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GLAUBER SÁ BRANDÃO

IMPACTO DE UM PROGRAMA DE EXERCÍCIO FÍSICO DOMICILIAR SEMISUPERVISIONADO NA QUALIDADE DO SONO DE IDOSOS DA COMUNIDADE: UM ENSAIO CLÍNICO RANDOMIZADO

TESE DE DOUTORADO

Salvador – Bahia
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Tese apresentada ao Programa de Pós-graduação Stricto-Sensu em Medicina e Saúde Humana da Escola Bahiana de Medicina e Saúde Pública como requisito parcial para obtenção do título de Doutor em Medicina e Saúde Humana.

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Co-orientador: Prof. Dr. Luis Vicente Franco de Oliveira

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RESUMO

Fundamento: O aumento da expectativa de vida está associado às alterações biopsicossociais que ocorrem naturalmente com o avançar da idade, implicando no sono, na mobilidade funcional e na qualidade de vida dos idosos. O exercício físico apresenta benefícios à saúde global dos idosos e é recomendado como um dos principais recursos, não farmacológico, de ação preventiva e terapêutica. Exercícios realizados no ambiente domiciliar apresentam maior adesão dos idosos, podendo repercutir em melhores resultados a médio e longo prazo. **Objetivos:** 1- Testar a hipótese de que exercício físico domiciliar e semisupervisionado melhora a qualidade do sono e a sonolência excessiva diurna de idosos da comunidade; 2- Testar a hipótese de que exercício físico domiciliar e semisupervisionado melhora a mobilidade funcional e a qualidade de vida de idosos da comunidade; 3- Testar a associação da qualidade do sono com a sonolência excessiva diurna e a qualidade de vida de idosos da comunidade; 4- Caracterizar o perfil de idosos da comunidade com má qualidade do sono. **Método:** Este estudo gerou três artigos originais, onde foram utilizadas duas metodologias diferentes. Para os objetivos 1 e 2 foi utilizado o método de estudo analítico, experimental do tipo ensaio clínico randomizado, controlado e cego e para os objetivos 3 e 4 foi realizado um estudo descritivo de corte transversal. Foram utilizados os seguintes instrumentos de avaliação: Indice de qualidade do sono de Pittsburgh (PSQI), Escala de sonolência Epworth (ESE), questionário clínico de Berlin, *Timed Up and Go test* (TUG), Questionário de qualidade de vida (WHOQOL-OLD), Questionário Internacional de Atividade Física adaptado para idosos (IPAQ) e o Mini-exame do estado mental. Participaram do estudo, idosos (60 anos ou mais) residentes no município de Senhor do Bonfim-Ba, que não tinham realizado exercício físico regularmente há pelo menos três meses antes do estudo, com pontuação ≥ 5 no PSQI, sem presença de declínio cognitivo, que não estavam realizando tratamento para transtorno do sono e sem condição clínica que contraindicasse a prática de exercício físico. Todos os idosos participaram de uma palestra com explicações sobre o procedimento experimental e receberam folhetos educativos contendo orientações sobre hábitos de vida relacionados à alimentação, hidratação e higiene do sono. Os participantes foram randomizados em dois grupos, sendo que o grupo intervenção (GI) recebeu uma cartilha sobre a forma de execução dos exercícios físicos e praticou estes exercícios domiciliares semisupervisionados por 12 semanas consecutivas e com frequência mínima de 3 sessões semanais de 30 a 40 minutos, além de seguir as orientações sobre hábitos saudáveis de vida e o grupo controle (GC) apenas seguiu as orientações referentes aos hábitos saudáveis de vida. Na análise estatística foram realizados testes de normalidade dos dados, análise descritiva, comparação de médias, proporções e análise de correlação. Foi considerado um nível de significância de 5% (α=0,05). **Resultados:** Predominou o sexo feminino (87%); média de idade 68 ± 7 anos, baixa renda (84,8% $\leq$ 2 SM), baixa escolaridade (86,3% $\leq$ 3 anos de estudo) e, em sua maioria, morando com familiares (67,9%), sendo casados (39,7%) ou em união estável (35,9%). Setenta e um por cento da amostra está acima do peso normal, 90,1% das mulheres apresentam circunferência abdominal $\geq$ 80cm e identificou-se, no auto-relato, elevada prevalência de doenças crônicas e psicossociais e a presença do risco da Apneia Obstrutiva do Sono em 38.2%. As médias do PSQI, Escala de sonolência de Epworth, WHOQOL-OLD e TUG foram iguais a, respectivamente, 11,2 ± 3,2; 8,32 ± 2,2; 84,8 ± 10,2 e 8,97 ± 2. Foi verificada associação da qualidade do sono com a sonolência excessiva diurna e a qualidade de vida. Após as 12 semanas de intervenção, o GI apresentou melhora significativa da qualidade do sono, sonolência diurna, mobilidade funcional e qualidade de vida ($p < 0.01$). **Conclusões:** Em idosos da comunidade com má qualidade do sono, foi possível constatar que o exercício físico domiciliar semisupervisionado é eficaz em melhorar

a qualidade do sono, a sonolência diurna, a mobilidade funcional e a qualidade de vida, além de identificara associação da qualidade do sono com a sonolência excessiva diurna e com a qualidade de vida desta população.

Palavras-chave: Idoso. Sono. Comunidade. Mobilidade funcional. Qualidade de vida.

