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Tecnologias inovadoras e disruptivas para prescrever, incentivar e avaliar a prática de exercício físico

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Tecnologias Inovadoras e Disruptivas para prescrever, incentivar e avaliar a prática de exercício físico

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RESUMO

Introdução: A inatividade física e o sedentarismo são responsáveis por 9% de todas as mortes no mundo, totalizando 5,3 milhões de pessoas por ano, representando grande impacto social e econômico. É urgente, portanto, criar ações estratégicas para promover atividade física a fim de melhorar o engajamento e a aderência à prática da atividade física. Uma estratégia relevante para a prática de exercício segura e na zona alvo adequada, é o uso do biofeedback da frequência cardíaca (FC) através de sensores vestíveis de baixo custo. **Objetivo geral:** Projetar, desenvolver e validar um sistema de *biofeedback*, com sensores vestíveis de FC para o monitoramento e a prescrição da intensidade de exercício físico durante sua realização. **Método:** Este é um estudo transversal piloto e exploratório. Na primeira fase, realizou-se o desenvolvimento do biossensor de pulso de baixo custo, utilizando a tecnologia de fotopletismografia, para medida da FC que foi testado em 20 indivíduos, idade de 20 a 60 anos, aparentemente saudáveis e sem contraindicação para a realização de exercício físico. Para testar e validar o sensor, os sujeitos realizaram o *"Incremental Shuttle Walk Test (ISWT)"* utilizando o frequencímetro Polar H10, referência para medida da FC, e o protótipo do biossensor vestível. A FC foi monitorada 3 minutos em repouso, durante todo tempo de realização do teste e 3 minutos no período de recuperação logo após a finalização do teste. As fases dois e três estão em desenvolvimento. **Resultados:** Esta dissertação é composta por dois artigos científicos: 1) Artigo de protocolo submetido ao periódico *"Trials"* (FI = 2,5) com o seguinte título *"Innovative and Disruptive Technologies to Prescribe, Encourage and Evaluate Physical Exercise in Healthy Adults: A Protocol of Exploratory Study Followed by a Noninferiority, Investigator-Blinded Randomized Clinical Trial"*. Neste artigo descrevemos detalhadamente as fases do estudo incluído a fase1 (desenvolvimento do sensor), fase 2 (teste do sensor em ambiente controlado) e a fase 3 que é um ensaio clinico randomizado para testar e implementar o uso do sensor em ambiente não controlado; 2) Artigo de validação do sensor a ser submetido ao periódico *"Journal of Medical International Research (JMIR,* FI = 7,4*)",* com o seguinte título: *"Validation of a wearable biosensor prototype for measuring heart rate to prescribe physical activity: a transversal exploratory pilot study."* O sensor desenvolvido apresentou excelente concordância para FC de repouso, FC média do teste e FC de recuperação com a referência para medida da FC (Polar H10). **Considerações finais:** Por fim, com o protótipo válido e confiável para medida da FC no repouso, durante o teste e na recuperação, espera-se ser possível fazer a conexão com a aplicação gamificada que está sendo desenvolvida para auxiliar na prescrição adequada da intensidade do exercício, melhorar o engajamento durante a prática de atividade física e reduzir os níveis de sedentarismo trazendo os seus benefícios para saúde da população.

Palavras-chave: Exercício Físico, Monitores de Aptidão Física, Frequência Cardíaca.

ABSTRACT

Introduction: Physical inactivity and a sedentary lifestyle account for 9% of all global deaths, resulting in 5.3 million fatalities annually. This represents a significant societal and economic burden. Consequently, there is an immediate need to implement strategic initiatives aimed at promoting physical activity with the goal of enhancing participation and compliance. One promising approach to facilitate safe exercise within the appropriate intensity range is the utilization of low-cost wearable sensors for heart rate (HR) biofeedback. **Objective**: Design, develop and validate a biofeedback system, with wearable HR sensors for monitoring and prescribing the intensity of physical exercise during exercise. **Method:** This is a pilot and exploratory cross-sectional study. In the first phase, the development of a low-cost pulse biosensor was carried out, using photoplethysmography technology to measure HR. The biossensor was tested on 20 individuals, aged 20 to 60 years, apparently healthy and without contraindications to performing physical exercise. To test and validate the sensor, the subjects performed the Incremental Shuttle Walk Test (ISWT) using the Polar H10 heart rate monitor, a reference for measuring HR, and the wearable biosensor prototype. HR was monitored for 3 minutes at rest, throughout the test and for 3 minutes during the recovery period immediately after completing the test. Phases two and three are under development. **Results:** This dissertation is composed of two scientific articles: 1) Protocol article submitted to the journal “Trials” (IF = 2.5) with the following title “Innovative and Disruptive Technologies to Prescribe, Encourage and Evaluate Physical Exercise in Healthy Adults: A Protocol of Exploratory Study Followed by a Noninferiority, Investigator-Blinded Randomized Clinical Trial”. In this article, we provide a comprehensive description of the study's phases, including phase 1 (sensor development), phase 2 (sensor testing in a controlled environment), and phase 3, which involves a randomized clinical trial to assess and implement the use of the sensor in an uncontrolled environment; 2) Sensor validation article to be submitted to the journal “Journal of Medical International Research (JMIR, FI = 7.4)”, with the following title: “Validation of a wearable biosensor prototype for measuring heart rate to prescribe physical activity: a cross-sectional exploratory pilot study.” The developed sensor demonstrated excellent agreement with the reference for heart rate measurement (Polar H10) for resting HR, average test HR, and recovery HR. **Final considerations:** Finally, with the valid and reliable prototype for measuring HR at rest, during the test, and during recovery, it is expected to be possible to connect it with the gamified application that is being developed to assist in the appropriate prescription of exercise intensity, improve engagement during physical activity, and reduce sedentary lifestyle levels, thereby bringing health benefits to the population.

Keywords: Physical Exercise, Physical Fitness Monitors, Heart Rate.

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AF	Atividade Física
FC	Frequência Cardíaca
FPG	Fotopletismografia
IBGE	Instituto Brasileiro de Geografia e Estatística
IPAQ	Questionário Internacional de Atividade Física
LPWA	Low Power Wide Area Network
METs	Equivalente Metabólicos de Tarefa
OMS	Organização Mundial da Saúde (World Health Organization)
PNS	Pesquisa Nacional de Saúde

SUMÁRIO

1 REFERENCIAL TEÓRICO E JUSTIFICATIVA

1.1 Inatividade Física e Comportamento Sedentário

A inatividade física é caracterizada por níveis insuficientes de atividade física (AF) que não atendem às recomendações atuais das organizações internacionais que regulamentam a pratica de atividade física como a Organização Mundial de Saúde (OMS) (TREMBLAY et al., 2017; LEE et al., 2012). Segundo a OMS, adultos com 18 anos ou mais devem realizar entre 150 a 300 minutos de AF aeróbica de moderada intensidade ou 75 a 150 minutos de AF em intensidade vigorosa por semana para obter benefícios significativos à saúde. Realizar mais de 300 minutos de atividade moderada ou mais de 150 minutos de atividade vigorosa por semana pode trazer benefícios adicionais (WHO, 2020).

Nesse contexto, o comportamento sedentário, definido pelo gasto energético menor ou igual a 1,5 equivalentes metabólicos de tarefa (METs) enquanto sentado, reclinado ou deitado, é uma preocupação crescente (SBRN, 2012; TREMBLAY et al., 2017). Reconhecido como a "doença do século XXI" (AROCHA, 2019), o comportamento sedentário e, os fatores de risco associados a ele, são amplamente estudados. Fatores sociodemográficos, como sexo, idade e renda, desempenham papel crucial. Por exemplo, mulheres e indivíduos mais velhos são mais propensos ao sedentarismo. Estar desempregado ou residir em um país de baixa renda também são fatores de risco (MARTINS et al., 2021). A resistência à prática de atividades físicas, muitas vezes atribuída à "preguiça", ressalta a necessidade de tornar a AF mais atraente (PYKE et al., 2015).

1.1.2 Epidemiologia

Desde 2001, a AF no mundo tem mostrado níveis estagnados. Em 2016, cerca de 1,4 bilhões de adultos, ou mais de um quarto da população global, não se mantiveram fisicamente ativos, elevando significativamente o risco de doenças não transmissíveis e morte precoce (LANCET, 2021). Pesquisas recentes revelam que 25% dos adultos e impressionantes 81% dos

adolescentes não seguem as diretrizes de exercícios aeróbicos estabelecidas pela OMS (GUTHOLD et al., 2018; GUTHOLD et al., 2020; WHO, 2010).

Em um panorama nacional, a Pesquisa Nacional de Saúde (PNS) de 2019, conduzida pelo Ministério da Saúde e divulgada pelo IBGE, destaca que 40,3% dos brasileiros com 18 anos ou mais não atingem os níveis recomendados de AF. Esta estatística leva em conta a AF no lazer, trabalho e deslocamento. Notavelmente, 59,7% das pessoas com 60 anos ou mais não são suficientemente ativas. Em contraste, os grupos de 18 a 24 anos e 25 a 39 anos apresentaram índices de inatividade de 32,8% e 32,9%, respectivamente.

Considerando apenas a AF de lazer, os dados da PNS 2019 mostram que 34,2% dos homens e 26,4% das mulheres, com 18 anos ou mais, alcançaram o nível recomendado. Isso gerou uma média nacional de 30,1%. Para comparar, em 2013, a média estava em 22,7%, com 27,3% dos homens e 18,6% das mulheres atingindo os níveis recomendados. Vale ressaltar que, para este cálculo, são consideradas atividades fora do contexto escolar ou profissional que totalizem pelo menos 150 minutos semanais em intensidade moderada ou 75 minutos em intensidade vigorosa (IBGE, 2019).

Finalmente, no contexto doméstico, 15,8% dos adultos se engajam em atividades físicas intensas, como limpeza pesada, por pelo menos 150 minutos por semana. Este padrão é mais evidente entre as mulheres, com 21,8% delas ativas neste contexto, em comparação com 9,1% dos homens (IBGE, 2019).

1.1.3 Impacto da inatividade física e comportamento sedentário

O baixo nível de AF é um problema de saúde pública não só no Brasil, mas também no mundo impactando diretamente na mortalidade da população. Em 2016, 13,2% e em 2021 11,6% de todas as mortes no Brasil foram relacionadas à inatividade física (GOPA, 2021). Há fortes evidências epidemiológicas demonstrando uma associação entre tempo de comportamento sedentário e taxas de mortalidade por todas as causas (USDH, 2018). Dada essa relação direta entre comportamento sedentário e mortalidade, torna-se imperativo abordar a inatividade física como uma prioridade em políticas de saúde pública.

O comportamento sedentário foi responsável por 9% de todas as mortes no mundo em 2008. Além disso, a inatividade física é responsável por causar de 6 a 10% das doenças não transmissíveis, como, diabetes tipo 2, doença arterial coronariana e cânceres de mama e cólon (LEE et al., 2012). Estudos demonstram que o tempo total sentado e o tempo de tela, que correspondem a comportamentos sedentários, estão associados ao aumento do risco de várias doenças e mortalidade. O risco parece ser mais relevante quando o tempo sentado é de 6 a 8 horas por dia, enquanto o tempo de tela é de 3 a 4 horas por dia (PATTERSON et al., 2018).

Diante disso, a OMS lançou seu primeiro plano de ação em 2013 para redução relativa de 10%, a partir dos dados do ano de 2010, da prevalência de inatividade física no mundo. A meta era promover a redução até 2025, mas o plano já foi reavaliado e estendido até 2030 com objetivo de reduzir as taxas de inatividade física de maneira relativa em 15% tendo como ano base 2016. O plano de ação é guiado por quatro objetivos: criar sociedades ativas, ambientes ativos, pessoas ativas e sistemas ativos. (WHO, 2018)

A análise da presença de dose-resposta parece ter aumento gradual do risco de mortalidade por doenças cardiovasculares. Os resultados de Pandey et al. verificaram aumento dos riscos para doenças cardiovasculares quando o tempo sedentário é superior a 6,8 horas por dia (PANDEY et al., 2016). Apesar disso, vale ressaltar que a falta de qualidade dos métodos de avaliação, que na maior parte dos estudos utilizam questionários autorrelatados, impossibilita a certeza da evidência. Portanto, não há consenso quanto à associação dose resposta de tempo sedentário e risco para doenças cardiovasculares (DURAN et al., 2022). Em vista dessas considerações, torna-se imperativo que futuras pesquisas empreguem métodos de avaliação mais robustos e confiáveis. A relação entre sedentarismo e doenças cardiovasculares é de grande importância para saúde pública, e entender com precisão essa associação pode orientar políticas e recomendações mais eficazes. Ainda que os resultados atuais sugiram uma correlação, a certeza dessa relação permanece um campo em aberto, reforçando a necessidade de estudos adicionais mais rigorosos.

1.1.4 Métodos para mensurar nível de AF

A avaliação do nível de AF pode compreender questionários globais, questionários de recordação de curto prazo, diário de AF, monitores de AF, pedômetros e acelerômetros para determinar a frequência, duração, intensidade, frequência e tipo de AF, bem como, comportamento sedentário (EPSTEIN et al., 1976; AINSWORTH et al., 2015).

