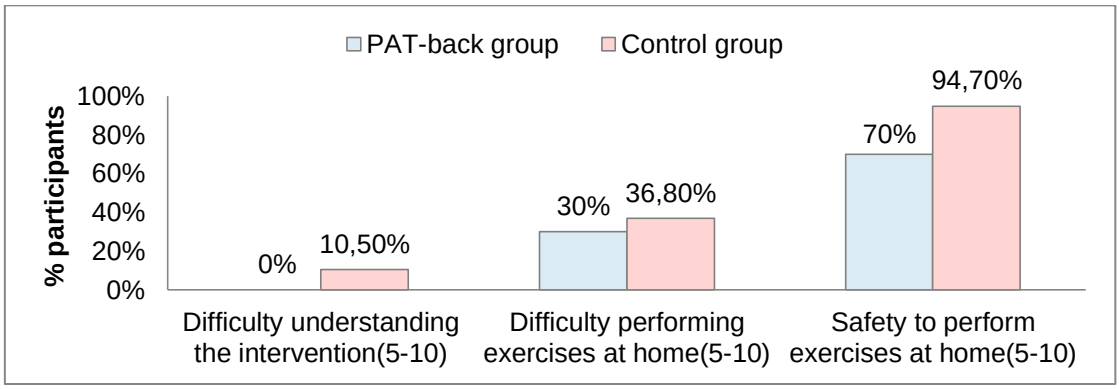

Figure 4. Perceptions about the difficulty and safety of interventions
*Percentage responses equal to or greater than 5 on a likert scale (0-10) indicate high difficulty or high safety.

Perception of utility of mobile technology

This feasibility criteria was assessed and met regarding PAT-back group. 95% (19/20) reported that text messages motivated them to perform the exercises. Three participants did not receive messages because they did not attend any sessions. Only one participant received SMS messages . The other patients prefer to receive messages by WhatsApp ®.

Adverse events

In total, six participants reported adverse events in each group. In the PAT-back, these events were related to extra medications for pain (n=3), other transient complaints (n=2) and functional limitation for 24 hours (n=1). In the group control, older adults reported four events associated extra medication, a fall in bathroom, and need for temporary assistance to specific activities due to the pain.

Secondary outcomes

Table 3 shows the group data at baseline and at eight weeks for the secondary outcomes. Participants in the intervention group self-reported less pain intensity and more functional capacity compared with the control group.

Table 3: Results of secondary outcome measures

	PAT-back group (n=20)			Control group (n=19)		
Outcome	Baseline Mean (SD)	Follow-up	Within-Group Change (95% CI)	Baseline Mean (SD)	Follow-up	Within-Group Change (95% CI)
Pain intensity[a]	6.55(2.37)	2.80(2.40)	3.75(1.9 to 5.5)	6.50(1.88)	6.06(2.93)	0.6(-0.6 to 1.9)
Disability[b]	16.7(5.63)	7.75(5.52)	8.95(6.1 to11.7)	14.4(3.44)	10.7(6.06)	3.7(1.0 to 6.5)
Patient-specific disability [c]	3.41(2.18)	7.05(2.18)	-3.6(-4.9 to -2.2)	3.87(1.95)	5.69(2.34)	-2.0(-3.4 to -0.6)
Self-efficacy[d]	161(46.5)	209.5(55.4)	-52.5(-80.9 to -24.1)	176(48.8)	202.5(43.6)	-27.1(-53.2 to -1.0)
Depression symptoms[e]	19.4(9.58)	14.6(10.2)	5.4(0.5 to 10.3)	18.1(9.07)	13.8(6.71)	3.8(0.2 to 7.4)
Self-reported Physical Activity[f]						
Total MET[g]	3119(7820)	2031.6(2317)	1087 (-2666.1 to 4840.2)	3863(4044)	1917.6(1532.7)	2056.0 (-125.9 to 4238.0)
Low level	11(55.5)	8(40)	-	7(35)	3(15.8)	-
Moderate level	5(25)	6(30)	-	4(20)	14(73.7)	-
High level	4(19.5)	6(40)	-	9(45)	2(10.5)	-
Functional capacity test[h]						
Total score	7.95(2.19)	10.2(1.69)	-2.1(-3.3 to -0.8)	7.90(2.00)	8.59(1.66)	-0.8(-2.1 to 0.3)
Low level	7(35)	0(0)	-	4(20)	1(5.9)	-
Moderate level	8(40)	8(45.5)	-	13(65)	11(64.7)	-
Good level	5(25)	10(55.5)	-	3(15)	5(29.4)	-

[a]Pain intensity measured with the numerical rating scale (0–10), [b]Disability measured with the Rolland-Morris Disability Questionnaire (0–24) [c] , Specific disability measured with the Patient Specific Functional Scale(0-10), [d]Depressive symptoms measured with the Depression Scale of the Center for Epidemiological Studies (CES-D) (0-60), [e]Self-efficacy measured with the Self-Efficacy Scale for Chronic Pain (30-300), [f]Physical activity per week measured with the International Physical Activity Questionnaire (IPAQ), [g]MET = metabolic equivalent of task, [h]Functional capacity measured with The Short Physical Performance Battery(0-12)

Other findings

In follow-up, we identified that 25% (5/20) of older adults in the PAT-back group and 31.5% (6/19) of the control group sought additional care. Pain medication was the commonest co-intervention (PAT-back group, n=4; Control group, n=6).

Discussion

This study aimed to evaluate the feasibility of an RCT investigating the effectiveness of a program of physical exercise and pain education, supported by low-cost mobile technology compared to best practice advice for older adults with chronic LBP within Brazilian primary care. Feasibility criteria related to recruitment, retention, adherence to unsupervised exercise, difficulty understanding the intervention, difficulty performing exercise, safety to perform exercise (Control group) and perception on the use of mobile technology criteria were met. Adherence to program and safety to perform exercise (PAT-back group) had almost met criteria.