ABSTRACT

Background: The increase of life expectancy is associated with biopsychosocial changes which occur naturally with the advancing age, implying sleep, functional mobility and elderly quality of life. Physical exercise has benefits to the overall elderly health, and it is recommended as one of the main non-pharmacological resources for preventive and therapeutic action. Exercises performed at home environment present greater adherence of the elderly, and it may have better results in the medium and long term. **Objectives:** 1- To test the hypothesis of home physical exercise and semi-supervised physical exercise improves the quality of sleep and excessive daytime sleepiness of the elderly in the community; 2- To test the hypothesis that home and semi-supervised physical exercise improves the functional mobility and the community's elderly quality of life; 3- To test the association of sleep quality with excessive daytime sleepiness; 4- To characterize the elderly profile with poor sleep quality. **Method**: This study produced three original articles, which were adopted two different methodologies. For the objectives 1 and 2 were used the analytical, randomized experimental method, controlled and blind clinical trial type, and a descriptive cross-sectional study was performed for the objectives 3 and 4. The following evaluation instruments were used: Pittsburgh Sleep Quality Index (PSQI), Epworth Sleepiness Scale (ESE), Berlin Clinical Questionnaire, Timed Up and Go Test (TUG), Quality of Life Questionnaire (WHOQOL-OLD), International Questionnaire on Physical Activity adapted for the elderly (IPAQ) and the Mini-Mental State Examination. The study population included elderly (aged 60 years or older) they are residents in the municipality of Senhor do Bonfim-Ba, who had not performed regular physical exercise for at least three months prior to the study, scored ≥ 5 on the PSQI, with no cognitive decline, who were not performing treatment for sleep disorder and without clinical condition that contraindicated the physical exercise practice. All the elderly participated of a lecture about the experimental procedure and they received educational leaflets containing guidelines on life habits related to feeding, hydration and sleep hygiene.
The participants were randomized into two groups, and the intervention group (GI) received a booklet on how to perform physical exercises and they practiced these semi-supervised home exercises for 12 consecutive weeks and with a minimum frequency of 3 weekly sessions, in addition to following the orientations about healthy habits of life and the control group (CG) only followed the guidelines referring to healthy habits of life. Statistical analysis included data normality tests, descriptive analysis, comparison of means, proportions and correlation analysis. It was considered a significance level of 5% ($\alpha = 0.05$). **Results:** Females predominated (87%); mean age 68 ± 7 years, low income (84.8% ≤ 2 MW), low schooling (86.3% ≤ 3 years of study), and most of them living with relatives (67.9%). married (39.7%) or cohabitation (35.9%). 71% of the sample is overweight, 90.1% of the women have an abdominal circumference ≥ 80cm and a high prevalence of chronic and psychosocial diseases was identified in the self-report and the risk of Obstructive Sleep Apnea in 38.2 %. The mean PSQI, Epworth Sleepiness Scale, WHOQOL-OLD and TUG were equal to, respectively, 11.2 ± 3.2; 8.32 ± 2.2; 84.8 ± 10.2 and 8.97 ± 2. Association of sleep quality was verified with excessive daytime sleepiness and quality of life. After 12 weeks of intervention, GI showed significant improvement in sleep quality, daytime sleepiness, functional mobility and quality of life ($p < 0.01$). **Conclusions:** It was possible to verify in elderly of the community with poor sleep quality that the semi-supervised home physical exercise is effective to improve sleep quality, daytime sleepiness, functional mobility, and also identify an association of sleep quality with an excessive daytime sleepiness and a quality of life of this population.

Keywords: Elderly. Sleep. Community. Functional mobility. Quality of life.

LISTA DE ILUSTRAÇÕES

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LISTA DE ABREVIATURAS E SIGLAS

AADS	Associação Americana de Distúrbios do Sono
ACSM	American College of Sports Medicine
AHA	American Heart Association
CONEP	Comissão Nacional de Ética e Pesquisa
CONSORT	Consolidated Standards of Reporting Trials
EEB	Escala de Equilíbrio de Berg
EEG	Eletroencefalograma
EMG	Eletromiograma
EOG	Eletrooculograma
ESE	Escala de sonolência de Epworth
GC	Grupo controle
GI	Grupo intervenção
IDH	Índice de desenvolvimento humano
IMC	Índice de massa corporal
IPAQ	Questionário Internacional de Atividade Física
MEEM	Mini-Exame do Estado Mental
MIF	Medida de independência funcional
NQSs	Núcleos supraquiasmáticos
PSG	Polissonografia
PSQI	Índice de Qualidade do Sono de Pittsburgh
ReBEC	Registro Brasileiro de Ensaios Clínicos
SAOS	Síndrome da apneia obstrutiva do sono
SNC	Sistema nervoso central
SpO2	Saturação de O_2 pela oximetria de pulso
SRAA	Sistema monoaminérgico Reticular Ativador Ascendente
STROBE	Reporting of Observational Studies in Epidemiology
TC6	Teste de caminhada de seis minutos
TS	Teste de Shuttle
TUG	Timed Up and Go
UATI	Universidade Aberta da Terceira Idade
UNEB	Universidade do Estado da Bahia

VLPO	Pré-óptico Ventrolateral
WHOQOL-OLD	World Health Organization Quality of Life Group-old

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1 INTRODUÇÃO

A população idosa é a que apresenta o maior índice de crescimento em todo o mundo. Nos países em desenvolvimento socioeconômico como o Brasil, o envelhecimento populacional é um processo relativamente novo e tem ocorrido de forma tão acelerada que as projeções mais conservadoras indicam que em 2025 seremos o sexto pais do mundo em número de idosos, correspondendo a 15% de todo o contingente populacional[1]. Esse progressivo aumento da população idosa contribui para que estudos sobre o envelhecimento humano tenham uma importante atenção dos profissionais de saúde e dos agentes governamentais, por configurar um grande desafio à saúde pública[2].

Associado ao envelhecimento humano ocorrem importantes alterações biopsicossociais que implicam na qualidade de vida dos idosos, dentre estas alterações destacam-se os distúrbios do sono, sendo o sono um dos aspectos vitais para a saúde em geral, especialmente em pessoas mais velhas[3-5]. Estes distúrbios apresentam grande prevalência na população geral, sendo considerados atualmente como importante problema de saúde pública, atingindo cerca de 45% da população mundial[6]. Foley et al[7]. em um estudo epidemiológico com mais de 9.000 participantes, apresentam que mais da metade dos idosos entrevistados relataram ter uma ou mais queixas de sono, e essa má qualidade do sono apresenta associação com deficiências físicas e mentais como sonolência excessiva diurna, aumento do risco de quedas, déficit cognitivo, depressão, fadiga, estresse emocional, limitações nas atividades da vida diária, redução da qualidade de vida e aumento da incidência de morbidade e mortalidade cardiovascular[3-7].

A prática de exercício físico de intensidade leve a moderada apresenta resultados positivos na melhoria da qualidade do sono de idosos[8-10]. Porém, apesar das evidencias científicas demonstrarem os benefícios do exercício físico na qualidade de vida de idosos, ainda há pouca adesão aos programas específicos de exercício físico, além da baixa taxa de continuidade desta prática[10-13]. Esta pequena inserção em programas de exercício físico específico e supervisionado, apresenta como possíveis justificativas a pouca oferta de programas gratuitos, associado ao baixo poder econômico da maioria dos idosos e a dificuldade de deslocamento até o local de realização dos exercícios[12]. Os idosos que procuram locais para se exercitar são os mais ativos e que apresentam melhores condições

econômicas, já os sedentários que apresentam maior sensação de cansaço, menos autonomia e menor poder econômico, são os mais difíceis de serem alcançados por preferirem permanecer em casa ou apresentarem algum tipo de empecilho para se deslocar até os programas de exercício[11,12,14]. Ashworth et al[15]. concluíram, em sua revisão Cochrane, que especialmente em períodos de longo prazo, os programas de exercícios domiciliares apresentam melhor adesão e maior continuidade quando comparados aos programas realizados em centros de treinamento, proporcionando melhores resultados. Entretanto, os trabalhos que avaliam os benefícios do exercício físico domiciliar na qualidade do sono ainda são incipientes.