Os questionários são uma forma de avaliação popular pela praticidade e baixo custo (CLARK et al., 2009). Dentre os questionários existentes, o Questionário Internacional de Atividade Física (IPAQ) é um método válido e reprodutível para a população brasileira. O questionário é um recordatório das atividades físicas realizadas em diferentes intensidades - leve, moderada e vigorosa-, o tempo e a frequência dos últimos sete dias (MATSUDO et al., 2023). Apesar disso, estudos mostram que recordar o tempo gasto sentado e em comportamentos sedentários específicos pode ser difícil e está suscetível a erros aleatórios e sistemáticos (HEALY et al., 2011).

Os acelerômetros são dispositivos leves e pequenos que permitem mensurar a AF habitual. Dentre os dispositivos mais utilizados estão os fabricados pela ActiGraph, (Pensacola, FL) e pela Phillips Respironics (Bend, OR). O dispositivo Actigraph GT3X é capaz de medir acelerações estáticas e dinâmicas, mede a aceleração linear em três eixos ortogonais que permite saber em qual posição o indivíduo se encontra: em pé, sentado ou deitado. (JOHN et at., 2012). O ActiGraph GT3X apresenta boa validade de critério para contagem de passos (NGUELEU et al., 2022). Pode ser utilizado no quadril ou no punho (CROUTER et al., 2006; JOHN et al., 2012; RICARDO et al., 2020).

Os protocolos de uso divergem conforme as populações e faixas etárias, por exemplo, em crianças recomenda-se três dias de monitoramento para AF geral, quatro dias para AF moderada e cinco dias para AF leve. Para pessoas com 30 anos recomenda-se três dias para AF geral e moderada e quatro dias para AF leve. Para jovens de 18 anos para medir AF geral recomenda-se dois dias e três dias para AF leve e moderada (RICARDO et al., 2020).

1.2 Benefícios da AF

A AF já é muito estudada na literatura científica e há fortes evidências que seja efetiva para prevenção primária e secundária de várias doenças (WARBURTON et al., 2006). Indivíduos que praticam AF em níveis recomendados apresentam menor risco de morte por todas as causas, doença arterial coronariana, hipertensão, acidente vascular encefálico, síndrome metabólica, diabetes tipo 2, câncer de mama e cólon. Somado a isso, a AF é capaz de aumentar a aptidão cardiorespiratória e muscular, melhorar a saúde óssea e a funcionalidade (USDH, 2008; WARBURTON et al., 2010; WHO, 2010). Outros potenciais benefícios da AF são: redução da resposta da FC durante o exercício submáximo, melhora da função músculo esquelética, redução do perfil inflamatório, melhora da função endotelial e sistema nervoso autônomo, aumento das defesas antioxidantes, aumento da força e da endurance muscular, melhora do estado de saúde geral e da qualidade de vida (LAVIE et al., 2015).

Aumentar o nível de AF influencia positivamente na qualidade de vida, reduz risco cardiovascular com a melhora do controle da pressão arterial, do risco de desenvolver doença coronariana e doença arterial periférica, melhora débito cardíaco, dispneia, angina pectoris e a distância de caminhada (NIED et al., 2002; STEWART et al., 2017; MANDOLESI et al., 2018; TIAN et al., 2019).

A AF regular é capaz de incrementar anos de vida na expectativa de vida da população (EZZATI et al., 2004). É uma das estratégias fundamentais para o envelhecimento saudável, pois auxilia na redução da fragilidade e dor, melhora a mobilidade e preserva a função cognitiva (ECKSTROM et al., 2020). O exercício reduz 23% o número de quedas em idoso e consequentemente reduz fraturas em idosos (SHERRINGTON et al., 2019; KEMMLER et al., 2013). Também ocorre a melhora subjetiva pelo aumento satisfação com a vida e felicidade em adultos jovens, meia idade e idosos (AN et al., 2020).

A função cognitiva é impactada positivamente pelo aumento dos níveis de atividade diária total reduzindo alterações cerebrais consideradas grosseiras e típicas de demências (BUCHMAN et al., 2018). Ademais, exercícios aeróbicos e de resistência são capazes de reduzir o risco de desenvolver demência em até 43% e melhorar o desempenho nos testes de função cognitiva em idosos (BOYLE et al., 2009).

1.3 Sensores Vestíveis

Um conceito recente no que se refere a saúde e tecnologia é a saúde móvel (mHealth), que é definida pela American Heart Association como o uso de computação móvel e tecnologias de comunicação, como, telefones celulares e dispositivos vestíveis para questões de saúde (BURKE et al., 2015)

Nesse contexto, a tecnologia de dispositivos vestíveis inteligentes está alinhada com uma nova oportunidade de fornecer assistência em saúde com informações portáteis e acessíveis (KIM et al., 2017). Os sensores vestíveis são disruptivos e úteis em todo o processo de atendimento em saúde: auxiliar no diagnóstico, tratamento e cuidado contínuo do paciente. O que torna esses sensores ainda mais atrativos é o relativo baixo custo e praticidade para coleta de dados (GODFREY et al., 2018).

A tecnologia vestível utiliza os dispositivos diretamente conectados ao indivíduo (AMFT et al., 2009). Os biossensores vestíveis podem ser ligados a tecidos do corpo humano ou dentro do corpo humano através de protótipos implantáveis. Os que são conectados aos tecidos permitem monitoramento confortável, fixação simples e desempenho de detecção não invasiva (MUKHOPADYAY et al., 2022).

Os sensores vestíveis podem ser utilizados em contextos e finalidades diversas. Uma das possibilidades de uso é para monitorar e avaliar a marcha em idosos, amputados, pacientes que tiveram acidente vascular encefálico, paralisia cerebral, parkinson, osteoartrite ou a presença de hemiparesia/hemiplegia não especificada (PRASANTH et al., 2021). Outra finalidade dos sensores vestíveis é a avaliação e prevenção do risco de quedas pela compreensão de associações intrínsecas (CHEN et al., 2022). Também a avaliação do equilíbrio em pé e a estabilidade da marcha de pessoas com Doença de Parkinson (HUBBLE et al., 2015).

Os dispositivos vestíveis podem monitorar biomarcadores de saúde como a FC, temperatura corporal, a variabilidade da FC, estresse e o sono não só em populações com diagnósticos específicos, mas também na população de adultos saudáveis (MILLER et al., 2022; LI et al., 2022; CHALMERS et al., 2021). Entre os biomarcadores estudados, a FC é bastante explorada e é foco de estudos para monitoramento de saúde e prescrição de exercícios.

1.3.1 Dispositivos vestíveis e biofeedback da FC

A FC pode ser mensurada através do padrão ouro, o eletrocardiograma, ou por monitores de frequência cardíaca (GIGGINS et al., 2013). Existem no mercado diversas marcas de monitores de FC, como Apple Watch, Fitbit, Garmin, Polar e Xiaomi (FULLER et al., 2020; CHOW et al., 2020). A medida da FC é medida com precisão dentro de uma faixa de erro de ± 3% com pequena subestimação (FULLER et al., 2020).

Dentre os dispositivos disponíveis, o Polar H10 é um modelo de frequencímetro torácico que se destaca na literatura e é comparável ao monitoramento da FC pelo eletrocardiograma, portanto, uma forma válida de mensuração da FC de forma portátil e não invasiva. Esse dispositivo possui confiabilidade e validade tanto para mensurar a FC em repouso quanto nas diferentes intensidades do exercício podendo ser considerado padrão ouro (SCHAFFARCZYK et al., 2022; GILGEN-AMMANN et al., 2019). Além disso, a variabilidade da FC com coleta de dados através do Polar H10 apresenta forte correlação com o eletrocardiograma e baixo viés de comparação. Portanto, é um dispositivo válido para realizar exame da variabilidade da frequência cardíaca (SCHAFFARCZYK et al., 2022).

Tais sensores vestíveis podem ser usados para o desenvolvimento de aplicativos para monitorar a intensidade de exercício, assim como redes de sensores sem fio baseadas em tecnologias Low Power Wide Area Network (LPWA) para transmitir os sinais coletados (Magrin et. al 2017). Isso ocorre por meio de biofeedbacks obtidos por esses sensores vestíveis, flexíveis e não invasivos (Rodrigues et. al, 2019).

A mensuração da FC pode ser muito importante para prescrição de exercícios através de biofeedback, ou seja, a utilização de um equipamento não invasivo para um determinado parâmetro que fornece sinal visual, auditivo ou tátil. A partir da informação recebida, o usuáriopode orientar seu cuidado para ajuste consciente do parâmetro físico de interesse, por exemplo, a FC (KOS et al., 2016).

O biofeedback pode ser dividido em mecânico e fisiológico; o biofeedback mecânico apresenta as medidas de força e do movimento; o biofeedback fisiológico é sobre medidas do sistema respiratório, cardiovascular

e neuromuscular. Sendo assim, a medida da FC é um tipo de biofeedback fisiológico disponibilizado aos pacientes através de um dispositivo vestível auxiliando no autocontrole de faixas ideais de FC para treinamento físico (GIGGINS et al., 2013).

O biofeedback é uma ferramenta promissora para auxiliar profissionais e pacientes na reabilitação. Atualmente, os estudos concentram-se na reabilitação de pacientes neurológicos, sendo necessários mais estudos para as demais populações (GIGGINS et al., 2013). O autogerenciamento do treino através do biofeedback da FC vem sendo abordado em indivíduos saudáveis com efeitos positivos na FC e na pressão arterial sistólica desde os anos 70 (GOLDSTEIN et al., 1977).

O biofeedback cardiorrespiratório já é usado na literatura em pacientes com IC podendo ser usado para melhorar o risco cardiovascular e aumentar a capacidade de exercício de pacientes com classe funcional I-III e fração de ejeção do ventrículo esquerdo de 31% ou mais (SWANSON et al., 2009). O uso do biofeedback da variabilidade da FC também é alvo de estudo em atletas a fim de melhorar o desempenho esportivo, apesar do número de estudos ainda ser limitado, parece que com os dados atuais o biofeedback da variabilidade da FC é eficaz, seguro e de fácil aplicação para treinadores e atletas (JIMÉNEZ MORGAN et al., 2017).

Um estudo realizado com crianças de 11 a 13 anos avaliou a influência do biofeedback da FC na compreensão da intensidade necessária de exercício descrita nas Diretrizes Nacionais de AF. Nessa população, a exposição a seis aulas de biofeedback da FC não melhorou a capacidade das crianças de estimar e reconhecer a intensidade da AF. Possivelmente a idade e a correlação com a capacidade cognitiva tenham produzido esse resultado (CONLEY et al., 2011). Em adolescentes o biofeedback em tempo real da FC durante a educação física promove alegria durante a corrida o que possivelmente auxilia na aderência ao exercício físico (STÖCKEL et al., 2021).

O uso de biofeedback da FC para definir e controlar a intensidade do exercício também já foi utilizado em esteira assistida por robótica e forneceu desempenho próximo ao nominal e acima do limiar anaeróbico, que foi estimado pelo método V-slope (SCHINDELHOLZ et al., 2012).

1.3.2 Fotopletismografia

Uma das tecnologias relativamente novas para mensurar a FC é a fotopletismografia (FPG) (FULLER et al., 2020). Os dispositivos que utilizam desta tecnologia são feitos de forma direta e considera-se concordâncias relativas de moderada a alta adequadas para monitorar FC (MILLER et al., 2022).

A FPG é medida pelo aumento da absorção de luz que corresponde ao aumento do volume de sangue arterial durante a sístole (NITZAN et al., 2014; YOSHIYA et al., 1980). A FPG é composta por uma fonte de luz em contato com a pele e um fotodetector que permite captar as intensidades da luz. Essa técnica de medição óptica mensura variações de volume sanguíneo dos tecidos captado pelas variações da intensidade de luz que estão associadas ao volume de perfusão (ALLEN et al., 2007; CHALLONER et al., 1974). A FPG é muito usada nos oxímetros de pulso, através das mudanças do volume de sangue arterial, para mensurar a saturação periférica de oxigênio e a FC (NITZAN et al., 2014; BABCHENKO et al., 2001).

1.3.3 Prescrição de exercício pela FC

A prescrição de exercício aeróbico pode ser realizada através de zonas alvos de FC de forma individualizada e eficaz para escolha da intensidade ideal - leve, moderada, vigorosa ou muito vigorosa. Usar a FC para prescrever e monitorar a intensidade de treino é um método de quantificação que certifica que a prescrição e a execução do treino estão sendo feitos na intensidade correta, principalmente, se acompanhados de biofeedback. A escolha desse método de prescrição de exercício aeróbio já é bastante descrita na literatura para diferentes populações: atletas, indivíduos saudáveis e pacientes em reabilitação cardiovascular (USDH, 2018; CARVALHO et al., 2020; RODRIGUES et al., 2019; BORRESEM et al, 2008; GOTTSCHALL et al., 2020; HERDY et al., 2014; NABIL GHORAYEB et al., 2013).

A intensidade de exercício prescrita pela FC leva em consideração percentuais da FC máxima, por exemplo, para intensidade leve a FC é de 35-59% da FC máxima. Já a intensidade moderada a zona alvo é de 60-79%,

vigorosa de 80-89% e muito vigoroso ≥90% da FC máxima (POLLOCK et al., 1990).