Primary feasibility outcomes

We had an adequate recruitment rate based on the criteria, with a significant number of people interested in participating in this study. This result supports that there are many older adults who need care services for LBP[13]. In the literature, the recruitment rate is interpreted in different ways. Different from our data, studies present target percentage of enrollments (e.g >85%) or ratio of enrollments per week (e.g four per week), making comparisons difficult.[35,36] Although the recruitment rate exceeded our target of 100 participants enrolled, the recruitment was a challenge because few people were eligible. This was an unexpected finding. Supplemented methods were needed to achieve older adults. We believe that eligibility criteria were too restrictive, as evidenced by the number of people excluded for not having LPB as the main complaint, with SBST<3 and physical therapy in the previous 12 months. Similar to two feasibility RCTs for older adults with LBP, a large number of participants was recruited to achieve small sample goals.[35,37]

High retention rate was observed based on the criteria and the literature[35,37,38], which supports progression to a large clinical trial. Although some older adults were unable to attend the follow-up visit, this criteria was fully met. Telephone calls can be a strategy to avoid losses at follow-up, but, caution is needed due to the value of face-to-face measures like performance physical tests. To minimize the dropout rate, before randomization, we highlighted the relevance of contributing to the study until its completion. We also kept in touch with participants through telephone calls or messages. In only two cases we made home visits to reinforce the importance of follow-up.

Strategies to improve adherence are needed. Minor modifications must be implemented to meet 75% or more of adherence to the program. Our findings are according to previous studies which indicated adherence rates from 60 to 70%[35,38]. Adherence to a physical activity program has been shown to be the key predictor of improved back pain and it can be influenced positively by better physical function, better socioeconomic conditions, empathy with the physical therapist and intervention in a group. [15,39–41] Similar to what is described in the literature, our data show that demands competing, poor/problems health, further distance from the care center are barriers to treatment adherence. [15,39,40] About unsupervised exercise adherence, we did not find studies using EARS in people with LBP. To our knowledge, only two studies in people with knee osteoarthritis investing telerehabilitation and home exercise (Brazil and Australia) assessed unsupervised exercise adherence based on scores EARS.[42,43] Compared to these studies, our data indicate higher EARS scores (PAT-back=19.1, telerehabilitation =18.1, home exercise =16.5). We hypothesized that motivational text messages and pain education strengthened exercise self-efficacy and reduced fear of movement.

Participants had a low level of difficulty of understanding, suggesting good acceptability of interventions, even our sample has a representative portion of older people with low schooling. This finding is in accordance with studies of high-income countries where older adults consistently reported that experience with pain education was interesting, clear, and either easy or very easy to understand.[38,44] A recent qualitative study highlighted that older adults can understand pain education concepts leading to pain reconceptualization and facilitating self-management and self-efficacy.[41] Additionally, the educational component has been shown preliminary positive effects in pain and disability for older population while combined with other intervention[45]. Patient education, delivered in both groups, can increase physical and psychological knowledge and skills needed to engage in the exercise recommendations[46]. However, it is important to highlight that our sample was screened for cognitive aspects and it may not represent the heterogeneous profiles of aging in Brazil. We emphasize that the way of delivery of the interventions was adapted and clear to the educational level of the population.

We also identified a low level of difficulty to perform exercise at home in both groups. We did not find about this aspect in the literature, but we emphasize the potential of graded activity as a highly acceptable strategy in age-specific programs, although some patients reported slightly too demanding.[47] Control group consistently reported high level safety (94%) whereas the PAT-back group had a lower than expected percentage (70%). About these criteria, we hypothesized that the difference between PAT-back and control groups was due to the greater number and complexity of the exercises prescribed for PAT-back group. Some older adults reported difficulty understanding the illustrations and descriptions of the exercises in the booklet. In addition, this data may be biased by the opinion of PAT-back participants who absented all sessions. The unsafely to perform exercises at

home reinforces the importance of supervision and physical therapist monitoring long-distance in-home exercises. Thus, mobile technology can be a strong ally.

The most of older adults in the PAT-Back group reported that text messages motivated them to perform the exercises, indicating that motivational text messages are possible to implement and well accepted. This is an unprecedented strategy for older people with LBP. A systematic review investigating the effects of text message interventions in the management of musculoskeletal pain found positive and small effects for pain intensity, function, care-seeking behavior, adherence, and quality of life when text messages were added to multicomponent interventions.[17] Text messages reminder also have showed to be a useful tool for empowerment and facilitating the memorization of exercises in older people with recurrent LBP[48]. Additionally, this approach may strengthen the therapeutic alliance and the sense of ongoing care, whereas messages by WhatsApp may be an accessible and cost-effective tool for older adults. Data from the Brazilian Institute of Geography and Statistics estimate that 95.7% of the Brazilian population uses text messaging applications, being an excellent opportunity to reduce costs and provide quality service.[49] Overall, our findings indicate that most of older adults accepted both interventions and their components.

Secondary outcomes

Within-group improvements in mean scores were observed for most outcomes in both groups. These findings may indicate the relevance and applicability of these measures to RCT questions in older adults. Although assessment of the effectiveness of the interventions on the secondary outcomes was not an aim of this study, we found a trend reducing pain intensity and increasing functional capacity in favor of PAT-back, even though adherence to program and safety to exercise at home has been partially limited. These results should be interpreted cautiously due to not being corrected for multiple analyses and small sample size. However, these results add strength to the feasibility results, indicating that our measures may be relevant for assessing change in a group of older adults with chronic non-specific LBP. Similar to our findings, the literature shows positive effects of exercise approaches. A systematic review indicates moderate evidence that physical exercise small improves disability in older people with LBP (MD = 1.7 [95% CI 0.3 to 3.0] on a 25-point scale)[11]. Another recent systematic review showed that multimodal intervention approaches that include exercise for older people with chronic pain are likely to have a positive effect on pain (MD= −0.71 [95% CI −1.08 to −0.34] on a 10 points scale) and disability(MD= −0.47 [95% CI −0.81 to −0.12]), with small to moderate effect sizes only for disability [14]. Once the age-related outcomes are under investigation in LBP field[11], we emphasize the importance of using objective measures of age-related physical performance to detect changes in the older population, such as the SPPB test that evaluates balance, gait speed and, lower limb strength, important variables for activities and social participation. In this

study, older adults changed categories from moderate performance for good performance in the PAT-back group.

Strengths and limitations

To our knowledge, This is the first study to examine the feasibility of an RCT investigating the effectiveness of a program of physical exercise and pain education, supported by low-cost mobile technology compared to best practice advice for older adults with chronic LBP within Brazilian primary care. Key strengths of this trial are the use of motivational text messages, monitoring unsupervised exercise adherence and age-related outcomes. Further, PAT-back was carefully developed based on the biopsychosocial model management of LBP, supervised and home exercises were individualized and performed at moderate intensity. Control group was active and had access to an evidence-based educational booklet and supported by phone calls. Additionally, study strengths include low risk bias (eg. random allocation, concealed allocation, intention to treat analysis, retention >85%), accordance with CONSORT guidelines, prospectively registered protocol and submission of a study protocol.