Considerando esta lacuna da literatura foi idealizado este trabalho, com o objetivo de testar a hipótese de que um programa não convencional de exercício físico, ou seja, exercícios realizados no próprio domicílio, com orientações periódicas, de fácil execução, baixo custo e com flexibilidade de horário, pode ser utilizado como recurso terapêutico para melhorar a qualidade do sono de idosos da comunidade. Então foram desenvolvidos cinco trabalhos aqui apresentados em artigos, sendo dois protocolos e três artigos originais: o primeiro artigo objetivou a descrição da amostra do estudo e faz associações da qualidade do sono com a sonolência excessiva diurna e com a qualidade de vida de idosos da comunidade. O segundo avaliou o efeito do exercício físico domiciliar na mobilidade funcional e na qualidade de vida dos idosos da comunidade. O terceiro artigo refere-se ao objetivo principal do estudo, onde o efeito do exercício físico na qualidade do sono e na sonolência excessiva diurna, foi avaliado em um ensaio clínico randomizado, controlado e simples cego, envolvendo 131 idosos da comunidade que apresentaram má qualidade do sono de acordo com um escore ≥ 5 identificado no questionário “Índice de Qualidade do Sono de Pitsburg” (PSQI).

2 OBJETIVOS

2.1 Objetivo primário

1. Testar a hipótese de que exercício físico domiciliar, semisupervisionado, melhora a qualidade do sono e a sonolência excessiva diurna de idosos da comunidade com má qualidade do sono.

2.2 Objetivos secundários

1. Testar a hipótese de que exercício físico domiciliar, semisupervisionado, melhora a mobilidade funcional e a qualidade de vida de idosos da comunidade com má qualidade do sono.
2. Testar a associação da qualidade do sono com a sonolência excessiva diurna e a qualidade de vida de idosos da comunidade.
3. Caracterizar o perfil de idosos da comunidade com má qualidade do sono.

3 REVISÃO DO CONHECIMENTO QUE EMBASA O ESTUDO

3.1 Caracterização do problema

3.1.1 Neurofisiologia do sono

O sono é uma condição fisiológica de atividade cerebral, dependente do sistema talamocortical, caracterizada por modificação do estado de consciência, redução da sensibilidade aos estímulos ambientais e associado às características autonômicas, motoras e posturais próprias. A capacidade de reversão do estado de sono, ou seja, da relativa reação a estímulos externos, é uma condição que permite distinguir o sono dos estados de perdas patológicas da consciência[16,17].

A necessidade do sono, sua profundidade e duração, além da influência dos hábitos pessoais, é regulada por fatores circadianos e fatores homeostáticos. O ciclo sono-vigília, regido pelo ciclo circadiano, é um estado encefálico ativo e resultante de vários mecanismos que determinam suas características, intensidade e distribuição ao longo do dia. O sono e a vigília contam com atividades e circuitos encefálicos próprios, porém interconectados, sendo que estes dois estágios encontram-se relacionados ao fotoperiodismo decorrente da alternância dia-noite e estão sob o controle dos núcleos supraquiasmáticos (NQSs) do hipotálamo anterior, que correspondem ao relógio biológico capaz de gerar um ritmo endógeno próprio sincronizado por sinais internos e externos (luz solar). A luz do dia estimula os receptores retinianos, que por meio do trato retino-hipotalâmico realizam a transdução deste estímulo ao NSQ e na sequencia este sinal foto-sincronizado das células do NSQ é transmitido multissinapticamente para a glândula pineal, responsável pela secreção de melatonina plasmática durante o período de sono noturno devido ao escuro da noite[17,18].

Os fatores homeostáticos do sono correspondem a sensação da “necessidade de dormir”, provavelmente vinculada à acumulação de substâncias hipnogênicas como a adenosina. Quanto maior o período de vigília, maior será o metabolismo neuronal, levando a um progressivo aumento da adenosina capaz de inibir áreas encefálicas responsáveis pela vigília e em consequência, desinibindo a área pré-óptica ventrolateral do hipotálamo anterior (VLPO)

que é promotora do sono, atuando assim como um regulador homeostático da necessidade de dormir[19,20].

A adenosina é um produto do metabolismo energético celular neuronal, acumulando-se na fenda sináptica durante a vigília e atuando localmente de forma inibitória, sendo as células colinérgicas do prosencéfalo basal a região onde ocorre o maior acúmulo local de adenosina durante a vigília e privação do sono. A redução da atividade das células do prosencéfalo basal, em conjunto com a ação do núcleo supraquiasmático do hipotálamo anterior, desinibem as células do VLPO ao mesmo tempo que deixam de estimular o sistema hipocretinas, dando início ao sono NREM[16,17,19].

Durante o sono ocorrem basicamente dois padrões eletroencefalográficos (EEG) específicos, o de movimentos rápidos dos olhos (*rapid eye movement* - REM), que corresponde a 25% do tempo total de sono, durante o qual se observa atividade encefálica rápida e de baixa amplitude com presença de ondas eletroencefalográficas dessincronizadas, episódios de movimentos rápidos dos olhos, instabilidade ventilatória e hipotonia de diversos grupos musculares; e o padrão sem movimentos oculares rápidos (*non-rapid eye movement* - NREM), que representa o estágio onde o sono é iniciado e aprofundado gradativamente à medida que as ondas encefálicas se tornam progressivamente mais lentas e sincronizadas. Este estágio é subdividido em fases I, II e III, sendo que a última fase corresponde ao "sono de ondas lentas", por ser caracterizado pela profundidade do sono e pelo aumento do limiar de excitação, momento em que o indivíduo torna-se menos reativo aos estímulos sensoriais. O sono NREM é considerado restaurador das funções orgânicas, por estar associado à restituição da estrutura proteica neuronal e ao aumento da secreção do hormônio do crescimento[16,20].