As atividades físicas podem ser classificadas em leves, moderadas e vigorosas. Atividades de intensidade leve gastam menos de 3,0 METs caminhar em ritmo lento e tarefas domésticas mais leves, atividades moderadas requerem mais de 3,0 METs e menos de 6,0 METs - andar rapidamente e varrer o quintal, atividade de intensidade vigorosa requer cerca de 6,0 METs ou mais - correr, carregar mantimentos pesados e participar de aula de ginástica extenuante (USDH, 2018).

A prescrição utilizando a FC já é muito abordada na literatura, portanto, a utilização do biofeedback da FC é válida e segura. Apesar disso, os dispositivos vestíveis disponíveis no mercado que realizam a medida da FC são de alto custo, assim sendo, não são de amplo acesso à população durante a prática de exercício. Por isso, são necessários dispositivos de baixo custo com acurácia da medida da FC para serem utilizados como biofeedback da FC para auxiliar na prática de exercício segura e na intensidade correta.

Por fim, com as altas taxas de de pessoas que não atingem níveis recomendados de atividade física e o impacto negativo que isso gera para a saúde, torna-se necessário estratégias tecnológicas e disruptivas que possam auxiliar nesse contexto de saúde. Além disso, é de extrema importância que essas tecnologias sejam seguras, precisas e de fácil acesso a população. Sendo assim, o uso de biossensores vestíveis para medida da FC pode ser uma alternativa eficaz para a correta prescrição da intensidade, e para segurança do indivíduo durante a prática de exercício.

2 OBJETIVOS

2.1 Objetivo Geral

- Projetar, desenvolver e testar um protótipo de biosensor vestível para medida de frequência cardíaca, permitindo seu monitoramento, bem como a prescrição da intensidade durante a realização do exercício físico.

2.2 Objetivos Específicos

- Projetar e desenvolver um protótipo de biossensor vestível para mensurar e monitorar a frequência cardíaca;
- Testar e validar o protótipo de biossensor vestível desenvolvido durante o repouso e durante um teste funcional.

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3 ARTIGO 1

INNOVATIVE AND DISRUPTIVE TECHNOLOGIES TO PRESCRIBE, ENCOURAGE AND EVALUATE PHYSICAL EXERCISE IN HEALTHY ADULTS: A PROTOCOL OF EXPLORATORY STUDY FOLLOWED BY A NONINFERIORITY INVESTIGATOR-BLINDED RANDOMIZED CLINICAL TRIAL

(Formatado conforme normas do periódico Trials; Fator de Impacto: 2,5)

Artigo já publicado.

Trials

STUDY PROTOCOL

Open Access

Innovative and disruptive technologies to prescribe, encourage, and evaluate physical exercise in healthy adults: a protocol of exploratory study followed by a noninferiority, investigator-blinded randomized clinical trial

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Abstract

Background Cardiovascular diseases are a leading cause of mortality worldwide. A significant contributing factor to this mortality is the lack of engagement in preventive activities. Consequently, strategies for enhancing adherence to and duration of physical activity (PA) have become pivotal. This project aims to create and validate innovative, disruptive, and secure technologies that ensure appropriate exercise intensity, bolster adherence to PA, and monitor health biomarker responses pre-, during, and post-physical activity.

Methods This exploratory study, followed by a noninferiority, investigator-blinded randomized clinical trial, will be divided into three phases: (1) development and validation of a sensor for real-time biofeedback during a functional assessment test; (2) integration of biofeedback and gamification into an app for the structured prescription of physical training within a controlled setting; and (3) implementation of biofeedback and gamification into an app for the prescription and monitoring of physical training in an uncontrolled setting. Phase 1 entails a validation test of a biosensor—monitoring heart rate (HR) and steps—during a modified shuttle walk test. In phase 2, the biosensor interfaces with a gamified smartphone application. The training regimen spans 6 weeks, 5 days weekly, with each session lasting 60 min: a five-min warm-up involving stationary gait, followed by 50 min of training at the target HR on the step and concluding with a five-min cool-down at a stationary pace. After 6 weeks of training, a new functional capacity test is conducted. Phase 3 involves an investigator-blinded, randomized clinical trial to demonstrate noninferiority. Participants are randomly assigned to either the intervention group (IG) or the control group (CG). IG participants practice exercise using the gamified application in an uncontrolled environment according to the prescribed method outlined in phase 2. CG participants receive PA practice guidelines exclusively.

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Discussion Anticipated outcomes include improved exercise adherence through the gamified application, better maintenance of prescribed exercise intensity, and enhanced health biomarkers. The results of this study will inform health-related decision-making.

Trial registration The study protocol received approval from the Ethics Committee of Universidade Federal de Ciências da Saúde de Porto Alegre (54,492,221.80000.5345) and has been registered with the Brazilian Registry of Clinical Trials (ReBEC, RBR-359p69v).

Keywords Exercise training, Exercise intensity, Mobile applications, Sedentary lifestyle

Administrative information

Note: The numbers in curly brackets in this protocol refer to SPIRIT checklist item numbers. The order of the items has been modified to group similar items (see)

Title {1}	Innovative and disruptive technologies to prescribe, encourage and evaluate physical exercise in healthy adults: A protocol of exploratory study followed by a noninferiority, investigator-blinded randomized clinical trial.
Trial registration {2a and 2b}.	The Brazilian Registry of Clinical Trials (ReBEC). Identifier: RBR-359p69v, registered on August, 21, 2023.
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Author details {5a}	Fernanda Laís Loro[1], Riane Martins[1], Cintia Laura Pereira de Araújo[1], Lucio Rene Prade[2], Denis Lima do Rosário[3], Marcos Cesar da Rocha Serruffo[3], Italo Adriano Moraes de Freitas, Jéferson Nobre[4], Cristiano Bonato Both[2], Pedro Dal Lago[1] 1- Universidade Federal de Ciências da Saúde de Porto Alegre (UFCSPA). Porto Alegre—Brazil 2- Universidade do Vale do Rio do Sinos (UNISINOS). Porto Alegre—Brazil 3- Universidade Federal do Pará (UFPA). Belém—Brazil 4- Universidade Federal do Rio Grande do Sul (UFRGS). Porto Alegre—Brazil
Name and contact information for the trial sponsor {5b}	São Paulo Research Foundation (FAPESP). Pio XI Streat, 1500—Alto da Lapa – CEP 0546–901- São Paulo -SP—Brazil. Telephone: + 55 011 3838 4000. Email address: converse2@fapesp.br.
Role of sponsor {5c}	The sponsor has no role in the research.

Introduction

Background and rationale {6a}

Roughly 9% of premature deaths worldwide, equivalent to 5.3 million individuals, are directly attributed to physical inactivity [1]. Recently, the World Health Organization (WHO) estimates highlight that over 1.4 billion adults face the risk of developing or worsening conditions linked to inactivity [2]. However, since 2001, global levels of physical activity (PA) have stagnated. In 2016, more than a quarter (1.4 billion) of the global adult population was physically inactive, falling short of WHO's aerobic exercise recommendations [3]. This sedentary lifestyle substantially heightens the risk of noncommunicable diseases and premature death [2]. The scientific community is intently focused on sedentary behaviour due to its detrimental link to health status, the rise of chronic noncommunicable diseases, and its prevalence across populations. Solid epidemiological evidence underscores the connection between sedentary behaviour duration and all-cause mortality rates [4].

According to WHO, up to 5 million deaths worldwide could be averted annually if people were more active and less sedentary. Moreover, engaging in physical exercises is pivotal for averting the onset and managing chronic noncommunicable diseases such as ischemic heart disease, stroke, chronic obstructive pulmonary disease, type 2 diabetes, and certain cancer types. In response, the WHO introduced a global action plan in 2018 aimed at reducing physical inactivity by 15% by 2030 [5]. Consequently, developing strategies to stimulate practice, participation, and adherence to physical activities within sedentary populations is imperative. The potential of gamified interventions is promising in promoting physical activity across diverse demographics [6]. These interventions leverage gaming techniques to infuse activities with playfulness, challenges, relevant rewards, and increased participant motivation, fostering lasting habits [7–9].

In this context, games offer a means to engage individuals in physical activity and educate them on cultivating regular exercise habits [10, 11]. For instance, games addressing healthy eating and exercise have been developed to combat childhood obesity [10]. Additionally, studies highlight the value of gaming in aiding respiratory rehabilitation [11].

Embracing new technologies, wearable sensors for tracking biological signals, and wireless sensor networks like low-power wide area network (LPWA) show promise in promoting physical exercise [12]. Their affordability, sustainability, and integration with the Internet of Things (IoT) make them accessible, especially when integrated into smartphones. Furthermore, they facilitate

noninvasive biofeedback of physiological variables such as heart rate (HR) [13].

There are several brands of wearable devices that measure HR; however, they are expensive for the population [14, 15]. In addition to this technology, gamification has been the subject of attention and study as a way of encouraging physical exercise since 2010. A gap in the literature refers to the integration of gamification with wearable sensors that promote HR biofeedback [16].

Objectives {7}

The primary goals of this study encompass three key objectives: (1) innovative technology development: the first objective revolves around the creation and validation of innovative and secure technologies—a biosensor and an app; these technologies are engineered to guarantee optimal intensity during prescribed physical exercises, setting the stage for a safe and effective workout experience; (2) enhanced adherence and monitoring: the second aim focuses on fostering heightened adherence to physical exercise routines while simultaneously monitoring health biomarker responses; these responses, encompassing heart rate and step data, will be tracked before, during, and after each session, providing valuable insights into the impact of the exercise regimen; and (3) sedentary lifestyle reduction: the third objective seeks to curb the prevalence of sedentary lifestyles within the population. By promoting engagement in physical activity through our technologies, we aim to contribute to a meaningful reduction in sedentary behaviours and their associated health risks.

Trial design {8}

This study employs an exploratory design, succeeded by a noninferiority, investigator-blinded randomized clinical trial, to assess the viability of a gamified application prototype. The prototype incorporates a biofeedback system to guide physical exercises, ensuring adherence to prescribed intensity levels. The study protocol adheres to the guidelines set by Standard Protocol Items: Recommendations for Interventional Trial (SPIRIT) [17] and was registered in the Brazilian Registry Clinical Trials (ReBEC) by the identifier RBR-359p69v.

The study unfolds in three distinct phases: (1) validation of biosensor and app: this phase involves validating the functionality of the biosensor and app within the context of a functional assessment test; (2) validation of biofeedback and gamified application: the second phase encompasses the validation of the biofeedback and gamified application for prescribing and conducting physical training in a controlled environment; (3) validation of gamified application in noncontrolled setting: the final phase entails validating the gamified application for prescription and physical training within a noncontrolled environment. This validation will be executed through a noninferiority, investigator-blinded randomized clinical trial. The flowchart depicting the progression of trial participants can be found in Fig. 1.

This study received approval from the Research Ethics Committee of UFCSPA prior to data collection, with registration number 54492221.80000.5345. The research team assumes responsibility for ensuring the integrity of this study.

Methods: participants, interventions, and outcomes

Study setting {9}

The sample will be conveniently recruited through a social media invitation in a city located in southern Brazil. This protocol was designed exclusively by researchers, without input from community members or patients.

Eligibility criteria {10}

The recruitment of individuals will adhere to specific inclusion criteria: (i) individuals aged between 20 and 60 years without medical contraindication to engage in physical exercise, (ii) possession of a smartphone (cell phone with Android operating system), and (iii) willingness to participate in the research by signing the informed consent form. The exclusion criteria were experience angina during exertion, history of acute myocardial infarction within the 12 months prior to the start of the protocol, require oxygen supplementation, exhibit clinical instability in the month preceding the protocol initiation, uncontrolled hypertension, visual diseases that prevent the performance of the protocol, chronic conditions hindering participation in the exercise protocol, illiterate, and refuse to sign informed consent form.

Who will take informed consent? {26a}

A proficient researcher will administer the informed consent form, ensuring that participants comprehend and willingly agree to participate in the study.

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

On the consent form, participants will be asked if they agree to use of their data should they choose to withdraw from the trial. Participants will also be asked for permission for the research team to share relevant data with people from the universities taking part in the research or from regulatory authorities, where relevant. This trial does not involve collecting biological specimens for storage.