The current study also has a number of important limitations. The main limitation of this trial is that we encountered difficulty ensuring access to an assessor blinded to group allocation at follow-up because some older adults commented about interventions in this moment. Only 30.7% (12/39) of participants had blinded assessment in follow-up. This fact could have influenced the follow-up assessment. Others limitations include that we do not use objective physical activity measures and some questionnaires (eg. Self-Efficacy Scale for Chronic Pain, EARS-Br) did not have their measurement properties tested in the older population. We observed difficulties in understanding, especially in the Self-Efficacy Scale for Chronic Pain, in which the questions were too long. To minimize this difficulty, the assessors repeated the questions and presented answer cards.

COVID-19 pandemic also may influence our data. This context was likely a barrier for recruitment for our research team and older adults. We also believe that the adoption of online recruitment strategies may have changed the profile of older adults. This change probably increased the educational level of our sample. In addition to difficulty at recruitment stage, we observed delaying the start of intervention and follow-up, as well as reducing the number of older people by group. Fidelity of treatment delivery was broken one moment in the control group because an older adult had COVID-19 between consultation and follow-up. Many older adults reported physical and psychological suffering related to the social isolation imposed by the pandemic, even though they are not infected. This fact can be evidenced by high prevalence of depressive symptoms (77.5%). To minimize these impacts, we follow all safety protocols recommended by health authorities and we adopt flexible deadlines.

Recommendations

Although the findings suggest that an RCT investigating the effectiveness of the PAT-back program compared a control group for older adults with chronic LBP within the Brazilian primary care is feasible, some improvements could be made. To minimize identified challenges related to feasibility, we mainly make recommendations for adherence to the intervention and safety of performing exercises at home. To improve adherence to the PAT-back program, the research team should make session times more flexible and refine the logistics of scheduling extra sessions during the intervention period to replace absences. The inclusion of others primary care centers is also necessary to improve accessibility for the older adults who live in peripheral areas. To increase the safety of performing the exercise, the physical therapist can send short audios or make calls explaining exercises, if needed. Refinement of illustrations and description of exercise in materials is also recommended. As only 18.5% (46/248) of the patients recruited were included, refinement of the eligibility criteria is necessary. We should also consider adjustments to adequate blinding of the assessor as well as refinement of the monitoring plan of missing data. We recommended keeping participants in separate rooms and different times during assessment follow-up to avoid greetings between participants the same group in front of the assessor. Additionally, we suggest separating the outcomes-related questionnaires and general questionnaires during administration. Final recommendations would be the addition of economic analysis and qualitative study about patient perceptions.

Conclusion

Feasibility criteria related to recruitment, retention, adherence to unsupervised exercise, difficulty understanding the intervention and performing exercise, safety to perform exercise (Control group), and perception on the use of mobile technology fully met criteria. Adherence to program and safety to perform exercise (PAT-back group) partially met criteria. Taken together, this feasibility study supports progression to a full trial by incorporating changes to optimize recruitment and eligible participants, adherence to program, and better managing of exercises.

Conflicts of interest

The authors declare that they have no competing interests

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4 CONSIDERAÇÕES FINAIS

A dor lombar é prevalente e altamente incapacitante entre idosos. Considerando o envelhecimento da população e a carga crescente de DL em países de baixa e media renda, o delineamento de programas de intervenção com olhar multidimensional da funcionalidade específico para aqueles com mais de 60 anos é urgente e necessário para redução do impacto desta condição. A abordagem integrada de aspectos biológicos e psicossociais por meio do uso combinado de exercícios, educação em dor e tecnologia móvel, baseados em princípios de terapia cognitivo-comportamental, podem ser favoráveis para a população idosa. No entanto, a viabilidade destas intervenções em contextos socioeconômicos limitados como o da Atenção Primária é uma lacuna na literatura.

A presente dissertação avaliou a viabilidade de um programa de exercícios físicos e educação para a dor, apoiado por tecnologia móvel de baixo custo e de condução de um ensaio clínico randomizado para avaliar eficácia da intervenção sobre dor, incapacidade e capacidade funcional em idosos com dor lombar crônica no ambiente de atenção primária. Os achados desta dissertação apontam para viabilidade da condução de um ensaio clínico futuro ampliado investigando o efeito das intervenções propostas na dor, incapacidade e capacidade funcional.

Com relação aos métodos do estudo, os resultados mostraram taxas satisfatórias de recrutamento e consentimento, e retenção, embora tenhamos observado dificuldade em incluir idosos no estudo devido aos critérios de elegibilidade. Durante o período de aproximadamente um ano, mais de duzentos idosos foram recrutados para a amostra alvo através do emprego de estratégias de recrutamento online e presenciais. A grande maioria dos idosos incluídos no estudo aceitaram participar das intervenções e das reavaliações presencial ou por telefone. Reavaliações por telefone foram necessárias e consideradas em poucos casos.

A viabilidade das intervenções também foi comprovada. Os aspectos educativos mostraram ser de fácil compreensão, ao mesmo tempo, que a dificuldade de realizar os exercícios em casa foi pequena entre os idosos abordados. Quando observamos a adesão aos exercícios em casa, um importante fator para o sucesso de intervenções com exercícios, uma taxa de 75% foi alcançada, indicando um comportamento de adesão satisfatório. A grande maioria dos idosos relatou que as mensagens de texto enviadas por WhatsApp® motivaram a realização dos exercícios em casa. Esta estratégia mostrou o potencial de uso na atualidade com idosos como suporte à educação e aos exercícios de um programa dessa natureza.

Alguns aspectos foram parcialmente alcançados na condução deste estudo, são eles: a adesão ao treinamento presencial em grupo e a percepção de segurança para realizar os

exercícios em casa. A taxa de adesão ao grupo foi parcialmente alcançada de acordo com nossos critérios. Neste sentido, as principais barreiras relatadas para descontinuidade foram: demandas competitivas e outros problemas de saúde. Com relação a segurança para implementar os exercícios em casa, o grupo intervenção demonstrou ter ficado com mais receio. Este fato pode estar relacionado as diferenças entre as intervenções. Para melhorar a adesão e a segurança diante dos exercícios em contexto ampliado, nós fizemos sugestões, as quais envolvem principalmente flexibilidade de horários e maior suporte por áudio ou chamadas telefônicas.

Neste estudo, nós também descrevemos o uso do diário exercícios pelo grupo intervenção e os eventos adversos em cada grupo. Estes dados atendem a demanda científica e clínica para aumentar o reporte de parâmetros de adesão e eventos adversos. Além disso, dados sobre diários de exercícios podem ser úteis para entender a viabilidade de uso desta ferramenta pelo público idoso como mais uma estratégia de monitoramento simples no estudo futuro.