A alternância dos estágios NREM-REM e vigília ocorre devido a atividade neuronal nos circuitos tálamo-corticais, em consequência da interação entre os núcleos monoaminérgicos e colinérgicos do tronco encefálico. O sistema monoaminérgico reticular ativador ascendente é constituído pelos núcleos dorsais da rafe (NDR serotoninérgicos) e Lócus cerúleos (LC noradrenérgicos) no tronco encefálico e núcleo tuberomamilar (NTM histaminérgico) no hipotálamo posterior, que se projetam difusamente para os núcleos reticulares do tálamo e para o córtex. A atividade destes núcleos aminérgicos, excita os circuitos tálamo-corticais promovendo a vigília e são denominados de *"REM-of"*. Os núcleos colinérgicos da ponte (latero-dorsais e tegumento pedúnculo-pontino) e o núcleo colinérgico do prosencéfalo basal

fazem conexões excitatórias com os núcleos reticulares do tálamo gerando projeções tálamo-corticais e tálamo-límbicas que são fundamentais ao sono REM, então estes núcleos colinérgicos que estão ativos durante o sono REM são denominados de *"REM-on"*. Portanto na vigília, os sistemas aminérgicos, colinérgicos, dopaminérgicos e histaminérgicos estão ativos, já no sono REM os sistemas aminérgicos não estão ativos, então a ativação colinérgica excita o córtex diretamente[16,17,20].

Durante a vigília o sistema aminérgico está tonicamente ativado e inibe o sistema colinérgico, suprimindo o sono REM. Quando as células aminérgicas silenciam e então o sistema colinérgico liberado das influencias inibitórias atinge o seu máximo, ocorre a indução ao sono REM. Os neurônios inibitórios gabaérgicos e galaninérgicos do VLPO ativam-se exclusivamente durante o sono NREM e REM e projetam-se diretamente para os núcleos aminérgicos (tuberomamilar, dorsal da rafe, locus cerúleos), colinérgicos pontinos (latero-dorsais e tegumento pedúnculo-pontino), do prosencéfalo basal e o sistema das hipocretínas, produzindo inibição destes núcleos excitatórios promotores da vigília, dando início ao sono NREM[16,19,20].

As hipocretínas/orexinas estão localizadas no hipotálamo posterior e projetam seus axônios excitatórios para diferentes áreas do sistema nervoso central (SNC), participando da regulação do ciclo sono-vigília, apetite, atividade do sistema nervoso autônomo, secreção neuroendócrina e atividade locomotora. As hipocretinas apresentam projeções excitatórias para as áreas encefálicas promotoras da vigília, recebe aferências excitatórias do prosencéfalo basal e do NSQ e aferências inibitórias do VLPO, apresentando atividade máxima durante a vigília (células *Wake-on-sleep-of*) e ausente durante o sono NREM e REM. Quando as hipocretinas elevam o tônus monoaminérgico mantem o VLPO inibido impedindo o início do sono, porém, a suspensão dos estímulos excitatórios do NSQ e do prosencéfalo basal (acumulo de adenosina), em conjunto com a inibição proveniente do VLPO no sistema hipocretinas, são responsáveis pelo início do sono[17,18].

O sono apresenta importantes funções para o adequado funcionamento dos sistemas orgânicos, que apesar de ainda não estarem completamente elucidadas, acredita-se que estejam relacionadas à conservação de energia, aprendizado e memória por meio de mudanças na plasticidade cerebral e sinaptogênese, processo restaurativo de componentes celulares chave de biossíntese de macromoléculas[16,18,20].

3.1.2 Envelhecimento e alterações do sono

O envelhecimento normal é acompanhado por alterações na qualidade, quantidade e arquitetura do sono, e estas alterações podem acarretar diversas doenças e originar problemas sociais e econômicos[21-24]. Por meio de estudos eletroencefalográficos foi possível constatar que o "status" cortical do idoso tende ao estado de alerta, com baixo limiar para acordar, tornando-o mais despertável por estímulos ambientais e aumentando a latência do sono. Desta forma, ocorre uma redução mensurável na capacidade dos idosos saudáveis em iniciar e manter o sono, associada a um prolongamento dos estágios 1 e 2 em consequência da redução do sono mais profundo, mais reparador (estágio 3 do sono NREM) e do sono REM[22,24]. Esta redução do sono de ondas lentas pode ser consequência da perda no predomínio da atividade parassimpática, demonstrada pela redução da variabilidade da frequência cardíaca durante o sono de idosos[23], e resultar em declínio da secreção do hormônio do crescimento humano, reduzindo assim a capacidade restaurativa[25,26].

Os indivíduos mais velhos, por serem menos cientes desta redução da capacidade de iniciar e manter o sono, subestimam a gravidade do seu comprometimento, comportamento percebido ao se fazer a comparação do auto-relato com os resultados de exames polissonográficos[27].

As modificações do sono em relação à idade podem estar relacionadas a mecanismos intrínsecos que incluem alterações na modulação circadiana, nos fatores homeostáticos e nas funções cardiopulmonar e endócrina, além dos mecanismos extrínsecos como fatores sociais e ambientais, sendo então classificadas como multifatoriais[23,25,26].

3.1.3 Envelhecimento e mobilidade funcional

O envelhecimento, especialmente quando associado ao sedentarismo, tende a desenvolver progressivas alterações fisiológicas, bioquímicas e de condução nervosa, que desencadeiam os processos de sarcopenia e osteopenia, culminando com o declínio da força, flexibilidade, amplitude articular, coordenação motora e equilíbrio. Condições estas que justificam a redução da capacidade funcional e consequente maior dificuldade para a realização das atividades da vida diária, tornando o idoso gradativamente mais dependente e com menos qualidade de vida[2,5,13,28]. Após a quinta década de vida pode ocorrer uma redução da força muscular de 12 a 15% por década[29]. Esta progressiva redução da força, que está associada ao

declínio da mobilidade funcional, é consequência da redução do número de fibras musculares e de irregularidades estruturais nos sarcômeros, sendo considerada como um importante fator de risco para quedas em idosos[30]. Outro aspecto importante que interfere nas atividades diárias é a alteração na absorção máxima de oxigênio, uma medida da capacidade de resistência física, que sofre redução de 3 a 6% por década após a quarta década, podendo chegar a mais de 20% durante a oitava década de vida, gerando sensação de fadiga e exaustão. Sendo assim, a execução de simples atividades cotidianas pode exigir o máximo esforço do idoso[31].

Análises cinesiológicas identificaram que o avançar da idade, em sedentários, tende a provocar restrições na mobilidade de grandes articulações como ombro, joelho e tornozelo, interferindo de forma significativa nas atividades da vida diária[32]. Outros estudos demonstram correlação positiva entre a flexibilidade do quadril e os escores de testes funcionais em mulheres idosas[33] e a existência de forte associação entre a mobilidade funcional e a mobilidade comportamental[34,35].