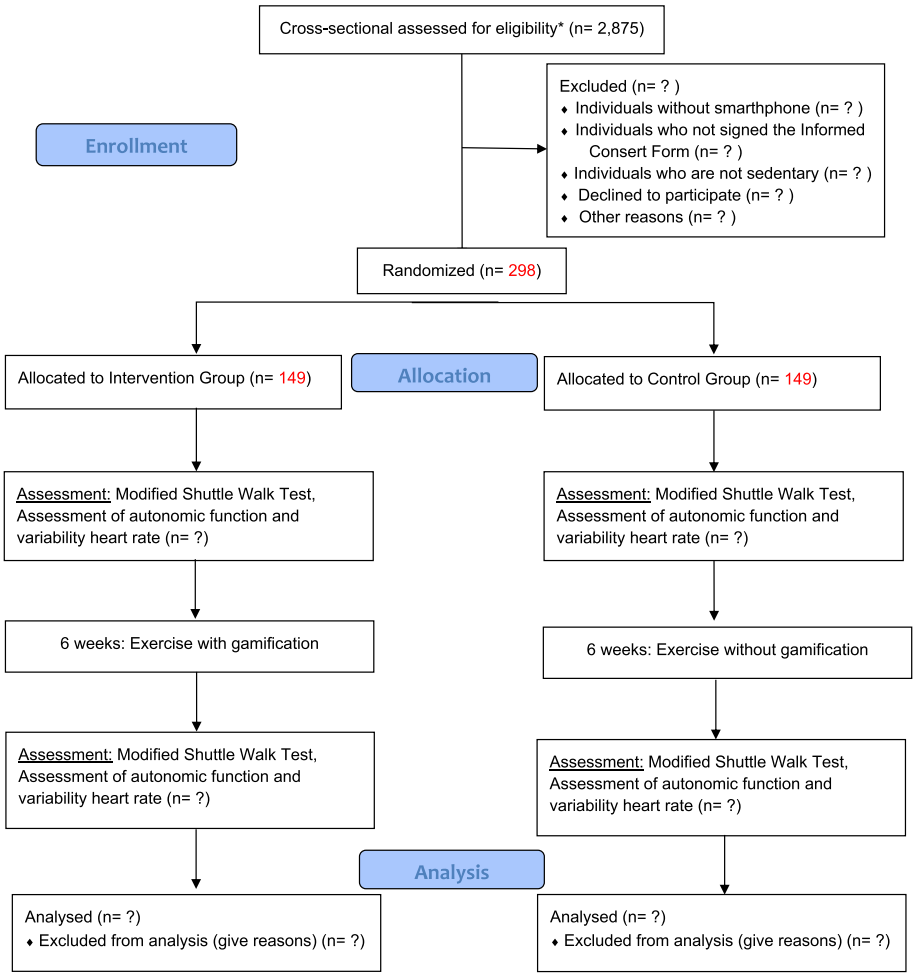

Fig. 1 Flow Chart of participants. Asterisk (*) symbol indicates the following: from the 2875 individuals interviewed using the IPAQ, those identified as sedentary will undergo our eligibility screening. Subsequently, the qualified participants will be randomized

Interventions

Explanation for the choice of comparators {6b}

The World Health Organization recommends engaging in physical activity as a preventive measure against various diseases and for promoting overall health. This recommendation will be implemented within the control group.

Intervention description {11a}

Phase 1: Functional assessment and biosensor validation

Following the development of the wearable biosensor designed for heart rate and step count monitoring, a validation test will be conducted during the incremental shuttle walk test (ISWT) [18, 19]. This ISWT is a recognized, reliable, and secure walking test for assessing functional capacity. Throughout the evaluation, participants will wear the biosensor on their nondominant wrist to capture HR and step data. For HR measurement, the Polar H10 chest strap (Polar Electro Oy, Kempele, Finland) will serve as the reference [20], while the triaxial Actigraph GT3X accelerometer (Actigraph, Pensacola, Florida) will be used on the nondominant wrist to measure step count [21].

The assessment will encompass several variables, including maximum distance, top speed, oxygen consumption (VO_2), tissue oxygenation, and blood pressure (measured at the test's outset and conclusion). Continuous HR tracking will be achieved by both the biosensor under evaluation and the Polar H10 monitor. Additionally, perceived exertion will be recorded using the modified Borg scale [22]; other data to be captured include the stage and corresponding stage at which the test is stopped. Two ISWTs will be conducted, with a maximum interval of one week between them. The results from the most successful trial will be utilized for subsequent analyses. This phase will be executed within a research laboratory environment by trained researchers.

Oxygen consumption

During ISWT, a comprehensive analysis of physiological responses will be conducted using the portable PNOĒ telemetry system (ENDO Medical, Palo Alto, CA). This system enables the assessment of variables like oxygen consumption (VO_2) and carbon dioxide (VCO_2) production through a breath-by-breath approach [23].

Muscle oxygenation

Employing the PortaMon spectrometer (Artinis Medical, Netherlands), alterations in oxyhemoglobin (O_2Hb) and deoxyhemoglobin (HHb) chromophore concentrations will serve as indicators for assessing blood volume and oxygen consumption in the lower limb muscles. For this purpose, an optode will be affixed to the skin using adhesive tape and then covered with black tissue over the proximal third of the vastus lateralis muscle on the dominant limb. Throughout the ISWT protocol, the concentrations of O_2Hb and HHb will be continuously monitored within the muscle [24, 25].

Phase 2: Evaluation of the gamified application for prescription and physical training in a controlled environment

Phase 2 will entail a comprehensive examination of the gamified application's effectiveness within a controlled laboratory setting. Assessments and interventions during this phase will be closely supervised by researchers. The functional test conducted during phase 1 will be replicated at both the outset and the conclusion of phase 2, with trained researchers overseeing the process.

Prescription of physical exercise

Building upon the ISWT results, the intensity of physical exercise will be tailored. The training protocol will span six weeks, with sessions conducted 5 days a week. The training volume will encompass a minimum of 300 min weekly at moderate intensity (40–60% of heart rate reserve) or a minimum of 150 min weekly at vigorous intensity (60–80% of heart rate reserve) [26]. The training will involve a one-step staircase (20 cm height, 60 cm length, and 40 cm width). The target intensity will range from 40 to 80% of the heart rate reserve, calculated based on ISWT. The heart rate reserve will be determined by subtracting the resting heart rate from the maximum heart rate achieved during the functional test. Throughout the exercise session, both HR monitors (Polar H10) and the test biosensor will be closely monitored.

The gamified smartphone application will offer visual feedback on intensity and heart rate, alongside researcher observation of heart rate measured by Polar H10 and the biosensor linked to the gamified application. Additionally, the biosensor, equipped with an accelerometer, will track step count during training. Phases within the scenario will be defined using gamification techniques, incorporating rewards, competitions, and other strategies to ensure adherence and engagement across varying intensities, including warm-up, maintenance, and cool-down phases.

In the initial week, sessions will last 30 min: a 5-min stationary gait warm-up, 20 min of step interval training (2 min at target HR and 3 min at low intensity), and a 5-min stationary gait cool-down. Over the subsequent 5 weeks, each session will extend to 60 min: a 5-min stationary gait warm-up, 50 min of step training at target HR, and a 5-min stationary gait cool-down. Sessions will occur at least twice a week and no more than five times. To meet the minimum adherence criterion, participants must achieve at least 70% of the prescribed training volume outlined in the protocol. Upon completing the 6-week training program, a new functional capacity assessment will be conducted.

Gamified application implementation

A mobile platform integrating gamification techniques will be deployed to ensure adherence to prescribed physical activity (PA) regimens, promoting user engagement. To select the most suitable platform, an analysis will be conducted of prevalent devices among the Brazilian population, as identified in PGB 2021 [27].

This system will enable the design of physical activities that ensure adherence, exercise intensity, and duration. Requirements will be categorized into functional and non-functional aspects. Functional requirements define the system's functions and responses to specific inputs and behaviours, while non-functional requirements outline quality standards and limitations on system services.

The development tools chosen for this system are Blender 2.91 [28] for creating models, animations, and textures and Unity 2020 [29] for animation, direction, rendering, and programming. These tools were selected due to their extensive use in similar solutions.

Avatars will reflect individual physical characteristics, including factors like body fat levels, which directly impact the avatar's appearance. Hair and facial hair customization will be offered with 15 distinct options for each. Additionally, the virtual store within the system will provide 15 clothing models for both genders.

Creating the scenarios involves compiling visual reference materials and adjusting scene elements to match common smartphone screen dimensions. Decoration pieces will be modelled for in-game scenarios and can be purchased using earned in-game coins obtained through exercising. An original soundtrack and synthesized sound effects will enhance the gaming experience, aligning with the game's artistic direction.

All interactions between characters and scenario items will be programmed, encompassing actions like sleeping, eating, and exercising on various equipment like treadmills and bicycles. Engaging mini-games will be integrated into equipment-based exercises, offering players points redeemable for in-game store items. To engage in exercises, players will expend energy points earned through real-world physical activity.

Phase 3: Evaluation of gamified in uncontrolled environment

Phase 3 comprises a noninferiority, investigator-blinded, randomized clinical trial with two distinct groups: the intervention and control groups. Participants within the intervention group (IG) will install the gamified application on their smartphones and use a biosensor during exercise sessions. These sessions will align with the prescribed intensity derived from the ISWT, following the 6-week regimen detailed in phase 2. Participants will be duly instructed to cease exercising if they experience symptoms like chest pain, discomfort, or dizziness.

Within the gamified application, participants will have access to a diary feature, enabling them to log notifications received and their efforts during exercise, both monitored by the biosensor and the gamified app. On the other hand, individuals in the control group (CG) will receive instructions to engage in physical activity at home without biosensor monitoring. They will use the app independently, aiming for a minimum of 300 min per week at moderate intensity or at least 150 min per week at vigorous intensity (self-assessed).

Preceding and following the 6-week period, both the IG and CG will undergo assessments akin to those conducted in phase 1. These include evaluations of functional capacity, muscle oxygenation, and further assessments led by trained and blinded researchers.

Endothelial function assessment

The evaluation of endothelial function will encompass two methods: pulse tonometry (EndoPAT2000, Itamar Medical, Caesarea Israel) [30–32] and ultrasonography to measure flow-mediated vasodilation (FMD) of the brachial artery (MyLab 70 Xvision, Esaote SpA, Florence, Italy) [33, 34].

Autonomic function assessment

The autonomic function of participants will be evaluated through the analysis of heart rate variability (HRV), involving the recording of R-R intervals utilizing the Polar H10 strap (Polar Electro Oy, Kempele, Finland) [21].

For HRV analysis, the time series of RR intervals, acquired from the Polar recordings, will undergo interpolation and decimation. This process aims to generate a time-equally spaced series, subsequently subjected to fast Fourier transformation (FFT) using a MATLAB-based algorithm (MATLAB 6.0, Mathworks Inc., USA). The spectral power will be calculated by integrating within each specified frequency band of interest. The RR time series will be explored in both time and frequency domains, including low frequency (LF), high frequency (HF), and very low frequency (VLF). This will yield parameters related to variability and autonomic balance.

In the time domain, computed parameters will encompass mean RR interval values, standard deviation, and the square root of the sum of the squares of successive differences (rMSSD).

Criteria for discontinuing or modifying allocated interventions {11b}

Physical exercise may lead to effects such as increased heart rate, sweating, fatigue, minor discomfort related to equipment use, discomfort in the lower limbs, and mild muscular fatigue after treadmill training. In the event of any of these mentioned episodes occurring, whether during assessments or physical training, researchers will halt the protocol and provide initial assistance if necessary. If the participant stabilizes and agrees, the protocol may be resumed.

During the execution of training in an uncontrolled environment (phase 3), participants will be advised to discontinue the protocol if any discomfort or symptoms arise. They should await the cessation of these symptoms. If conditions permit, participants should resume from where they left off. If there is no improvement, they will be instructed to contact the researchers via telephone for appropriate measures.

Strategies to improve adherence to interventions {11c}

Following participant randomization, the research team will refrain from implementing specific operational measures to ensure the desired follow-up level. This approach aligns with one of the study's primary objectives, which is to assess exercise adherence facilitated by gamification. What will be done is to send a standard message weekly to both groups requesting weekly recording of the activity carried out during the week in a spreadsheet.

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

Participants in the study will be advised against participating in any other exercise programs simultaneously.

Provisions for post-trial care {30}

The investigators will bear the responsibility of providing assistance to participants who experience any harm during the execution of the protocol.

Outcomes {12}

Primary outcomes will encompass the following: (1) the concordance between HR and step count measurements assessed by the biosensor under test compared to standard devices (Polar H10 and ActiGraph, respectively); (2) participant perception regarding the utility of the gamified application for exercise engagement; (3) comparison with the prevalence of adherence to the physical activity protocol between the control and intervention groups; (4) evaluation of exercise capacity through ISWT, including stage and the corresponding phase at which the test was halted; and (5) measurement of oxygen consumption (VO_2).

Secondary outcomes will include the following: (1) tissue oxygenation assessed via near-infrared spectroscopy (NIRS), (2) subjective perception of exertion during ISWT, (3) evaluation of endothelial function, and (4) assessment of autonomic function.

Participant timeline {13}

After randomization, participants will perform the initial assessment and in the following 6 weeks will perform the exercise prescribed according to the allocation group. After 6 weeks, the assessment will be repeated and participation in the study will end. The chronological schedule for participants can be found in Fig. 2.

Sample size {14}

Since phases 1 and 2 consist of a pilot study for the clinical evaluation of a biosensor prototype and the gamified application that considers a biofeedback system for

	STUDY PERIOD				
	Enrolment	Allocation	Post-allocation		Final Assessment
TIMEPOINT	$-t_1$	0	t_{1-}	t_2	t_x
ENROLMENT:					
Eligibility screen	X				
Informed consent	X				
Allocation		X			
INTERVENTIONS:					
Intervention Group (Exercise with gamification)				X	
Control Group (guidelines for physical activity)				X	
ASSESSMENTS:					
Functional Capacity			X		X
Heart Rate			X		X
Number of steps			X		X
Oxygen consumption			X		X
Tissue oxygenation			X		X
Endothelial function			X		X
Autonomic function			X		X
Adherence					X

Fig. 2 Schedule of enrolment, interventions, and assessments

performing physical exercises, a convenience sample of 15 individuals without medical contraindications for PA will be studied. Assuming a sample loss of 30%, we will recruit 20 participants.