Os desfechos secundários avaliados neste estudo indicaram benefícios em nossa amostra. Embora o foco deste estudo não seja o efeito de intervenção, foi observada tendência de melhora na dor e capacidade funcional a favor do grupo intervenção. Estes dados reforçam a viabilidade de um estudo ampliado, possíveis benefícios para a melhor funcionalidade dos idosos e destacam o valor do uso de medidas baseadas em performance específicas para o público idoso com DL.

Além dos desafios inerentes de um estudo clínico, a pandemia de Covid-19 influenciou modificações ao longo do estudo. Medidas foram adotadas para minimizar, mas estas possivelmente interferiram no recrutamento e nos prazos dos processos subsequentes, bem como na ausência do uso do acelerômetro numa subamostra e na quebra de protocolo em um momento. Vale destacar que nossos resultados foram positivos mesmo diante desta circunstância extenuante global e extremamente desafiadora no Brasil.

Os resultados deste estudo de viabilidade têm implicações importantes para pesquisadores, clínicos e pacientes. Na perspectiva do pesquisador, este estudo demonstra que é viável a condução de um ensaio clínico randomizado ampliado no futuro. Ele, potencialmente, diminui a distância entre uma hipótese/teoria e implementação na prática clínica, pois pode ser considerado o primeiro passo para que nos próximos anos existam opções de tratamentos com eficácia comprovada para idosos com DLC. Ademais, este estudo colabora para antecipar desafios de condução de uma pesquisa em contextos socioeconômicos desfavoráveis e reduz o risco de desperdícios de recursos em um estudo grande não viável,

bem como aponta para a seleção de desfechos relevantes para medir o efeito de intervenções em idosos com DL.

Para clínicos, entendemos que seus resultados não devem servir de apoio para tomada de decisão sobre o efeito de exercícios para esta população, entretanto, este estudo pode ampliar as perspectivas sobre o potencial de intervenções com exercício e educação apoiadas por tecnologia móvel baseadas no modelo biopsicossocial para idosos com DLC na atenção primária, bem como chamar atenção para aspectos de adesão aos atendimentos e segurança da prescrição dos exercícios em casa. Para o público idoso, estudos desta natureza podem trazer a perspectiva destes pacientes para o desenvolvimento de intervenções mais inclusivas, acessíveis e seguras, e que em breve, estas sejam testadas e, se comprovadamente eficazes, implementadas em unidades de atenção primária. Neste sentido, nossos resultados caminham para ampliar o olhar da funcionalidade específico para aqueles com mais de 60 anos. A integração de um programa de atividade física, educação e tecnologia móvel pautado na pessoa idosa e em aspectos biopsicossociais corrobora para redução da incapacidade relacionada a DLC e favorece a implementação do modelo de funcionalidade preconizado pela CIF.

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ATIVIDADES DESENVOLVIDAS DURANTE O MESTRADO

Durante o período de mestrado (fevereiro de 2020 a março de 2022) atividades complementares foram desenvolvidas em diferentes âmbitos. Segue a descrição abaixo:

Projeto de extensão Movimento vinculado a Pró-reitoria de extensão da UFC

- Planejamento e condução para reuniões quinzenais de capacitação e científicas (março a setembro de 2021)

- Telemonitoramento de idosos com dor lombar (maio a junho 2020)

- Desenvolvimento de postagem sobre atividade física para idosos na Pandemia – Página Instagram @movimento.ufc (2020)

Ensino/treinamentos

- Tutora em capacitação online sobre dor lombar em idosos para projeto multidisciplinar - Projeto Serrinha de acompanhamento familiar - PROSAF (junho/2021) – carga horária: 4h

- Participante de oficina de Planejamento de Disciplinas Remotas (junho/2020) – carga horária:8h

- Reuniões quinzenais de acompanhamento dos projetos de mestrado (fevereiro/2021 a fevereiro/ 2022)

Cursos

- Curso Intermediário de Língua Inglesa da Casa de Cultura Britânica. (Carga horária: 448h). Universidade Federal do Ceará, Fortaleza.

- Curso de Formação em Pilates clínico (carga horária: 200h). Lé Sante, Fortaleza

-Intermediário de Pesquisa Clínica. (Carga horária: 70h). Hospital Alemão Oswaldo Cruz, HAOC, Brasil, online.

Dor Lombar para Profissionais da Área de Atenção Básica à Saúde. (Carga horária: 40h).Universidade Federal do Ceará, UFC, Brasil (formato online).

- Elaborando um protocolo de ensaio clínico randomizado (I, II, III) (Carga horária: 30h). Hospital Moinhos de Ventos, HMV, Brasil (formato online)

- Estratificação dos perfis de funcionalidade (Carga horária: 24h). Escola Fiocruz de Governo, FIOCRUZ, Brasil (formato online).

- Curso - Classificação Internacional de Funcionalidade, Incapacidade e Saúde (Carga horária: 20h). Conselho Federal de Fisioterapia e Terapia Ocupacional, COFFITO, Brasil (formato online).

- Atenção à pessoa idosa com deficiência(Carga horária: 60h). Universidade Federal do Maranhão (formato online).

- Curso Saúde da mulher. (Carga horária: 60h).Universidade Federal de São Paulo, UNIFESP, Brasil. (formato online).

- Elaboração de Artigos Científicos(Carga horária: 16h). Universidade Federal do Ceará, UFC, Brasil (formato online).

- Escrita Científica (Carga horária: 16h).Universidade Federal do Ceará, UFC, Brasil. (formato online).

- Disseminação do conhecimento científico(Carga horária: 10h). Hospital Moinhos de Ventos, HMV, Brasil (formato online).

Participação em eventos

- Encontro Universitários da UFC 2021 - setembro/2021(online).

- BACK & NECK PAIN FORUM. 2021 - novembro/2021 (online).

- 1º CONGRESSO ONLINE INTERNACIONAL DE FISIOTERAPIA MÚSCULOESQUELÉTICA (carga horária: 18h) - abril/2021 (online).

- Encontro Universitários da UFC 2020. Março/2021 (online)

- III Simpósio Multidisciplinar em Atenção à Saúde do Idoso(carga horária: 8h) - novembro/2021 (online).