3.2 Revisão do conhecimento que justifica a hipótese testada

3.2.1 Exercício físico e envelhecimento

Idosos podem apresentar benefícios biopsicossociais com a pratica de exercício físico, proporcionando maior expectativa de vida e com mais qualidade quando comparados aos sedentários[2,11,36]. Isso ocorre porque o exercício tem a capacidade de minimizar o declínio da capacidade funcional, além de atuar na prevenção e controle de doenças crônico-degenerativas, sarcopenia, osteopenia e distúrbios do sono[10,11,14,27]. Porém, para que o exercício físico possa contribuir de forma significativa com o envelhecimento saudável, entidades normativas como o Associação Americana do Coração (AHA) e o Colegio Americano de Medicina do Esporte (ACSM) recomendam programas multidimensionais, que devem incluir treinamento das quatro habilidades motoras básicas que são compostas por exercícios de resistência, força, equilíbrio e flexibilidade[2].

3.2.2 Efeitos do exercício físico no sono do idoso

Os distúrbios do sono em pacientes idosos são comuns[7], multifatoriais, e contribuem com o aumento da utilização dos serviços de saúde[2]. Há fortes evidências epidemiológicas de que esta redução da capacidade de iniciar, manter e finalmente alcançar uma boa qualidade do sono, pode ser um marcador de aumento da morbidade e mortalidade cardiovascular e ainda disfunção cognitiva[3,6,7].

Objetivando minimizar estas alterações do sono são desenvolvidas pesquisas utilizando diferentes tipos de terapias, entretanto o método que ainda é mais utilizado para melhorar e aumentar a qualidade do sono em idosos é a administração de medicamentos como benzodiazepínicos, dopaminérgicos, anticonvulsivantes e os hipnóticos[37], porém este método geralmente proporciona efeitos indesejáveis como dependência, insônia rebote e efeitos residuais diurnos[16,37]. Além disso, estudos revelaram que os efeitos dos tratamentos não farmacológicos são melhor sustentados ao longo do tempo quando comparados com as intervenções farmacológicas[38]**,** tornando-se necessários para melhorar a qualidade do sono da população idosa[16]. Dentre estes recursos, o exercício físico se constitui como um dos mais acessíveis, além de apresentar efeito semelhante ou superior ao tratamento com a administração de sedativos hipnóticos, assim como demonstrado em uma revisão sistemática[39], e ao manter os idosos fisicamente ativos, torna-se possível a prevenção e o tratamento de doenças crônico-degenerativas e incapacitantes, além de melhorar a qualidade do sono e a qualidade de vida[4,8-10].

Com o intuito de manter os idosos ativos, de forma segura e eficaz o Colégio Americano de Medicina do Esporte (ACSM) recomenda que os programas de exercício físico para idoso sejam com intensidade moderada e multidimensional para proporcionar um condicionamento físico global[11]. Estes exercícios apresentam importantes resultados na melhoria e manutenção da qualidade do sono de idosos, com redução da sonolência diurna, aperfeiçoamento na realização das atividades da vida diária, restauração da saúde mental e aumento da qualidade de vida[4,8-11,40].

Dentre os principais mecanismos putativos referentes à influência do exercício físico no sono, destacam-se os seguintes:

1- Termorregulação: a redução da temperatura corporal constitui um importante estímulo fisiológico para o início do sono[40]. O exercício físico, ao aumentar a temperatura corporal, estimula o hipotálamo a promover a dissipação de calor pelo aumento do fluxo sanguíneo periférico em decorrência da vasodilatação, tendo como consequência o aumento da sudorese, a redução da temperatura e da taxa metabólica, contribuindo assim com a indução ao sono[41,42];
2- Efeito restaurador: Em consequência do aumento do metabolismo e do catabolismo decorrentes da prática de exercício físico, surge a necessidade de ativação dos processos restaurativos como a reposição energética e a reparação muscular (anabolismo), e para satisfazer esta demanda é induzido um aumento do sono de ondas lentas que corresponde a fase de maior liberação do hormônio do crescimento humano, proporcionando aumento da capacidade restauradora[40,43,44];
3- Aumento do gasto energético: o exercício físico estimula, de forma imediata, áreas encefálicas relacionadas à vigília, minimizando os cochilos diurnos frequentes entre os idosos, tendo como consequência maior metabolismo energético neuronal durante o dia, acentuando a acumulação de adenosina na fenda sináptica. Este importante sonógeno vai atuar localmente de forma inibitória, reduzindo a atividade, principalmente, das células colinérgicas do prosencéfalo basal (homeostato do sono), abrandando seus estímulos excitatórios às hipocretinas que diminui sua excitação aos núcleos aminérgicos e, como consequência, minimizam suas ações inibitórias aos neurônios do VLPO (promotores do sono) e estes, por se tornarem mais ativos, irão inibir os neurônios do Sistema monoaminérgico Reticular Ativador Ascendente (SRAA), além de atuar inibindo as hipocretinas e o prosencéfalo basal, desencadeando assim, um mecanismo em alça que vai possibilitar a transição da vigília para o sono, dando início ao sono NREM[40,44], assim como esquematizado na figura 1.

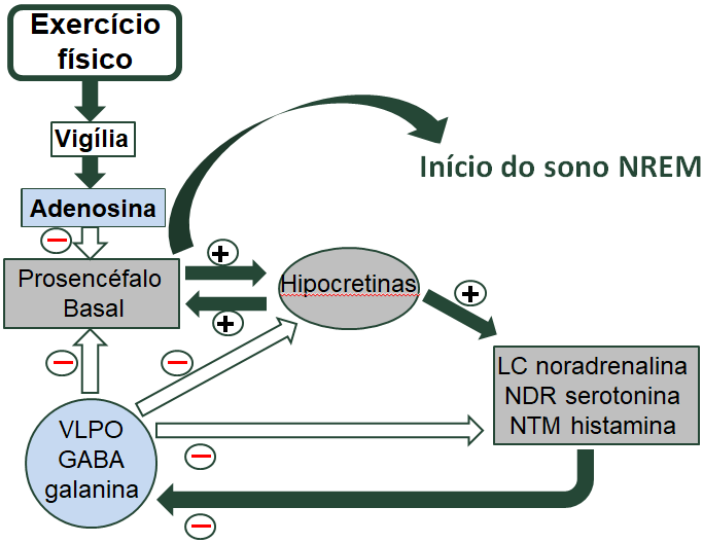

Figura 1 - Esquema da influência do exercício físico no metabolismo energético neuronal e consequente indução ao sono
Fonte: Figura adaptada da referência 17.