The third phase will be a noninferiority, investigator-blinded randomized clinical trial of the individuals eligible for the study—considering the same eligibility criteria as in phases 1 and 2, in addition to being sedentary—will be divided into two groups: the intervention group (IG), which will receive the exercise protocol through the biosensor and gamified application, and the control group (CG), which will only receive guidelines for performing PA. Considering a confidence level of 95%, power of 80%, ratio of 1:1 between the CG and IG, and estimated prevalence of adherence to the protocol of 70% and 50% for the IG and CG, respectively, it would be necessary to allocate 104 individuals in each group. Adding 30% for possible follow-up losses, 149 sedentary individuals will be assigned to each group, totalling 298 subjects in the study.

Recruitment {15}

The recruitment of sedentary individuals will involve a cross-sectional investigation that will utilize the International Physical Activity Questionnaire (IPAQ), which assesses the frequency, duration, and type of physical activity an individual engages in across various settings, such as work, transportation, leisure time, and domestic chores. This outreach endeavour will be geared towards the broader population, focusing on identifying potential eligible candidates for the study within a specific city in southern Brazil. To achieve random allocation between the CG and the IG, a preliminary cross-sectional study targeting the general population will be executed. This study aims to pinpoint sedentary individuals suitable for inclusion in the randomized clinical trial.

Consequently, considering a confidence level of 95%, a power of 80%, an estimated sedentary lifestyle prevalence of 50%, and a margin of error of 2 percentage points, it will be imperative to interview 2875 individuals (factoring in a 20% allowance for possible losses and refusals). This approach is designed to successfully identify an adequate number of sedentary individuals for participation in the randomized trial's phase 3.

Assignment of interventions: allocation

Sequence generation {16a}

We will employ a computerized random number generator to allocate individuals to either the IG or the CG in a 1:1 ratio. Given the potential variability in VO2 values based on age and gender, we have chosen to utilize block randomization. This method will help us ensure that there is a comparable distribution of age and gender between the two groups, thereby mitigating any potential bias.

Concealment mechanism {16b}

The allocation sequence for this process will be implemented using sealed envelopes to maintain the integrity of the randomization process.

Implementation {16c}

Notably, the researcher entrusted with generating the allocation sequence will remain uninvolved in participants' data collection. Additionally, the investigator responsible for conducting the functional assessments will be kept blind to the participants' allocation status.

Assignment of interventions: blinding

Who will be blinded {17a}

Owing to the nature of our intervention, which encompasses physical activity and gamification, participant blinding will not be feasible. However, the researcher overseeing the evaluation process will be kept blinded.

Procedure for unblinding if needed {17b}

Unblinding will not be permitted at any point during the study due to its inherent design and the nature of the interventions involved.

Data collection and management

Plans for assessment and collection of outcomes {18a}

Participants will be provided transportation vouchers for their visits to Universidade Federal de Ciências da Saúde de Porto Alegre. Reminder calls will be placed to inform participants of their assessment days. During the intervention, no proactive contacts will be initiated to enhance adherence, as adherence is one of the evaluated outcomes.

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

Since one of the study's goals is to assess the impact of gamification on adherence to PA, no specific measures will be undertaken during the study to bolster adherence. Upon the study's conclusion, all participants will be contacted for a final assessment. For measuring adherence, the intervention group will register their adherence via a dedicated application. Meanwhile, the control group will be guided to record their physical activities on a weekly basis added to plans to promote participant retention and complete follow-up.

Data management {19}

Characterization data collection and evaluation result recording will be documented on paper forms.

Subsequently, the principal investigator or their delegate will input the data into an Excel spreadsheet. Another investigator will review this data entry to mitigate potential errors.

Confidentiality {27}

All participant information will be securely stored in locked file cabinets, located in restricted-access areas, for a duration of 5 years post-study completion.

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

See the "Additional consent provisions for collection and use of participant data and biological specimens {26b}" section; there will be no biological specimens collected.

Statistical methods

Statistical methods for primary and secondary outcomes {20a}

Data distribution will be assessed using the Kolmogorov–Smirnov test. Parametric data will be presented as mean ± standard deviation, while non-parametric data will be displayed as median (interquartile range). In phase 1, resting and maximum HR assessed by both the Polar H10 monitor and the test biosensor will be compared using either *t*-test or Wilcoxon test, based on data distribution. The same comparison will be applied to the step count measured by the test biosensor and the ActiGraph triaxial accelerometer. Intraclass correlation coefficient (ICC) will also be computed, along with Bland–Altman analysis to assess HR and step count agreement.

During phase 2, a quantitative analysis will be conducted on the frequency of possible gamified application failures. Pre- and post-exercise protocol data, including functional capacity, VO_2, tissue oxygenation, maximum and resting HR, systemic blood pressure, and perceived exertion, will be compared using *t*-test or Wilcoxon test, based on data distribution. Similarly, the number of steps evaluated by the biosensor under test and the ActiGraph accelerometer will undergo the same analysis, along with ICC calculation.

For phase 3, a qualitative analysis will be performed on participants' diary reports and a quantitative assessment of potential gamified application failures. Step count measured by the biosensor will be compared to the ActiGraph accelerometer using Student's *t*-test or Wilcoxon rank-sum test, depending on residual distribution. Agreement between step counts will be evaluated using Bland–Altman test, Lin's correlation coefficient, and intraclass correlation coefficient. Pre- and post-exercise protocol data, encompassing functional capacity, VO_2, tissue oxygenation, maximum and resting HR, systemic blood pressure, subjective exertion perception, endothelial function, and HRV, will be analysed using Student's *t*-test for paired samples or Wilcoxon signed-rank test, aligned with residual distribution. Participants achieving a minimum of 70% completion of the prescribed protocol will be classified as adherent. As the random allocation is anticipated to ensure baseline comparability between the control and intervention groups, unadjusted analyses will primarily be carried out. In the event of any non-comparability in baseline characteristics due to chance, appropriate adjustments will be made to prevent potential biases. Significance level will be set at $p < 0.05$. The data will be analysed using Statistical Package for the Social Sciences (SPSS) 20.0 (SPSS, Chicago, IL, USA).

For the progression of our study through its phases, we have set clear criteria to determine the acceptability of outcomes: *Phase 1*: We regard the study as satisfactory if the standard error between the biosensor under test and the reference measurements is within 5%. If this criterion is not met, we would reconsider moving to the next phase until the discrepancies are addressed. *Phase 2*: The study's progression will depend on the functionality of the application. Should there be serious errors within the application that prevent exercise or significantly hinder adherence, we would need to address these issues before considering progression to phase 3. *Phase 3*: Here, our benchmark for continuation is achieving at least 70% adherence. Any value below this would prompt us to assess the reasons for the reduced adherence and potentially re-evaluate our approach. Additionally, it is important to note that throughout all phases, we have ensured that there are no operational issues related to the app. Thus, significant data recording failures in earlier phases would indeed influence our decision to proceed to the next phase.

Interim analyses {21b}

No interim analyses are planned throughout the duration of the study.

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

No additional analyses are planned.

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

Intention-to-treat (ITT) analyses will be carried out for the primary outcomes to uphold the initial randomization and maintain the real-world context of participants' treatment assignments. This approach involves including all randomized participants within their originally allocated groups, ensuring the preservation of the study's initial design.

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

If deemed necessary, the corresponding author will provide access to the complete protocol, participant-level dataset, and statistical code.

Oversight and monitoring

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

The biosensor prototype development involves Universidade do Vale do Rio dos Sinos and Universidade Federal do Rio Grande do Sul, while the gamified application is a task for Universidade Federal do Pará. Universidade Federal de Ciências da Saúde de Porto Alegre will handle data collection and analysis. The roles and responsibilities are as follows: the coordinating centre (Universidade Federal de Ciências da Saúde de Porto Alegre) is responsible for overseeing the overall progress of the trial, ensuring adherence to protocols, and liaising with involved universities. The trial steering committee will guide the direction of the trial, ensure milestones are met, and review progress. Day-to-day support is as follows: Universidade Federal de Ciências da Saúde de Porto Alegre will be the primary institution providing daily operational and organizational support for the trial. Meeting frequency is as follows: the group responsible for daily operations meets bi-monthly to review progress, address concerns, and plan for upcoming tasks.

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

Given the trial's single-centre nature, we have not instituted a separate data monitoring committee. All data collection procedures will occur at Universidade Federal de Ciências da Saúde de Porto Alegre and be supervised by the research coordinator (PD).

Adverse event reporting and harms {22}

Any adverse events that occur after enrolment in the study will be documented, and the research team will provide assistance to participants who experience harm during the protocol implementation.

Frequency and plans for auditing trial conduct {23}

We did not consider a trial steering group and independent data monitoring and ethics committee given the low-risk nature of the intervention. The project management group will meet monthly to review trial conduct. The main researcher (PD) will be responsible for monthly monitoring of research conduction and ethical adequacy.

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

Any adjustments to the protocol that could influence the execution of the investigation, encompassing alterations in research goals, research structure, or methodologies, will necessitate an official revision to the protocol.

Dissemination plans {31a}

The outcomes of the research will be showcased in both domestic and international scientific gatherings, in addition to being featured in peer-reviewed journals on a national and global scale. The attribution of authorship in any publications will adhere to the four criteria outlined by the International Committee of Medical Journal Editors.

Discussion

This study focuses on evaluating the development and integration of innovative and safe technologies, such as biosensors and apps, to ensure appropriate intensity during prescribed physical exercises. The aim is to enhance individuals' adherence to physical activity, monitor health biomarker responses (heart rate and steps), and to examine the effects of combining gamification with wearable activity devices to improve exercise engagement.

Gamification's role in promoting PA

Gamification interventions have shown potential in boosting PA participation and self-monitoring while also promoting a sense of enjoyment. However, the literature lacks exploration of the impact of combining gamification with wearable activity devices for promoting PA, as evidenced by divergent findings from a recent systematic review [16]. This study aims to address this gap by investigating the effects of this combination. The hypothesis is that merging gamification with wearable devices can lead to improved adherence to exercise routines.

Reviving enjoyment through gamification

The concept of "serious games" has evolved to a point where the element of fun has diminished, affecting adherence [35]. In response, our study's gamification approach seeks to reintroduce the enjoyment associated with physical exercise, making the activity pleasurable and facilitating adherence. Key aspects of our gamification strategy involve incorporating game elements, utilizing feedback, and setting goals to enhance the effectiveness and perceived reliability of the approach [35].

Gamification's evolving role in health care

Since 2010, gamification has garnered interest among researchers as a tool to enhance engagement in healthcare. However, the existing literature lacks sufficient publications to definitively establish the efficacy of gamification in e-Health contexts [36]. If successful, the outcomes of this trial will furnish the necessary evidence to inform future public health decisions related to exercise practices. The expectation is that the app will foster engagement and bolster adherence to PA, addressing a significant challenge. Moreover, the integration of biosensors into the gamification framework will elevate exercise intensity, accuracy, and safety.

In conclusion, this study endeavours to bridge gaps in knowledge by examining the effects of combining gamification with wearable devices in the context of exercise promotion. The anticipated outcomes include improved exercise adherence, engagement, and intensity, thereby contributing valuable insights for shaping future approaches to public health interventions aimed at enhancing physical activity levels.

Limitations of the study

The study acknowledges several inherent limitations. Primarily, our choice to encompass a broad age range presented challenges, particularly in app communication. Research consistently indicates that distinct age groups, from the elderly to younger individuals, have varying preferences in terms of language use, visual aesthetics, and technological interface design. Elderly participants might find modern app interfaces or overwhelming, while younger participants could desire more dynamic and interactive features. Additionally, individuals in the aged bracket occasionally face challenges in adapting to rapidly evolving technological platforms, which might lead to frustration. This could deter them from consistently engaging with a gamified exercise application. While this age diversity was intentional to achieve a comprehensive understanding, it inadvertently introduced complexities in app design experience. Future iterations of the study might benefit from tailored app versions or additional training sessions to bridge this technological gap across age groups.

Trial status

The recruitment phase for the exploratory study was initiated in August 2022. Looking ahead, the recruitment process for the randomized clinical trial is scheduled to commence in June 2023 and is anticipated to conclude around December 2026. Although the protocol submission took place, a protocol number has not yet been assigned. This ongoing effort aims to rigorously investigate the outlined objectives, contributing valuable insights to the field.

Abbreviations

CG	Control group
FFT	Fast fourier transformation
FMD	Flow-mediated vasodilation
HHb	Deoxyhaemoglobin
HR	Heart rate
HRV	Heart rate variability
ICC	Intraclass correlation coefficient
IG	Intervention group
IoT	Internet of things
ISWT	Incremental shuttle walk test
ITT	Intention-to-treat
LPWH	Low power wide area network
O_2H_b	Concentration of oxyhaemoglobin
PA	Physical activity
REBEC	The brazilian registry of clinical trials
SPIRIT	Standard protocol items recommendations for interventional trials
SPSS	Statistical package for the social sciences
VCO_2	Carbon dioxide
VO_2	Oxygen consumption
WHO	World health organization

Acknowledgements

Not applicable.