- Simpósio Internacional Online em Ciências da Reabilitação(carga horária: 17h) - março/2021 (online)

- II Congresso Online do Portal Fisio em Ortopedia (carga horária: 15h) - junho/2020 (online)

- II Semana da Atenção Primária do PROSAF (carga horária: 12h) - agosto/2020 (online)

- II Simpósio Multidisciplinar em Atenção à Saúde do Idoso (carga horária: 10h) - agosto/2020 (online)

- Curso - Classificação Internacional de Funcionalidade, Incapacidade e Saúde (carga horária: 20h) - novembro/2020 (online)

Produção e apresentação de resumos

- **SANTOS, A. E. N.;** PEREIRA, J. O. ; PITOMBEIRA, M. H. S. ; SILVA, P. M. S. ; NUNES, A. C. L. ; MORALEIDA, F. R. J. . ESTRATÉGIAS E TAXAS DE RECRUTAMENTO DE UM ESTUDO DE VIABILIDADE PARA IDOSOS COM DOR LOMBAR NA ATENÇÃO PRIMÁRIA: DADOS PARCIAIS. In: Encontros Universitários 2020, 2021, Fortaleza. Revista Encontros Universitários UFC. Fortaleza, 2021. v. 5.

- **SANTOS, A. E. N**.; SILVA, S. L. ; BARRETO, M. C. A. ; NUNES, A. C. L. ; MORALEIDA, F. R. J. . EVOLUÇÃO TEMPORAL DOS DOMÍNIOS DA CLASSIFICAÇÃO INTERNACIONAL DE FUNCIONALIDADE NA AVALIAÇÃO NA DOR LOMBAR CRÔNICA. In: 1o Congresso Internacional de Fisioterapia Musculoesquelética, 2021. Arquivos Brasileiros de Educação Física, 2021. v. 4.

- **SANTOS, A. E. N**.; NUNES, A. C. L. ; PEREIRA, J. O. ; ANDRADE, A. G. P. ; MORALEIDA, F. R. J. . Association between the clinical profile of different groups of patients with chronic low back pain and the Start Back Screening Tool risk groups. In: BACK & NECK PAIN FORUM, 2021. Abstract booklet - Oral apresentations, 2021.

- **SANTOS, A. E. N.;** NUNES, A. C. L. ; PITOMBEIRA, M. H. S. ; PEREIRA, J. O. ; MORALEIDA, F. R. J. . TAXAS DE RETENÇÃO E ADESÃO DE UM ESTUDO DE VIABILIDADE PARA IDOSOS COM DOR LOMBAR NA ATENÇÃO PRIMÁRIA: DADOS PARCIAIS. In: Encontros Universitários 2021, 2021, Fortaleza. Revista Encontros Universitários da UFC. Fortaleza, 2021. v. 6.

- **SANTOS, A. E. N.;** PITOMBEIRA, M. H. S. ; PEREIRA, J. O. ; SILVA, P. M. S. ; NUNES, A. C. L. ; MORALEIDA, F. R. J. . TAXA DE RECRUTAMENTO E ADESÃO DE UM ESTUDO DE VIABILIDADE PARA IDOSOS COM DOR LOMBAR: DADOS PARCIAIS. 2021. (Apresentação de Trabalho/Congresso Brasileiro de Geriatria e Gerontologia)

SANTOS, A. E. N.; NUNES, A. C. L. ; PEREIRA, J. O. ; ANDRADE, A. G. P. ; MORALEIDA, F. R. J. . Association between the clinical profile of different groups of patients with chronic low back pain and the Start Back Screening Tool risk groups. In: BACK & NECK PAIN FORUM, 2021. Abstract booklet - Oral apresentations, 2021

LELES, A. S. ; **SANTOS, A. E. N**. ; ANDRADE, A. L. A. ; NUNES, A. C. L. ; MORALEIDA, F. R. J. . ACEITABILIDADE DO TELEMONITORAMENTO EM IDOSOS COM DOR LOMBAR CRÔNICA. In: Encontros Universitários 2020, 2021, Fortaleza. Encontros Universitários da UFC. Fortaleza, 2021. v. 5.

ANDRADE, A. L. A. ; NUNES, A. C. L. ; LELES, A. S. ; **SANTOS, A. E. N**. ; MORALEIDA, F. R. J. . PERFIL CLÍNICO E SOCIODEMOGRÁFICO DE IDOSOS COM DOR LOMBAR CRÔNICA NA ATENÇÃO PRIMÁRIA: UMA ANÁLISE SECUNDÁRIA. In: Encontros Universitários 2020, 2021, Fortaleza. Revista Encontros Universitários UFC. Fortaleza, 2021. v. 5.

PITOMBEIRA, M. H. S. ; **SANTOS, A. E. N.** ; PEREIRA, J. O. ; NUNES, A. C. L. ; MORALEIDA, F. R. J. . AUTOEFICÁCIA PARA DOR CRÔNICA E SINTOMAS DEPRESSIVOS EM IDOSOS COM DOR LOMBAR CRÔNICA. In: Encontros Universitários 2021, 2021, Fortaleza. Revista Encontros Universitários da UFC. Fortaleza, 2021. v. 6.

PEREIRA, J. O. ; **SANTOS, A. E. N**. ; PITOMBEIRA, M. H. S. ; COSTA, C. S. ; NUNES, A. C. L. ; MORALEIDA, F. R. J. . QUAL A INTENSIDADE DE DOR E O NÍVEL DE INCAPACIDADE EM IDOSOS COMUNITÁRIOS COM DOR LOMBAR CRÔNICA COM DIFERENTES PERFIS DE CAPACIDADE FUNCIONAL?. In: Encontros Universitários 2021, 2021, Fortaleza. Revista Encontros Universitários da UFC. Fortaleza, 2021. v. 6.

Artigos submetidos

- Programa de exercícios físico e educação em dor para adultos com dor lombar crônica na Atenção Primária brasileira - Brazilian Journal of Pain.

- Physical activity supported by mobile technology program (PAT-Back) for older adults with back pain at Primary Care: a feasibility study protocol – Motriz.