Indivíduos fisicamente ativos, quando comparados com sedentários, declaram que adormecem mais rápido, dormem melhor e se sentem menos cansadas durante o dia, resultados que podem estar fundamentados no aumento do tempo de sono de ondas lentas que se caracteriza como um sono restaurador, que auxilia na reparação e revitalização das pessoas[7,45].

Uma noite de sono eficiente e o despertar repousado, com a manutenção do estado de alerta durante o dia são, no idoso, um dos aspectos mais relevantes do envelhecimento normal e saudável. Sendo assim, o sono de boa qualidade pode ser considerado um importante marcador do bom funcionamento homeostático entre os sistemas orgânicos dos idosos[21-24].

3.2.3 Efeitos do exercício físico na mobilidade funcional do idoso

O exercício físico é essencial para um envelhecimento saudável, influenciando positivamente na manutenção da mobilidade funcional e independência física[2,4,11,14,35].
Os programas de exercício físico multidimensional proporcionam melhoria da mobilidade funcional do idoso de diversas formas, destacando-se algumas de grande relevância funcional como apresentado a seguir:

- A prática de exercício físico contra resistência desencadeia hipertrofia das fibras musculares de contração rápida (fibras tipo II) e das fibras de contração lenta (tipo I), sendo que a hipertrofia das fibras rápidas proporcionam aumento

da potência muscular, capacidade do musculo exercer força no menor intervalo de tempo possível, aumentando a eficácia nas ações de readequação postural, minimizando o risco de quedas e facilitando a realização das atividades da vida diária. Já a hipertrofia das fibras de contração lenta, associada à neoformação vascular e aumento do aporte sanguíneo intramuscular, intensificam a resistência muscular, reduzindo a sensação de cansaço que é muito frequente entre os idosos[2,35,46-48].

- O fortalecimento muscular periarticular protege as articulações, conferindo mais estabilidade articular, além de contribuir com a dinâmica do líquido intra-articular, minimizando os processos degenerativos e assim reduzindo as artralgias e melhorando a postura corporal[35,48-50].

- O equilíbrio postural necessita de acuidade proprioceptiva e controle neuromuscular preciso. A propriocepção é a informação aferente que contribui para a sensação consciente da postura total (equilíbrio postural) e da postura segmentar (estabilidade articular)[51]. Considerando que a propriocepção diminui com a idade[52,53] e que a sua redução dificulta a detecção de mudanças na posição do corpo, prejudicando a capacidade compensatória para evitar quedas[54] manter essa habilidade torna-se imprescindível para os idosos. Uma importante estratégia para prevenir ou minimizar o declínio proprioceptivo é a prática de exercício físico[55]. O exercício físico promove estímulos dos proprioceptores capsulares nos diferentes graus de amplitude das articulações, além de desenvolver coordenação neuromuscular específica e maior capacidade de consciência corporal, sendo esse desenvolvimento proprioceptivo fundamental para o equilíbrio corporal do idoso[48,50,56].

Entretanto, uma importante limitação a essa abordagem por meio da prática de exercícios físicos é que geralmente são aplicadas por profissionais qualificados em centros de treinamento e/ou reabilitação, tornando-se um recurso dispendioso para o idoso que em sua maioria possui baixa renda, além da dificuldade apresentada por muitos idosos em se locomoverem até o local de treinamento/reabilitação.

3.3 Instrumentos de avaliação do sono

O sono pode ser avaliado de forma direta por meio da polissonografia ou poligrafia ou de forma indireta por meio da aplicação de questionários como o PSQI, a ESE e o questionário clínico de Berlin.

3.3.1 Polissonografia

A Polissonografia (PSG) é o padrão ouro para avaliação e diagnóstico de distúrbios do sono, seu registro é realizado por meio de um polissonígrafo, sendo que um técnico treinado prepara e acompanha a PSG durante toda a noite de registro. A montagem da PSG incluiu: 4 canais para eletroencefalograma (EEG), 2 canais para eletrooculograma (EOG), 1 canal para eletromiograma (EMG) da região submentoniana, 1 canal para EMG do músculo tibial anterior bilateral, 1 canal para fluxo aéreo nasal por cânula nasal associado a transdutor de pressão, 1 canal para fluxo aéreo oronasal por termístor, 2 canais para esforço respiratório por pletismografia de indutância (tórax e abdome), 1 canal para saturação da oxihemoglobina (SpO2) por oximetria digital de pulso, 1 canal para ronco e 1 canal para posição corporal[57].

3.3.2 Poligrafia (Polissonografia nível III)

A Poligrafia (polissonografia nível III) é um sistema polissonográfico portátil para a monitoração domiciliar do sono. É recomendada pala Associação Americana de Distúrbios do Sono (AADS) para pacientes com sintomas clínicos da síndrome da apnéia hipopnéia obstrutiva do sono ou quando a polissonografia clássica não esteja disponível, além de ser aceita no acompanhamento terapêutico dos pacientes cujo diagnóstico já tenha sido realizado por meio da PSG convencional. É uma modalidade que avalia cinco parâmetros fisiológicos: saturação de oxigênio pela oximetria de pulso SpO2 (sensor posicionado no dedo), frequência cardíaca (sensor posicionado no dedo), fluxo aéreo (cânula nasal acoplada a um transdutor de pressão), esforço respiratório (cinta com sensor piezo elétrico ajustada na região do esterno) e posição corporal (dispositivo posicionado na altura do esterno)[57].

3.3.3 Índice de Qualidade do Sono de Pittsburgh (PSQI)

O PSQI é um instrumento validado para o Brasil[58] e foi elaborado em 1989 por Buysse DJ.[(59)]. Fornece uma medida de qualidade do sono padronizada, que discrimina os participantes em bons ou maus dormidores. É composto por sete componentes, cada qual pontuado em uma escala de zero a três. Os componentes são, respectivamente: qualidade subjetiva do sono; latência do sono; duração do sono; eficiência habitual do sono; alterações do sono; uso de medicações para o sono e disfunção diurna. Os escores dos sete componentes são somados para conferir uma pontuação global que varia de 0 a 21, sendo que as pontuações de 0-4 indicam boa qualidade do sono, de 5-10 indicam qualidade ruim e acima de 10 pontos indicam distúrbio do sono[(58,59)].

3.3.4 Escala de sonolência de Epworth (ESE)

A ESE contém oito situações envolvendo atividades da vida diária em ocorrência de sonolência diurna. Os participantes são orientados a classificar em um escore de 0 a 3 sobre a probabilidade de vir a sentir vontade de cochilar ou adormecer em cada uma das oito situações específicas, sendo que escores mais altos indicam maior chance de cochilar e escores acima de 10 sugerem diagnóstico de sonolência diurna excessiva[(60)].