Authors' contributions {31b}

CBB and PD were responsible for the conceptualization of the study, protocol development, and data analysis and interpretation, as well as writing and approving the final review. FLL, RM, CLPA, LRP, DLR, MCRS, IAMF, and JN contributed to the method development, data acquisition, analysis and interpretation, writing, final review, and approval of the submitted version. The final version of the manuscript was approved by all author.

Funding {4}

This study is funded by the grant n° 2020/05155–6, São Paulo Research Foundation (FAPESP). The funding source played no part in shaping the study's design and will have no involvement in its execution, data analysis, interpretation, or the decision to publish the findings.

Availability of data and materials {29}

Data can be provided upon a reasonable request.

Declarations

Ethics approval and consent to participate {24}

The research protocol received ethical approval from multiple committees: the Research Ethics Committee of Universidade Federal de Ciências da Saúde de Porto Alegre (CAEE 54492221.80000.5345), the Research Ethics Committee of Universidade do Vale do Rio dos Sinos (CAEE 54492221.8.3001.5344), and the Committee of Ethics in Research of Universidade Federal do Rio Grande do Sul (CAEE 54492221.8.3004.5347). Prior to enrolment, all study participants will undergo a comprehensive informed consent process conducted by trained researchers, ensuring that each participant provides written consent to participate in the study. This meticulous approach underscores our commitment to ethical standards and participant well-being.

Consent for publication {32}

An explicit consent will be sought from participants to ensure their willingness to share their data and contributions in academic and public domains.

Competing interests {28}

The authors declare no competing interests.

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Publisher's Note

4 ARTIGO 2

VALIDATION OF WEARABLE BIOSENSOR PROTOTYPE FOR MEASURING HEART RATE TO PRESCRIBE PHYSICAL ACTIVITY: A TRANSVERSAL EXPLORATORY PILOT STUDY

Formatado conforme normas do periódico Journal Medical Internet Research (JMIR) – *Qualis A1, Fator de Impacto 7,4*)

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Abstract

Background: Biosensors and wearable systems are evolving, especially in health, because they promote continuous or on-demand physiological monitoring**. Objective:** This study aimed to design and validate a wearable biosensor prototype with photoplethysmography and LoRaWAN technology to measure heart rate (HR) during a functional test. **Methods:** A transversal exploratory pilot study with 20 healthy subjects within 20 and 30 years, without contraindications for physical exercise was conducted. First of all, a pulse biosensor prototype for HR monitoring was developed by our laboratory. After evaluation with Actigraph to daily physical activity measurement subjects were asked to perform the Incremental Shuttle Walk Test with a Polar H10 HR chest strap sensor (reference for HR measurement) concomitantly to the wearable biosensor during the test to compare HR responses in real time between the devices. **Results:** The mean difference between Polar H10 rest HR and the sensor during the test was -2.6 [95%CI: -3.5 to -1.8], maximum HR -4.1 [95%CI: -5.3 to -3], mean test HR -2.4 [95% CI: -3.5 to -1.4] and mean recovery HR -2.5 [95% CI: -3.6 to -1.5]. The mean absolute percentage error at rest was -3%, maximum HR test -2,2%, mean test HR -1,8%, and Recovery HR -1,6%. Agreement between the Polar H10 and the biosensor under test were considered excellent for rest HR ($ICC_{3.1}$=0.96), mean HR during the test ($ICC_{3.1}$=0.92), and mean recovery HR ($ICC_{3.1}$=0.96). As for the maximum HR($ICC_{3.1}$=0.78), that can be considered a good response. **Conclusion:** The pulse wearable biosensor prototype tested is a valid tool to monitor HR at rest, during functional test and recovery using to Polar H10 with reference in laboratory.

Introduction

In recent decades, technological advancements have facilitated the advent of wearable sensors. These state-of-the-art instruments bridge the interface between human physiological systems and wireless communication, fostering an enhanced integration of the two domains.[1] Notably, the health field has witnessed significant innovations in biosensors and wearable systems, offering capabilities for continuous and intermittent physiological surveillance.[2]

Such advancements enable the acquisition of a broad spectrum of physiological and health metrics, encompassing parameters like movement detection, heart rate, its variability, sleep cycles, stress markers, fall risk assessments, cutaneous temperature, and respiratory parameters.[3-8]

Within this array of metrics, heart rate emerges as a pivotal parameter. It is utilized as a primary determinant to individualize aerobic exercise regimens via delineated training zones, spanning intensities from light to moderate and vigorous.[9,10] With the capability to non-invasively capture and disseminate biofeedback, wearable sensors present a promising modality for optimizing exercise regimens based on heart rate metrics.[11]

The current market landscape is saturated with diverse brands of heart rate monitoring devices, each claiming precision in their measurements. Prominent entities in this context include Apple Watch, Fitbit, Polar, Xiaomi, and Garmin.[12-14] However, it is noteworthy that many of these equipment options come with a hefty price tag, making them prohibitively expensive for a significant portion of the population. The Polar H10 chest strap, in particular, has received validation for its accuracy in heart rate assessments, especially when benchmarked against the electrocardiogram - a gold standard apparatus for heart rate assessment. This instrument consistently exhibits reliability during rest and various physical activity intensities.[15-16] Nevertheless, its economic implications hinder its ubiquity. Given these considerations, this study aims to to design and validate a wearable biosensor prototype with photoplethysmography and LoRaWAN technology to measure heart rate (HR) during a functional evaluation.

Methods

Study Design

This was a transversal exploratory pilot study conducted from August to December of 2022. The approach was chosen to assess the feasibility and initial outcomes of the wearable biosensor prototype. The study received approval from the local Ethical Committee for Research on Human Beings at the Universidade Federal de Ciências da Saúde de Porto Alegre (approval number 54492221.80000.5345). All participants provided their consent by signing the Informed Consent Form.

Participants

To be included, subjects would be healthy adults (20 to 30 years) without medical contraindications for physical exercise. Exclusion criteria encompassed individuals with visual diseases, chronic conditions such as musculoskeletal or neurological diseases that could hinder the exercise protocol, and those unable to read or write. As the study consists of a pilot and exploratory study for the clinical evaluation of a biosensor prototype, a convenience sample of 20 participants was recruited.

Developed Wearable Biosensor Prototype

The developed prototype employs photoplethysmography (PPG) and traditional PPG heart rate extraction algorithm based on Discrete Fourier Transform (DFT).[17] A method measuring changes in light absorption corresponding to arterial blood volume fluctuations during systole using optical measurements.[18,19] Figure 1 illustrates the prototype of the biosensor developed. This technology, analogous to the one used in pulse oximeters, relies on optical techniques to estimate HR.[18,20] It requires a photodetector and a light source that illuminates the skin to detect variations in light caused by changes in skin blood flow.[20] After prototype development, the LoRaWAN network was selected for transmitting data from the sensor across an exercise area spanning 10 km. The sensor data undergoes pre-processing and is then transmitted via the LoRaWAN network to a concentrator. This data is

subsequently sent to a database where it's encrypted. Each user's data history is stored within this database for sensor validation, statistical analysis, and potential future gamification interfaces.

Data Collection

Incremental Shuttle Walk Test (ISWT)

Following the biosensor prototype's development for HR monitoring, a validation test was conducted during the ISWT-a reputable, reliable, and safe walking test for gauging functional capacity.[21,22] Participants undertook two ISWTs, with the second test occurring seven to fourteen days after the initial examination. Figure 2 displays the methodical procedures' flowchart.

The ISWT is a graded bidirectional test involving movement across a 10-meter corridor in response to audio cues. The standard test encompasses 12 one-minute stages, starting at 0.5 m/s and increasing by 0.17 m/s each minute.[21,22] This protocol was modified to include three additional stages, potentially allowing healthy participants to achieve maximum exertion.[23] The test concludes when participants signal their inability to continue or when they fail to maintain pace.[22] During the ISWT, participants wore the wearable biosensor prototype on their non-dominant wrist and the Polar H10 chest strap (Polar Electro Oy, Kempele, Finland), which served as the HR reference.[15,16] HR data was collected at three points: 3 minutes pre-test, during the test, and 3 minutes post-test. The average collected in each period was used in the analyses.

Statistical Analysis

Absolute and relative frequencies represented qualitative variable results, while quantitative outcomes were depicted as means and standard deviations. The Shapiro-Wilk test assessed data normality.

Heart rate (HR) measurements from the Polar H10 and the wearable biosensor prototype were compared using the paired t-test. Agreement between these measurements was determined using the intraclass correlation coefficient

[$ICC_{(3,1)}$], with interpretation as follows: < 0.5: poor; 0.5 –0.75: moderate; 0.75–0.9: good; > 0.9: excellent.[24] Lin's Concordance Correlation Coefficient (r_c) was also used to check agreement between methods as follows: <0.9: poor; 0.9–0.95: moderate; 0.95–0.99: substantial; >0.99: almost perfect[25].

The mean absolute percentage error (MAPE) was also calculated. High reliability or validity was indicated by MAPE values ≤ 5%.[26] Bland-Altman plots displayed agreement upper and lower limits and bias (mean difference),, as described by Bland et al. (1986).[27] A significance level of 0.05 was set for all tests. Analyses were conducted using IBM SPSS Statistics for Windows, Version 27.0 (Armonk, NY: IBM Corp.).

Results

Twenty participants (men: n = 12, women: n = 8; age: 23.3 ± 2.1 years; height: 169 ± 8.4 cm; weight: 71 ± 31 kg; IMC: 24.55 ± 4.55 kg/ m^2; Distance performed in ISWT: 1190.26 ± 250.62) were recruited via convenience sampling through social media invitations.

The mean differences in heart rate (HR) measurements between the Polar H10 and the wearable biosensor prototype were as follows (Table 2): Rest HR: -2.6 (95% CI: -3.5 to -1.8); Maximum HR: -4.1 (95% CI: -5.3 to -3); Mean test HR: -2.4 (95% CI: 3.5 to -1.4); Mean recovery HR: -2.5 (95% CI: -3.6 to -1.5).

Analyses between the Polar H10 chest strap and the wearable biosensor prototypeshowed (Table 3) : Excellent agreement for rest HR ($ICC_{3.1}$ = 0.96), mean HR during the test ($ICC_{3.1}$ = 0.92), and mean recovery HR ($ICC_{3.1}$ = 0.96); Good agreement for maximum HR ($ICC_{3.1}$ = 0.78). By Lin's Concordance Correlation Coefficient, the agreement is substancial to rest HR (r_c = 0.96) and recovery HR (r_c = 0.96), moderate to mean HR during the test (r_c = 0.92) and poor to maximum HR (r_c = 0.78).

We present the agreement for all the variables in Figure 3 using Bland-Altman plots. Most HR measurements at rest, during the test and during recovery are within the upper and lower limits of the Bland-Altman graphs, therefore, they show measurement agreement.Although some tests did not fall within the upper and lower limits, the error is tolerable, as the values presented

for the clinical measurement of HR are not significant considering the exercise prescription based on HR zones.

Discussion

Principal finding

Our analysis revealed a significant agreement between the HR measurements taken by our developed biosensor prototype and the Polar H10 strap. The biosensor is a valid instrument for HR monitoring during rest, exercise, and recovery periods. On the other hand, the prototype does not accurately measure maximum HR.

Comparison with Prior Work

Low-cost sensors (priced below USD 100) are pivotal in clinical practice and rehabilitation. They aid in physiological measurements for diagnosis and evidence-based practices and also emerge as a vital tool for gamified applications promoting physical activity and rehabilitation.[28] Our findings advance the incorporation of low-cost sensor feedback into gamified applications.

We opted for Low Power Wide Area Network (LPWA) technology due to its cost-effectiveness and expansive range. Furthermore, the ease of its integration with smartphones made it a compelling choice.[29]

Monitoring HR is pivotal for accurate exercise intensity determination and prescription. It's a proven method for athletes, healthy individuals, and cardiovascular patients.[10,11,30-3] Our results corroborate that our sensor is reliable, with intraclass correlation coefficients (ICCs) excellent to rest HR, mean test HR and recovery. By Lin the agreement ranging substantial between moderate in same variables.

Our error percentages are in alignment with the established literature. For instance, Fuller et al. (2020) showcased that 56.5% of wearable HR measurements had an error within ±3%. Our prototype displayed consistent accuracy with MAPE values lower than 3%, aligning with prior research stipulating such thresholds for reliability and validity[12].

We observed the most significant MAPE during resting periods. However, as the literature suggests, pulse sensors often exhibit reduced MAPE during escalated speeds.[14,33] This matches our findings during the ISWT.

In Bland Altman's plots, the agreement was within the upper and lower limits, but some tests were outside this range. This may be due to the difference in the technology used by the Polar H10 and the prototype that used the PPG. PPG technology has a limitation of susceptibility to motion artifacts caused by hand movement and differences in photosensitivity between individuals which may limit data precision[34,35]. In Bland Altman's plots, the agreement must be evaluated from a clinical point of view. In this context, the error HR is tolerable and does not limit the use of the wearable biosensor prototype in exercise.