Colaboração em outras pesquisas

- Associação entre o perfil clínico de diferentes agrupamentos de pacientes com dor lombar crônica e os grupos de risco Start Back Screening Tool: Estudo transversal com analises de clusters
- Colaboração na orientação de trabalhos de conclusão de curso (2021-2022)

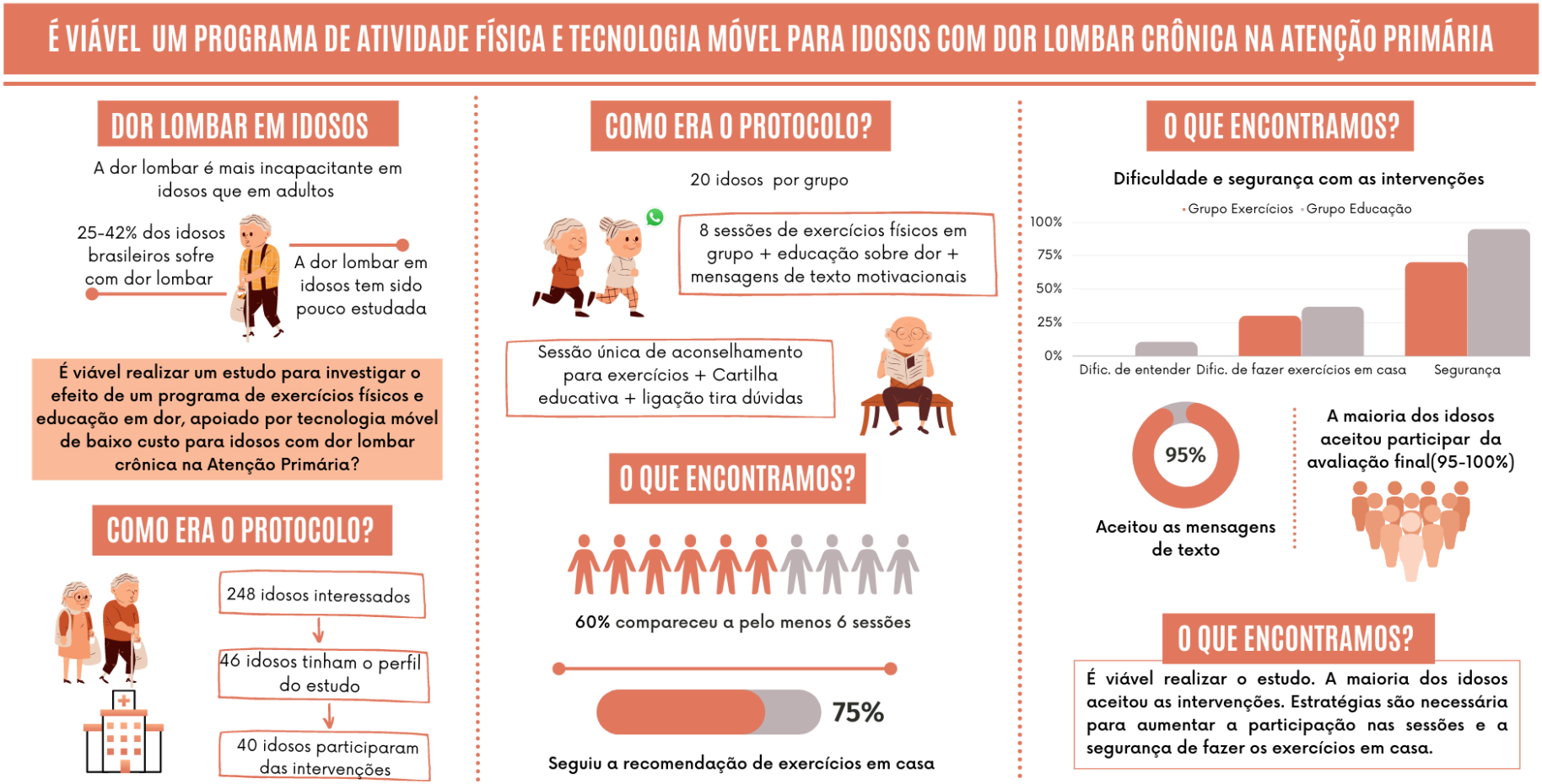
    - Não existe correlação da intensidade de dor e incapacidade relacionada a dor lombar com a capacidade funcional em idosos comunitários com dor lombar crônica (Autora: Jessilane Pereira)

    - Autoeficácia, sintomas depressivos e adesão à exercícios em idosos com dor lombar crônica (Autora: Maria Helena Pitombeira)

Participação em banca

Antonia Thais Guimarães Gomes. Autopercepção da intensidade da dor e os fatores biopsicossociais associados em indivíduos com dor lombar crônica. 2022. Trabalho de Conclusão de Curso (Graduação em Fisioterapia) - Universidade Federal do Ceará.

APÊNDICE A – MATERIAL ILUSTRATIVO PARA DIVULGAÇÃO DO ESTUDO PARA O PÚBLICO LEIGO



Referência: Santos, Ana Ellen do Nascimento. Integração de programa de atividade física e tecnologia móvel para redução da dor e incapacidade em idosos com dor lombar na Atenção Primária: Estudo de viabilidade de ensaio clínico aleatorizado/ Ana Ellen do Nascimento Santos. – 2022

APÊNDICE B – FORMULÁRIO DE VIABILIDADE

Formulário de viabilidade

Identificação: _____

Data: ____/_____/_____

_____

1. Quanta dificuldade você teve para entender algum conteúdo/instrução no momento de treinamento?

0	1	2	3	4	5	6	7	8	9	10
Nenhuma dificuldade										Extrema dificuldade

2. Quanta dificuldade você teve para executar os exercícios em casa?

0	1	2	3	4	5	6	7	8	9	10
Nenhuma dificuldade										Extrema dificuldade

3. O quão seguro você se sentiu para executar os exercícios em casa?

0	1	2	3	4	5	6	7	8	9	10
Nenhuma segurança										Extrema segurança

4. O quanto você acredita que as mensagens de texto motivaram a execução dos exercícios?(não se aplica ao grupo controle)

0	1	2	3	4	5	6	7	8	9	10
Nenhuma motivação										Estrema motivação

4. Você teve algum evento adverso/colateral indesejável relacionado ao aumento da dor como:

- Limitação funcional por 24h
- Necessidade de medicalização extra
- Necessidade de hospitalização
- Outro_____
- Nenhum