3.3.5 Questionário Clínico de Berlin

O Questionário Clínico de Berlin é utilizado para avaliar o potencial risco de presença da síndrome da apneia obstrutiva do sono (SAOS)[(61)]. Este instrumento inclui dez itens organizados em três categorias relativas como, ronco e apneia, (contendo 5 itens), sonolência diurna (4 itens), hipertensão arterial sistêmica e obesidade (1 item). As categorias 1 e 2 são consideradas positivas se a pontuação de cada uma for maior ou igual a dois pontos, já a categoria 3 é considerada positiva se a resposta à questão 10 for SIM ou se o índice de massa corporal (IMC) for superior a 30 kg/m². São considerados doentes de alto risco para SAOS, quando duas ou mais categorias apresentarem pontuação positiva e, quando não apresentar nenhuma ou apenas uma categoria com pontuação positiva, o risco para SAOS é baixo[(61)].

3.4 Instrumentos de avaliações físico-funcionais

3.4.1 Teste *Timed Up and Go* (TUG)

O participante inicia na posição sentado em uma cadeira com braços (altura do assento de 45 cm e dos braços de 65 cm), firme ao chão, com o dorso apoiado no encosto da cadeira, sendo orientado a levantar-se, percorrer uma distância de três metros à frente, fazer um giro de 180º em uma marcação feita no solo, retornar e sentar-se novamente, executando o mais rápido possível, porém de forma segura e confortável, minimizando a possibilidade de acidentes. Caracteriza um conjunto de ações tipicamente rotineiras, fundamentais para mobilidade independente do idoso. O desempenho é afetado pelo tempo de reação, força muscular dos membros inferiores, equilíbrio dinâmico e a facilidade da marcha. O tempo despendido é medido pelo avaliador com um cronômetro a partir da ordem de "vá". Valores de tempo menores que 10 segundos sugerem indivíduos totalmente livres e independentes; os que realizam o teste entre 10 e 19 segundos são considerados independentes, de 20 e 29 segundos estão em uma faixa denominada de "zona cinzenta", ou seja, demonstram dificuldades para tarefas da vida diária e capacidade funcional. Os que apresentam escore de tempo de 30 ou mais segundos tendem a ser totalmente dependentes para muitas atividades básicas e instrumentais da vida diária[62].

3.4.2 Escala de Equilíbrio de Berg (EEB)

A escala de equilíbrio de Berg, criada em 1992 por Katherine Berg, foi traduzida e adaptada para a língua portuguesa por Miyamoto et al.[23], é um instrumento confiável para ser usado na avaliação do equilíbrio dos pacientes idosos. A EEB é uma avaliação funcional do desempenho do equilíbrio baseada em 14 itens comuns do dia a dia, que avaliam o controle postural, incluindo o estável e o antecipatório, e que requerem diferentes forças, equilíbrio dinâmico e flexibilidade. Consegue diferenciar os idosos mais propensos a quedas, além de estar correlacionada a outros testes de equilíbrio e de mobilidade como o TUG[63].

3.4.3 Medida de independência funcional (MIF)

A MIF é um instrumento que avalia 18 categorias pontuadas de um a sete, sendo classificadas quanto ao nível de dependência para a realização da tarefa. Cada dimensão é analisada pela

soma de suas categorias referentes, sendo assim quanto menor a pontuação maior será o grau de dependência. O instrumento atende a critérios de confiabilidade, validade, precisão, praticidade e facilidade[19] e sua natureza é multidimensional, podendo ser utilizada como forma de planejamento terapêutico, ou para avaliar a aplicabilidade em protocolos de geriatria e gerontologia[64].

3.4.4 Teste de caminhada de seis minutos (TC6)

É um teste simples que não necessita de equipamentos para avaliar o exercício físico e nem treinamento para o avaliador. Esse teste avalia respostas globais e integradas de todos os sistemas envolvidos durante o exercício, incluindo o sistema pulmonar e cardiovascular, as unidades neuromusculares e o metabolismo muscular. É considerado um teste submáximo, pois o idoso é instruído a caminhar na máxima velocidade tolerada durante seis minutos, mediante incentivos verbais padronizados. Depende, portanto, de características de ajuste individual da velocidade durante o desempenho do teste, que é determinado pelo idoso, o qual pode, inclusive, realizar a interrupção da deambulação se assim desejar[28]. O TC6 tem sido muito utilizado como forma de avaliação da aptidão física em indivíduos pouco condicionados que não realizam, por motivos variados, o teste ergométrico[65].

3.4.5 Teste de Shuttle (TS) ou teste de caminhada com velocidade progressiva

O TS é considerado um teste incremental máximo, pois o participante é impelido a andar até a exaustão de acordo com velocidades crescentes padronizadas em doze níveis, com duração de um minuto em cada nível e impostas por um sinal sonoro ao redor de um circuito de dez metros em cada sentido, separado por dois cones. É considerado um teste simples, baseado em caminhadas em superfície plana e com boa reprodutibilidade, não requerendo ergômetro específico. O TS possui uma boa correlação com o pico de VO2 obtido em um teste de exercício cardiopulmonar[66].

3.4.6 Testes Ergométricos Convencionais

O teste ergométrico é um procedimento não invasivo, que pode conferir informações diagnósticas e prognósticas, além de avaliar a capacidade cardiológica em exercícios dinâmicos, é o procedimento mais utilizado na avaliação funcional cardiovascular de

idosos[34], sendo um exame de baixo custo, fácil execução e alta reprodutibilidade. Considerando a condição socioeconômica da população brasileira, esse é um teste interessante, pois apresenta uma boa relação custo-benefício, mesmo em pacientes muito idosos[35]. Existem diversos ergômetros (bicicleta, esteira, banco e ergometria de membros superiores), porém, a esteira e bicicleta ergométrica são os mais utilizados em testes cardiorrespiratórios. A preferência é devido ao maior nível de padronização, adequado estresse sistêmico e maior representatividade das atividades diárias[67].

3.5 Caracterização do município de Senhor do Bonfim e os programas de exercício para idosos

O município de Senhor do Bonfim está localizado na região norte da Bahia, a 376 Km da capital Salvador. A população total é aproximadamente 74.419 habitantes, sendo 51,6% de mulheres e 8,2% de idosos; com índice de desenvolvimento humano (IDH) municipal de 0,666, IDH de longevidade de 0,773 e renda domiciliar per capta de R$ 407,79. A população idosa é predominantemente de baixa renda, baixa escolaridade e residente na zona urbana[1].