Limitations

This study primarily was conducted in a lab setting with young participants. Hence, extrapolating the results to different environments or age groups might be premature. Future research will consider diverse settings and broader demographics.

Conclusion

In conclusion, our wearable biosensor prototype effectively measures HR, drawing parallels with the Polar H10 sensor for waste HR, during testing and recovery in the laboratory environment. By validating this prototype, there is potential to integrate it into gamified applications, thus intensifying future benefits in adhering to regular exercise and correct intensity prescription

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Competing interests

The authors have declared that no competing interests exist.

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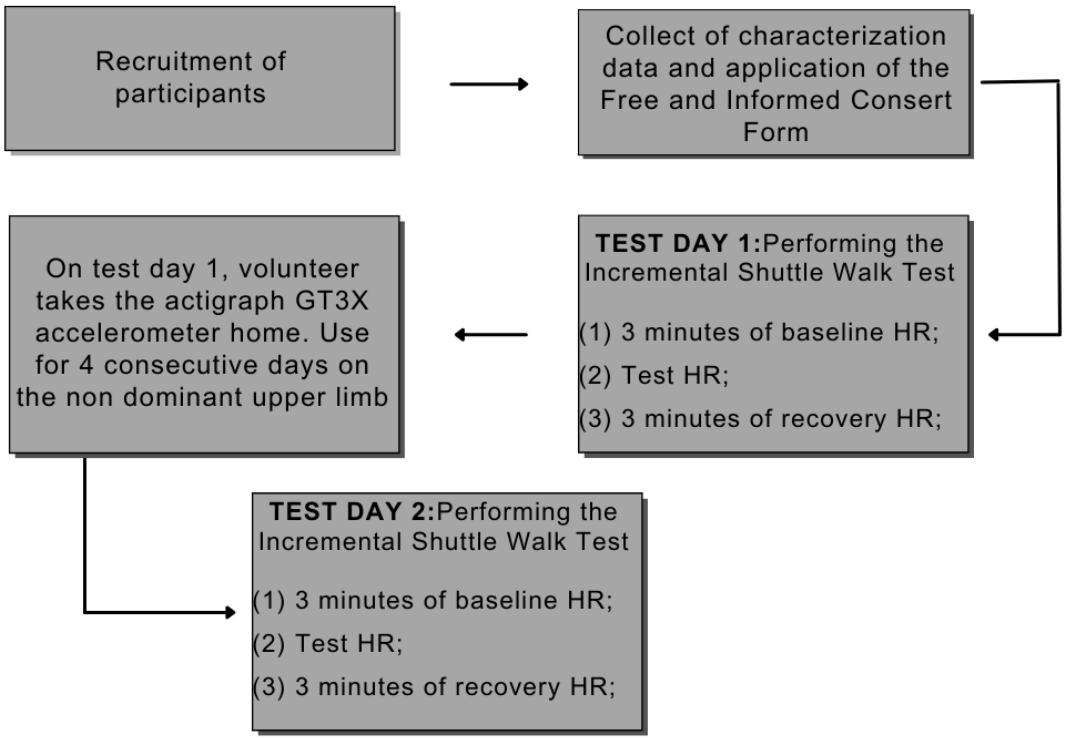
Abbreviations

DFT: Discrete Fourier Transform
HR: Heart Rate
ISWT: Incremental Shuttle Walk Test
ICCs: Intraclass correlation coefficients
LoRaWA: Long Range Wide Area Network
LPWA: Low Power Wide Area Network
MAPE: Mean absolute percentage error
PPG: Photoplethysmography (PPG)

Figure 1- Fluxogram of methodical procedure

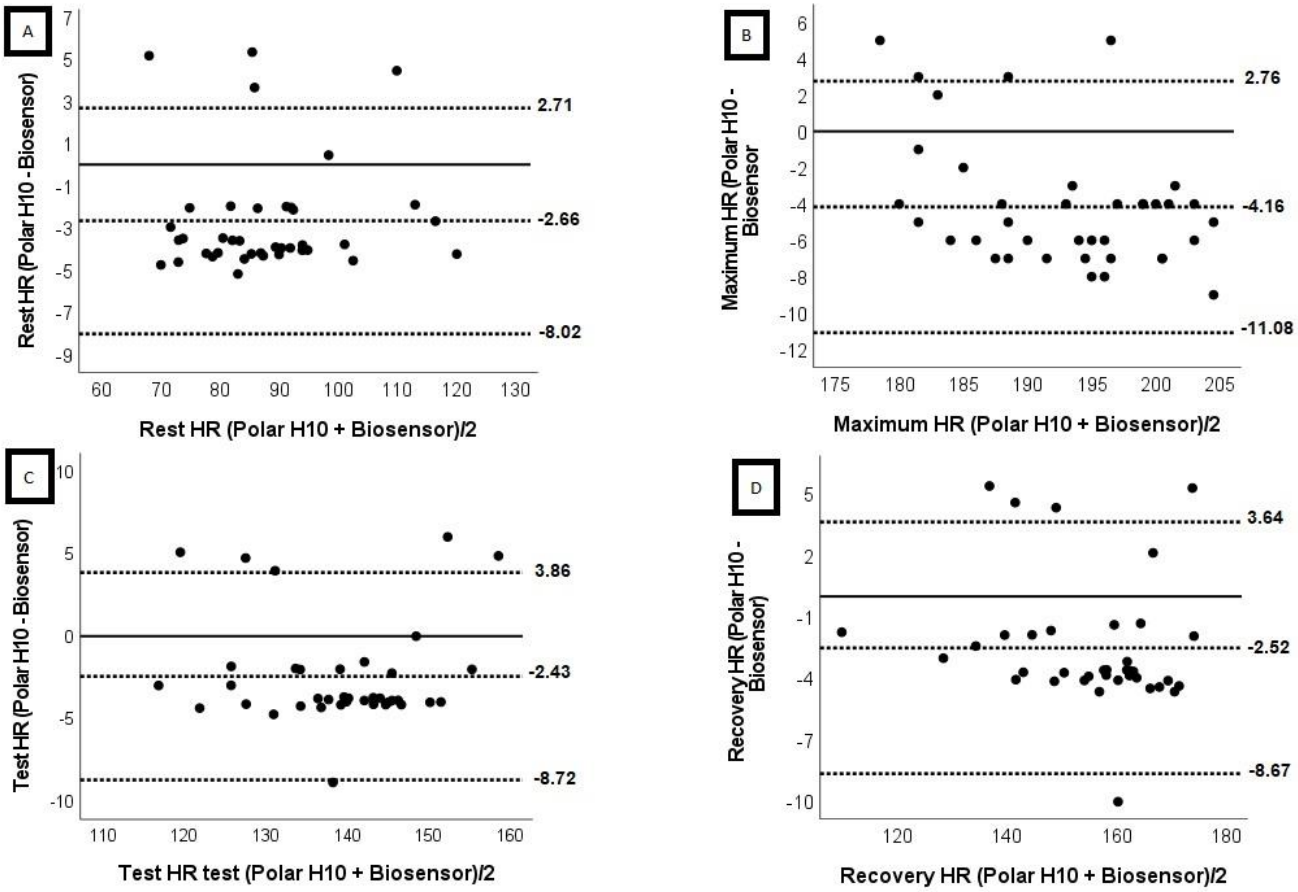


Legend: Heart rate (HR).

Figure 2: Wearable biosensor prototype developed

Legend: Photoplethysmograph (PPG); Long Range Wide Area Network (LoRaWAN).

Figure 3. Bland-Altman analysis to compare the heart rate of the Polar H10 sensor chest strap and the pulse biosensor prototype during the rest period (A), maximum HR (B), mean test HR (C), recovery HR (D).



Legend: Heart rate (HR).

Table 1: Mean, standard deviation and mean absolute percentage error (MAPE) obtained for HR of the chest strap of the Polar H10 sensor and pulse biosensor prototype during the rest period, maximum HR, mean test HR, mean HR 3 minutes of recovery.

	Polar H10		Biosensor		Difference (Polar H10 - Biosensor)			
	Mean	SD	Mean	SD	Bias	MAPE%	CI95%	
Rest HR	86.7	12.6	89.4	12.5	-2.6	-3	-3.5	-1.8
Maximum HR test	190.7	7	194.9	8.4	-4.1	-2.2	-5.3	-3
Mean Test HR	137.5	9.7	139.9	9.7	-2.4	-1.8	-3.5	-1.4
Recovery HR	153.8	13.6	156.3	14.2	-2.5	-1.6	-3.6	-1.5

Legend: Heart Rate (HR); Standard deviation (DP); Mean absolute percentage error (MAPE); Confidence Interval (CI), Intraclass correlation coefficient (ICC).

Table 2: Agreement between the heart rate measurement of the biosensor prototype and Polar H10 evaluated by the intraclass correlation coefficient ($ICC_{3.1}$) and Lin's Concordance Correlation Coefficient (r_c).

	$ICC_{3.1}$	**CI95%**		**r_c**	**CI95%**	
Rest HR	0.96	0.71	0.98	0.95	0.92	0.97
Maximum HR test	0.78	0.09	0.93	0.78	0.66	0.86
Mean Test HR	0.92	0.7	0.97	0.92	0.85	0.95
Recovery HR	0.96	0.82	0.98	0.96	0.92	0.97

Legend: Heart Rate (HR); Confidence Interval (CI), Intraclass correlation coefficient (ICC); Lin's Concordance Correlation Coefficient (r_c).

5 CONCLUSÃO GERAL

Com base nas análises e experimentos realizados é possível concluir que o estudo atingiu os objetivos esperados de projetar, desenvolver e testar um protótipo de biosensor vestível para medida de frequência cardíaca, permitindo seu monitoramento, bem como a prescrição da intensidade durante a realização do exercício físico. O protótipo de biossensor vestível desenvolvido é válido e confiável para mensuração da frequência cardíaca em ambiente de laboratório, sendo possível utilizá-lo para feedback da intensidade de exercício pensando na monitorização e prescrição de protocolos de exercício físico.

Nesse sentido, com a validação do protótipo será possível acoplar a aplicação gamificada em desenvolvimento ao biossensor vestível tornando possível a sequência do estudo. Sendo assim, espera-se que a integração entre o biossensor vestível desenvolvido e aplicação gamificada permita a aderência, engajamento, intensidade e tempo de exercício corretos para auxiliar no combate a inatividade física.

6 IMPACTOS DO TRABALHO

O sedentarismo é uma realidade preocupante tanto na população brasileira quanto mundial, acarretando diversas consequências adversas para a saúde. Diante disso, é primordial desenvolver métodos para a prescrição de exercícios físicos que sejam seguros e na intensidade correta. Este estudo ressalta a adoção de uma tecnologia vestível prática e acessível capaz de mensurar a FC, essencial para a adequada prescrição da intensidade dos exercícios. Graças ao biossensor vestível, confiável e preciso na mensuração da FC, podemos garantir uma prática de atividade física mais segura e ajustada à realidade e necessidade de cada indivíduo. Acredita-se que o custo do protótipo será menor dos que estão disponíveis no mercado o que irá ampliar a possibilidade de democratizar o acesso a essa inovação, fomentando uma rotina de exercícios mais segura para a população. Ao validar esse protótipo, há potencial para integrá-lo a aplicativos gamificados, intensificando, assim, os benefícios futuros na adesão à prática regular de exercícios, combate ao sedentarismo e promoção da saúde pública. Isso ainda abre portas para a criação de novos produtos e serviços voltados ao enfrentamento do sedentarismo.