APÊNDICE C – DETALHES DAS MENSAGENS MOTIVACIONAIS

Conceitos alvos	Conteúdo da mensagem 1	Conteúdo da mensagem 2	Conteúdo da mensagem 3
Entendendo a dor lombar A dor lombar é multifatorial, não é grave na maioria dos casos e pode ser manejada.	Bom dia, Sr(a) _____. Momentos de relaxamento podem evitar sensações dolorosas. Respire lentamente como praticamos no grupo. Abraços, Ana.	Bom dia, Sr(a) _____. A dor nas costas pode ser tratada com atitudes simples. Busque colocar o exercício de relaxamento muscular no seu dia e sinta-se bem de novo. Abraços, Ana.	Bom dia, Sr(a) _____.O repouso por muito tempo não é indicado para a dor crônica. Movimente-se, alongue e sinta o corpo mais livre. Abraços, Ana.
A importância de se movimentar Movimento é o melhor remédio para a dor lombar	Bom dia, Sr(a) _____. Lembra dos benefícios de se movimentar? Incentivamos uma dose diária dos nossos exercícios! Consulte a cartilha! Abraços, Ana.	Bom dia, Sr(a) _____. Caminhada é indicada para dor lombar! Caminhe em praças ou calçadões próximo a sua casa. Use roupas e calçados confortáveis. Cada passo conta. Abraços, Ana.	Bom dia, Sr(a) _____. O movimento quebra o ciclo da dor. Exercitar-se regularmente na semana trará maior bem-estar e capacidade de realizar tarefas. Abraços, Ana.
Exposição gradativa a atividade Movimento gradual pode quebrar o ciclo de medo e evitação	Bom dia, Sr(a) _____. A atividade física pode ajudar a melhorar a sua dor! O movimento gradual vai ajudá-lo a ter confiança para se sentir mais livre. Abraços, Ana.	Bom dia, Sr(a) _____. Se o movimento gerar dor ou incômodo, não se preocupe, isso não representa lesão! Respeite seu limite e siga se exercitando aos poucos. Abraços, Ana.	Bom dia, Sr(a) _____. Realizar as atividades aos poucos lhe ajudará a fazer melhor coisas importantes para você. Persevere, a cada dia ficará mais fácil. Abraços, Ana.
Manejo de fatores biopsicossociais na dor lombar e envelhecimento Cuidar da saúde geral tem impacto na dor lombar	Bom dia, Sr(a) _____. Sua saúde geral tem impacto na dor lombar. Experimente as dicas para melhorar seu sono e atividades de lazer para lidar com estresse. Abraços, Ana.	Bom dia, Sr(a) _____.O bem-estar também envolve estar junto de outras pessoas. Busque atividades na comunidade. Movimentar e compartilhar momentos ajuda o corpo e a mente. Abraços, Ana.	Bom dia, Sr(a)_____. Permanecer ativo reduz risco de derrame, diabetes, infarto, além de dor. Fique atento para o controle de outras doenças. Abraços, Ana.

Importância do planejamento Planejar é primeiro passo os exercícios entrarem na rotina	Bom dia, Sr(a)_____. Você já pensou em como vai estar ativo amanhã? Planeje suas atividades para ficar ativo e ter menos dor. Abraços, Ana.	Bom dia, Sr(a)_____. Equilibrar atividades do dia a dia é fundamental para não ficar cansado. Faça pausas nas tarefas, respire um pouco e mude de posição. Abraços, Ana.	Bom dia, Sr(a)_____. Organizar a rotina com horário para os exercícios ajudam a sair do sedentarismo. Lembre-se do seu propósito e vamos seguir com as metas. Abraços, Ana.
Como fazer o auto gerenciamento na dor? Você é capaz de monitorar e agir sobre a sua dor	Bom dia, Sr(a)_____. Você lembra o que fazer se a dor atacar? Você pode utilizar de compressas e os exercícios de relaxamento. Abraços, Ana.	Bom dia, Sr(a)_____. Observar como estamos e saber agir diante de momentos de dor é fundamental. Você está sendo treinado e é capaz de colocar em prática as dicas. Abraços, Ana.	Bom dia, Sr(a)_____.Perceber a sensação após exercício faz parte do seu monitoramento. O exercício na dose certa gera cansaço moderado e traz benefícios. Abraços, Ana.
O que aprendemos até aqui? Estamos aprendendo muito sobre dor	Bom dia, Sr(a)_____ Aprendemos muito como lidar com a dor até aqui. Qualquer dúvida consulte a cartilha ou fale conosco. Abraços, Ana.	Bom dia, Sr(a)_____ O exercício estimula substâncias naturais para o controle da dor e nos deixa menos sensíveis a dor. Exercício é o melhor remédio para dor. Relembre sua meta. Abraços, Ana.	Bom dia, Sr(a)_____. Realizar as atividades aos poucos e ir progredindo ajuda a superar o medo do movimento. Como está evoluindo? Continue em frente. Abraços, Ana.
Você está no controle, mas não está sozinho! Mantenha-se ativo e procure ajuda quando precisar	Bom dia, Sr(a)_____Você está no controle, mas não está sozinho. Continue progredindo com os exercícios. Aguardamos você. Abraços, Ana.	Bom dia, Sra_____! Superar barreiras para fazer exercícios pode ser mais fácil com a ajuda de familiares e amigos. Busque alguém para fazer junto. Abraços, Ana.	Bom dia, Sr(a)_____Lembre-se momentos de lazer devem ter espaço no nosso dia. Que tal dançar hoje ou sair para um passeio com amigos? Abraços, Ana.

ANEXO A – ESCALA DE ADESÃO AO EXERCÍCIO

Escala de Avaliação de Adesão ao Exercício (EARS-Br) (não se aplica ao grupo controle)

Seção A: Questionário sobre Exercícios Prescritos

Os profissionais de saúde normalmente recomendam que pessoas com condições crônicas de saúde façam exercícios e/ou atividades para melhorar sua qualidade de vida e lidar melhor com sua condição. As pessoas geralmente encontram sua própria maneira de fazer seus exercícios/atividades. Nós gostaríamos que você nos contasse como você costuma fazer seus exercícios/atividades.

Por favor, marque todas os quadrados que se aplicam a você.

1) Qual exercício/ atividade você foi solicitado a fazer?

☐ Sessões de exercícios individuais com um profissional de saúde

Sessões de exercícios em grupo

☐

☐ Exercícios individualizados para fazer em casa, conforme recomendado por um profissional de saúde

☐ Exercícios regulares em geral

☐ Caminhar

☐ Permanecer ativo em sua vida diária

☐ Outros_____

2) Com que frequência você foi convidado a fazer esses exercícios e/ ou atividades?

☐ todo dia

☐ 4 a 6 dias por semana

☐ 2 a 3 dias por semana

☐ 1 dia por semana

☐ Menos do que isso

☐ Outro_____

3) Por quanto tempo você foi convidado a continuar fazendo esses exercícios e/ ou atividades?

☐ Contínuo

☐ Por uma duração fixa (por favor, especifique-se) _____

☐ Outro (por favor, indique) _____

4**) Com que frequência você está fazendo esses exercícios e/ ou atividades?**

☐ todo dia

☐ 4 a 6 dias por semana

☐ 2 a 3 dias por semana

☐ 1 dia por semana

☐ De modo nenhum

5) Se você parou de fazer seus exercícios / atividades, quando você parou e por quê?

6) Em suas próprias palavras, por favor, você pode nos dizer por que você fez ou não, seus exercícios?

Seção B: Comportamento de adesão

Para cada uma das 6 frases abaixo, por favor marque com um "X" no quadrado que melhor descreva a maneira como você faz seus exercícios/atividades recomendados. Ao pensar em suas respostas, por favor considere quaisquer exercícios/atividades que você foi convidado a fazer como parte do seu tratamento.

1. Eu faço os meus exercícios de acordo com a frequência recomendada

Concordo totalmente	Concordo parcialmente	Nem discordo, nem concordo	Discordo parcialmente	Discordo totalmente
0	***1***	***2***	***3***	***4***

2. Eu esqueço de fazer os meus exercícios

Concordo totalmente	Concordo parcialmente	Nem discordo, nem concordo	Discordo parcialmente	Discordo totalmente
0	***1***	***2***	***3***	***4***

3. Eu faço menos exercício do que o recomendado pelo meu professional de saúde

Concordo totalmente	Concordo parcialmente	Nem discordo, nem concordo	Discordo parcialmente	Discordo totalmente
0	***1***	***2***	***3***	***4***

4. Eu encaixo os meus exercícios na minha rotina

Concordo totalmente	Concordo parcialmente	Nem discordo, nem concordo	Discordo parcialmente	Discordo totalmente
0	***1***	***2***	***3***	***4***

5. Eu não consigo me organizar para fazer os meus exercícios

Concordo totalmente	Concordo parcialmente	Nem discordo, nem concordo	Discordo parcialmente	Discordo totalmente
0	***1***	***2***	***3***	***4***

6. Eu faço a maioria, ou todos, os meus exercícios

Concordo totalmente	Concordo parcialmente	Nem discordo, nem concordo	Discordo parcialmente	Discordo totalmente
0	***1***	***2***	***3***	***4***

Seção C: Razões de adesão ao exercício

Para cada uma das 9 frases abaixo, por favor marque com um "X" no quadrado que melhor descreva o motivo pelo qual você faz ou não seus exercícios/atividades recomendados.

1. Eu não tenho tempo para fazer os meus exercícios

Concordo totalmente	Concordo parcialmente	Nem discordo, nem concordo	Discordo parcialmente	Discordo totalmente
0	***1***	***2***	***3***	***4***

2. Outros compromissos impedem que eu faça os meus exercícios

Concordo totalmente	Concordo parcialmente	Nem discordo, nem concordo	Discordo parcialmente	Discordo totalmente
0	***1***	***2***	***3***	***4***

3. Eu não faço os meus exercícios quando estou cansado(a)

Concordo totalmente	Concordo parcialmente	Nem discordo, nem concordo	Discordo parcialmente	Discordo totalmente

0	*1*	*2*	*3*	*4*

4. Eu sinto autoconfiança para fazer os meus exercícios

Concordo totalmente	Concordo parcialmente	Nem discordo, nem concordo	Discordo parcialmente	Discordo totalmente
0	*1*	*2*	*3*	*4*

5. Minha família e amigos me motivam a fazer os meus exercícios

Concordo totalmente	Concordo parcialmente	Nem discordo, nem concordo	Discordo parcialmente	Discordo totalmente
0	*1*	*2*	*3*	*4*

6. Eu faço os meus exercícios para melhorar a minha saúde

Concordo totalmente	Concordo parcialmente	Nem discordo, nem concordo	Discordo parcialmente	Discordo totalmente
0	*1*	*2*	*3*	*4*

7. Eu faço os meus exercícios porque gosto deles

Concordo totalmente	Concordo parcialmente	Nem discordo, nem concordo	Discordo parcialmente	Discordo totalmente
0	*1*	*2*	*3*	*4*

8. Eu interrompo o exercício quando minha dor piora

Concordo	Concordo	Nem discordo,	Discordo	Discordo

totalmente	parcialmente	nem concordo	parcialmente	totalmente
0	***1***	***2***	***3***	***4***

9. Eu não tenho certeza de como fazer os meus exercícios

Concordo totalmente	Concordo parcialmente	Nem discordo, nem concordo	Discordo parcialmente	Discordo totalmente
0	***1***	***2***	***3***	***4***

ANEXO B – PARECER DO COMITÊ DE ÉTICA

UFC - UNIVERSIDADE FEDERAL DO CEARÁ /

PARECER CONSUBSTANCIADO DO CEP

DADOS DA EMENDA

Título da Pesquisa: Integração de programa de atividade física e tecnologia móvel para redução da dor e incapacidade em idosos com dor lombar na atenção primária: ensaio clínico aleatorizado

Pesquisador: Fabianna Resende de Jesus Moraleida

Área Temática:

Versão: 5

CAAE: 26253519.0.0000.5054

Instituição Proponente: UNIVERSIDADE FEDERAL DO CEARÁ

Patrocinador Principal: Financiamento Próprio

DADOS DO PARECER

Número do Parecer: 5.187.327

Apresentação do Projeto:

A dor lombar (DL) é a condição de saúde mais incapacitante mundialmente, e a queixa musculoesquelética mais reportada em idosos. Abordagens terapêuticas que envolvem atividade física apontam para o prognostico favorável à recuperação da DL em nível de atenção primaria em saúde, embora idosos tenham baixa adesão a terapias com este perfil e sejam pouco representados em estudos com investigações envolvendo exercícios e DL. Logo, estratégias multifacetadas acessíveis e inovadoras para a atenção básica que agreguem programas de atividade física e tecnologias moveis de baixo custo apresentam potencial para reduzir o impacto funcional da DL nesta população. Portanto, o objetivo deste projeto será investigar o efeito de um programa de treinamento em grupo baseado em: 1) exercícios , 2) educação em neurofisiologia da dor, 3) exposição gradativa a atividades, e 4) atividade física orientada, suportado por tecnologia móvel de baixo custo, em dor e incapacidade em idosos com DL crônica (DLC) atendidos na atenção primaria na cidade de Fortaleza.

Objetivo da Pesquisa:

Objetivo Geral

Investigar a viabilidade e o efeito de um programa de treinamento em grupo baseado em exercícios , educação em neurofisiologia da dor, exposição gradativa a atividades, e atividade física orientada, suportado por tecnologia móvel de baixo custo, em dor e incapacidade em idosos

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