ANEXOS

ANEXO A- Carta de Aprovação no Comitê de Ética em Pesquisa

UNIVERSIDADE FEDERAL DE CIÊNCIAS DA SAÚDE DE PORTO ALEGRE

PARECER CONSUBSTANCIADO DO CEP

DADOS DO PROJETO DE PESQUISA

Título da Pesquisa: PROJETO ATIVARS: MOVIMENTO CONTRA O SEDENTARISMO
Pesquisador: Pedro Dal Lago
Área Temática:
Versão: 2
CAAE: 54492221.8.0000.5345
Instituição Proponente: Universidade Federal de Ciências da Saúde de Porto Alegre
Patrocinador Principal: Financiamento Próprio

DADOS DO PARECER

Número do Parecer: 5.299.274

Apresentação do Projeto:
Trata-se de uma resposta ao parecer: 5.203.462 emitido pelo colegiado do CEP/UFCSPA.
Conforme o autor a inatividade física e o sedentarismo são responsáveis por 9% de todas as mortes no mundo, totalizando 5,3 milhões de pessoas por ano, com um custo estimado em 53,8 bilhões de dólares, representando um grande impacto social negativo. No Brasil, em 2021 o sedentarismo foi responsável por 11,6% de todas as mortes. O comportamento sedentário tem recebido muita atenção por parte da comunidade científica mundial, pois se caracteriza como um problema de saúde pública, uma vez que apresenta associação negativa com a saúde das pessoas e com o desenvolvimento de doenças crônicas não transmissíveis. Dados recentes do IBGE indicam que 47% da população adulta brasileira não atinge as recomendações de atividade física da Organização Mundial da Saúde (OMS). Para a OMS, dentre os países da América Latina o Brasil é o mais sedentário. É urgente, portanto, criar ações, investimentos prioritários e estratégicos para promover de forma efetiva o aumento da prática, o engajamento e a aderência em atividades físicas para a população sedentária. A utilização efetiva da prescrição de exercícios em uma intensidade adequada melhora significativamente a qualidade de vida e reduz radicalmente os efeitos negativos do sedentarismo na saúde da população. Neste sentido, o desenvolvimento de estratégias para aumentar a aderência e, consequentemente, o tempo de atividade física da população como um todo torna-se uma meta fundamental para amenizar este problema sério de saúde pública. Diversos avanços tecnológicos recentes como a internet das coisas e redes de

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sensores, podem prover uma melhoria no monitoramento e prescrição da atividade física. Tais avanços podem ser integrados a fim de fornecer biofeedbacks sobre as atividades físicas prescritas, os quais podem ser acessados através de smartphones. Nesse sentido, a hipótese geral desta proposta é que o uso de um modelo de prescrição da intensidade adequada para prática de atividade física juntamente com o uso de um game para feedback aumenta a aderência, diminui o sedentarismo e melhora os parâmetros marcadores de saúde dos indivíduos que realizam este protocolo de atividade física. Objetivo: O objetivo geral do projeto e desenvolver e implementar tecnologias inovadoras, disruptivas, e seguras para garantir a intensidade adequada durante a realização da atividade física prescrita, aumentar a adesão das pessoas para prática de atividade física e monitorar as respostas de biomarcadores de saúde antes, durante e depois da prática de atividade física para redução dos níveis de sedentarismo da população. Método: O projeto propõe superar este desafio através de três abordagens integradas: (i) implantar e testar um sistema protótipo para prática de atividade física; (ii) o uso de aplicações com um sistema de gamificação para aumentar a adesão dos usuários; e (iii) a utilização de um sistema de biofeedback para o monitoramento das atividades físicas prescritas. O estudo será subdivido em três fases, duas fases de desenvolvimento (1 e 2) e uma fase de aplicação (fase 3): 1) desenvolvimento do sensor e teste do biofeedback durante a avaliação funcional; 2) desenvolvimento do game e teste do biofeedback e da aplicação gamificada para prescrição e controle de treinamento físico em ambiente controlado; e 3) teste da aplicação gamificada para prescrição e controle de treinamento físico em ambiente não controlado.

Objetivo da Pesquisa:

Objetivo Primário: - Desenvolver e implementar tecnologias inovadoras, disruptivas, e seguras para garantir a intensidade adequada durante a realização da atividade física prescrita, aumentar a adesão das pessoas para prática de atividade física e monitorar as respostas de biomarcadores de saúde antes, durante e depois da prática de atividade física para redução dos níveis de sedentarismo da população.

Objetivo Secundário: - Avaliar biomarcadores de saúde (respostas fisiológicas e bioquímicas) antes e depois da realização do programa de atividade física prescrito.- Projetar, desenvolver e implantar um sistema de biofeedback, com sensores vestíveis de frequência cardíaca e número de passos para o monitoramento e prescrição das atividades físicas durante sua realização. - Projetar, desenvolver e implantar um sistema móvel utilizando técnicas de gamificação para garantir a aderência a prescrição da atividade física.- Prescrever atividades físicas dentro de um aplicativo

gamificado para garantir aderência, intensidade e tempo de exercício. - Criar um ecossistema sustentável com a solução proposta.

Avaliação dos Riscos e Benefícios:

Riscos: Em relação as avaliações, antes, durante e após a realização dos testes o participante será monitorado em relação a suas condições físicas (frequência cardíaca, saturação parcial de oxigênio, pressão arterial) e seus sintomas (dispneia e fadiga). Os eventuais riscos durante as avaliações funcionais incluem aumento da frequência cardíaca, aumento da pressão arterial, dispneia e sensação de fadiga. No entanto, os riscos são mínimos, sendo os testes físico-funcionais considerados seguros para avaliação da população em estudo e sempre realizados por profissionais capacitados e treinados, seguindo as regras de biossegurança. O exercício físico pode levar a efeitos como taquicardia, sudorese, cansaço, algum desconforto relacionado a utilização do equipamento, desconforto nos membros inferiores e cansaço muscular leve após treinamento em esteira. Caso ocorra qualquer episódio citado, tanto durante as avaliações quanto no treinamento físico, os pesquisadores interromperão o protocolo e, caso necessário, prestarão atendimento inicial. Se houver estabilização do quadro e afirmativa do participante, o protocolo poderá ser retomado. Durante a execução do treinamento em ambiente não controlado, o indivíduo será orientado a interromper o protocolo caso apresente algum desconforto ou sintoma e que deverá aguardar sua cessação. Caso haja condições físicas adequadas, ele deverá retomar de onde parou e não havendo melhora ele será orientado a entrar em contato telefônico com os pesquisadores para as devidas medidas. Referente à coleta de sangue, essa será realizada por um profissional devidamente qualificado e habilitado, bem como o local previamente preparado, higienizado e refrigerado para a realização do procedimento; respeitando os critérios de biossegurança. Ainda assim, existe a possibilidade de equimose e dor leve no local onde a coleta de sangue for realizada, que deve desaparecer em poucos dias. Os participantes terão garantia de plena assistência médico-hospitalar da instituição responsável pelo protocolo de treinamento, sendo que os pesquisadores irão se responsabilizar por todos os custos relacionados à pesquisa no caso de algum evento adverso, arcando com qualquer possível despesa com deslocamento e logística. Não haverá danos de ordem psíquica, moral, intelectual, social, cultural ou espiritual do ser humano, em qualquer fase desta pesquisa, bem como não há risco processo e risco produto, visto que, garante-se o total sigilo dos dados obtidos e o repasse a sociedade preservando a fidedignidade desta pesquisa.

Riscos: Em relação as avaliações, antes, durante e após a realização dos testes o participante será

monitorado em relação a suas condições físicas (frequência cardíaca, saturação parcial de oxigênio, pressão arterial) e seus sintomas (dispneia e fadiga). Os eventuais riscos durante as avaliações funcionais incluem aumento da frequência cardíaca, aumento da pressão arterial, dispneia e sensação de fadiga. No entanto, os riscos são mínimos, sendo os testes físico-funcionais considerados seguros para avaliação da população em estudo e sempre realizados por profissionais capacitados e treinados, seguindo as regras de biossegurança. O exercício físico pode levar a efeitos como taquicardia, sudorese, cansaço, algum desconforto relacionado a utilização do equipamento, desconforto nos membros inferiores e cansaço muscular leve após treinamento em esteira. Caso ocorra qualquer episódio citado, tanto durante as avaliações quanto no treinamento físico, os pesquisadores interromperão o protocolo e, caso necessário, prestarão atendimento inicial. Se houver estabilização do quadro e afirmativa do participante, o protocolo poderá ser retomado. Durante a execução do treinamento em ambiente não controlado, o indivíduo será orientado a interromper o protocolo caso apresente algum desconforto ou sintoma e que deverá aguardar sua cessação. Caso haja condições físicas adequadas, ele deverá retomar de onde parou e não havendo melhora ele será orientado a entrar em contato telefônico com os pesquisadores para as devidas medidas. Referente à coleta de sangue, essa será realizada por um profissional devidamente qualificado e habilitado, bem como o local previamente preparado, higienizado e refrigerado para a realização do procedimento; respeitando os critérios de biossegurança. Ainda assim, existe a possibilidade de equimose e dor leve no local onde a coleta de sangue for realizada, que deve desaparecer em poucos dias. Os participantes terão garantia de plena assistência médico-hospitalar da instituição responsável pelo protocolo de treinamento, sendo que os pesquisadores irão se responsabilizar por todos os custos relacionados à pesquisa no caso de algum evento adverso, arcando com qualquer possível despesa com deslocamento e logística. Não haverá danos de ordem psíquica, moral, intelectual, social, cultural ou espiritual do ser humano, em qualquer fase desta pesquisa, bem como não há risco processo e risco produto, visto que, garante-se o total sigilo dos dados obtidos e o repasse a sociedade preservando a fidedignidade desta pesquisa.

Comentários e Considerações sobre a Pesquisa:

Os apontamentos, sugestões e pendências foram atendidas pelos pesquisadores e tais adequações foram explicitadas via carta-resposta.

Considerações sobre os Termos de apresentação obrigatória:

Anexar, via emenda, um novo termo de entrega de relatório.

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Recomendações:

Caso haja necessidade em prorrogação de prazo, deve ser realizada via emenda antes do término do projeto.

Conclusões ou Pendências e Lista de Inadequações:

O colegiado do CEP/UFCSPA não encontrou óbices éticos para a realização desse projeto, pois segue os preceitos da resolução 466/2012. Embora esteja aprovado por esse comitê, os pesquisadores devem acrescentar via emenda, os custos de alimentação e locomoção dos participantes, mesmo que tenham indicado que ficariam por conta dos pesquisadores, esses itens devem ser estimados na brochura e nas informações básicas do projeto, pois são itens indispensáveis por esse comitê. Além disso, apesar dos pesquisadores em sua carta resposta terem escrito que o termo de entrega do relatório foi corrigido, o novo documento anexado tem o mesmo texto do anterior. O cronograma do projeto tem como data final dezembro de 2025 e no novo termo ainda consta dezembro de 2026.

Essas correções deverão ser efetuadas via emenda para os documentos estarem atualizados na plataforma Brasil.

Ressalta-se que cabe ao pesquisador responsável encaminhar os relatórios parciais e final da pesquisa, por meio da Plataforma Brasil, via notificação do tipo "relatório" para que sejam devidamente apreciadas no CEP, conforme Norma Operacional CNS no 001/13, item XI.2.d.

Previsão de término do projeto: 31 de dezembro de 2025.

Considerações Finais a critério do CEP:

Parecer ratificado pelo Colegiado.

Este parecer foi elaborado baseado nos documentos abaixo relacionados:

Tipo Documento	Arquivo	Postagem	Autor	Situação
Informações Básicas do Projeto	PB_INFORMAÇÕES_BÁSICAS_DO_PROJETO_1860936.pdf	16/02/2022 21:46:21		Aceito
Outros	CARTA_COMITE_ETICA.pdf	16/02/2022 21:39:44	Pedro Dal Lago	Aceito
Projeto Detalhado / Brochura Investigador	PROJETO_ATIVARS_MOVIMENTO_CONTRA_O_SEDENTARISMO_PLATAFORMA_BRASIL_VERSAO_DOIS.pdf	16/02/2022 21:38:45	Pedro Dal Lago	Aceito
Outros	Termo_entrega_relatorio_corrigido.pdf	16/02/2022 21:37:35	Pedro Dal Lago	Aceito

Declaração de Instituição e Infraestrutura	termo_anuencia_responsavel_local_pesquisa_lab_analises_clinicas.pdf	16/02/2022 21:36:49	Pedro Dal Lago	Aceito
Declaração de Instituição e Infraestrutura	termo_anuencia_laboratorio_unijui.pdf	16/02/2022 21:36:34	Pedro Dal Lago	Aceito
Outros	divulgacao_ATIVARS.png	16/02/2022 21:35:21	Pedro Dal Lago	Aceito
TCLE / Termos de Assentimento / Justificativa de Ausência	TCLE_ATIVARS_MOVIMENTO_CONTRA_SEDENTARISMO_VERSAO_DOIS.pdf	16/02/2022 21:33:15	Pedro Dal Lago	Aceito
Declaração de Pesquisadores	TERMOS_DE_UTILIZACAO_DE_DADOS_17_PESQUISADORES.pdf	21/12/2021 12:59:05	Pedro Dal Lago	Aceito
Orçamento	ORCAMENTO_ATIVARS.pdf	20/12/2021 17:35:15	Pedro Dal Lago	Aceito
Projeto Detalhado / Brochura Investigador	PROJETO_ATIVARS_MOVIMENTO_CONTRA_O_SEDENTARISMO_PLATAFORMA_BRASIL.docx	20/12/2021 17:33:42	Pedro Dal Lago	Aceito
Cronograma	Cronograma_ATIVARS.pdf	20/12/2021 16:41:56	Pedro Dal Lago	Aceito
Outros	TERMO_DE_COMPROMISSO_PARA_ENTREGA_DE_RELATORIO_SEMESTRAL_OU_FINAL_ATIVARS_MOVIMENTO_CONTRA_SEDENTARISMO.pdf	15/12/2021 09:46:20	Pedro Dal Lago	Aceito
Declaração de Instituição e Infraestrutura	Termo_anuencia_responsavel_pelo_setor_ATIVARS_MOVIMENTO_CONTRA_SEDENTARISMO.pdf	15/12/2021 09:43:39	Pedro Dal Lago	Aceito
Folha de Rosto	Folha_de_rosto_PROJETO_ATIVARS_MOVIMENTO_CONTRA_SEDENTARISMO.pdf	15/12/2021 09:38:21	Pedro Dal Lago	Aceito

Situação do Parecer:
Aprovado

Necessita Apreciação da CONEP:
Não

PORTO ALEGRE, 18 de Março de 2022

Assinado por:
Fernanda Bordignon Nunes
(Coordenador(a))

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