A cidade possui três programas gratuitos de exercício físico, um oferecido pela polícia militar à população adulta em geral, independente da faixa etária e desenvolvido em praça pública. Os outros dois são específicos para a população de idosos, sendo um oferecido pela prefeitura municipal aos idosos cadastrados na secretaria de ação social, com frequência de uma a duas vezes por semana e realizados em ambientes fechados de prédios municipais no centro da cidade e o outro programa oferecido pela Universidade do Estado da Bahia – UNEB, Departamento de Educação, Campus VII, por meio do projeto de extensão universitária "Exercício físico e qualidade de vida na terceira idade" realizado com os idosos cadastrados na Universidade Aberta da Terceira Idade – UATI e com frequência de duas vezes por semana.

Devido às limitações referentes ao baixo quantitativo de profissionais envolvidos na prática dos exercícios, deficiente infraestrutura dos locais utilizados para a realização dos mesmos, dificuldade de deslocamento dos idosos até estes locais e ainda limitação do número de vagas disponíveis, estes programas conseguem atender uma pequena parcela da população idosa do município.

3.6 Revisão dos trabalhos com objetivos semelhantes ao do estudo

3.6.1 Exercício físico domiciliar para idosos da comunidade

Os benefícios do exercício físico para idosos da comunidade foram, inicialmente descritos, apenas por autores que utilizaram programas de exercícios supervisionados e realizados em locais específicos de treinamento[2,4,8-11,36,39]. Porém, considerando a baixa adesão dos idosos a estes programas[10-13] e a demonstração por alguns autores de que a prática de exercícios domiciliares pode aumentar a adesão ao treinamento, com consequentes melhores resultados a médio e longo prazo[15,58], mais recentemente, surgiram estudos constatando os benefícios da prática do exercício físico domiciliar para idosos[8,14,76].

Gill et al.[76] demonstraram que o declínio funcional pode ser prevenido ou atenuado, mesmo em idosos frágeis da comunidade, com a prática de programas de exercícios domiciliares semi-supervisionados. Yamauchi et al.[14] realizaram um ensaio clínico randomizado sobre os efeitos de um programa de exercício multidimensional domiciliar para idoso por um período de 12 semanas e constataram melhorias significativas de todos os parâmetros funcionais avaliados quando comparados ao grupo controle. Outros estudos constataram que, especialmente a longo prazo, os programas de exercícios domiciliares apresentam melhor adesão do que os programas conduzidos em centros de treinamento[15,58]. Por outro lado, o exercício em grupo pode apresentar benefícios referentes ao contato social, que geralmente é de grande importância para os idosos[35].

Está documentado na literatura que o exercício físico no ambiente domiciliar para idosos pode apresentar algumas relevantes vantagens quando comparados aos exercícios realizados em locais específicos de treinamento/reabilitação[15,77] e também, que existem importantes mecanismos putativos referentes à influência do exercício físico na qualidade do sono[40-45]. Porém, os trabalhos que avaliam os benefícios do exercício físico domiciliar na qualidade do sono de idosos ainda são incipientes. Considerando esta lacuna do conhecimento, a importância dos exercícios para idosos e suas vantagens quando realizados no domicílio, foi idealizado esse trabalho com objetivo de testar a hipótese de que a prática de exercício físico domiciliar semisupervisionado melhora a qualidade do sono de idosos da comunidade que apresentam má qualidade do sono.

4 METODOLOGIA

4.1 Desenho do estudo

Este trabalho gerou cinco artigos, sendo dois protocolos de pesquisa (artigos 1 e 2) e três artigos originais (artigos 3, 4 e 5). Em relação aos artigos originais foram utilizadas duas metodologias diferentes. Para o artigo 3 foi realizado um estudo descritivo de corte transversal, em que o desenho e sua condução seguiram as normas do STROBE (Reporting of Observational Studies in Epidemiology)[68]. Os artigos 4 e 5 utilizaram o método de estudo analítico, experimental do tipo ensaio clínico randomizado, controlado e cego, sendo que ambos seguiram as diretrizes da declaração CONSORT (Consolidated Standards of Reporting Trials)[69].

4.2 Local do estudo e seleção dos participantes

A pesquisa foi realizada com idosos de 60 anos ou mais, residentes no município de Senhor do Bonfim-Ba, na região nordeste do Brasil, no período de julho a dezembro de 2015. O recrutamento ocorreu em toda a comunidade, inicialmente por meio de divulgação da realização da pesquisa em jornais locais, rádios, centros religiosos, grupos de encontro de idosos, residência sênior, associação de bairros e no projeto da terceira idade desenvolvido pela prefeitura municipal. Neste anuncio era fornecido um telefone para que os interessados entrassem em contato com a equipe de pesquisadores. Os critérios de inclusão desta pesquisa foram: não ter realizado exercícios regularmente há pelo menos três meses antes do estudo, assim como em trabalhos anteriores[8], pontuação maior ou igual a 5 no Índice de Qualidade do Sono de Pittsburgh (PSQI-BR)[58]. Foram excluídos participantes com presença de declínio cognitivo de acordo com o Mini-Exame do Estado Mental[70], estar realizando algum tratamento para transtorno do sono e apresentar qualquer condição clínica que contraindicasse a realização de exercício físico, identificada por meio de uma avaliação médica e fisioterapêutica.

4.3 Randomização

Após preencherem os critérios de elegibilidade, os idosos receberam numeração por ordem consecutiva de entrada no estudo, sendo, em seguida, alocados aleatoriamente de acordo com

uma sequência de números randômicos geradas pelo *Research Randomizer* (www.randomizer.org). Esta randomização foi do tipo fechada, com ocultação da alocação e gerou dois grupos, sendo um grupo controle (GC) e um grupo intervenção (GI).

4.4 Protocolo do estudo

Todos os idosos participaram de uma palestra de 40 minutos de duração com explicações sobre o procedimento experimental e receberam folhetos educativos contendo orientações sobre hábitos de vida relacionados à alimentação, hidratação e higiene do sono[70]. Os participantes do GI foram informados de que deveriam seguir as orientações referentes aos hábitos de vida e realizar um programa de exercício físico domiciliar. Para isto, participaram de um treinamento teórico-prático da adequada realização dos exercícios propostos e receberam uma cartilha (apêndice D) desenvolvida pelos pesquisadores, com orientações ilustrativas e por escrito sobre a realização dos exercícios, além de um diário para registrar a frequência semanal de sua realização. Os pesquisadores, após certificarem-se de que os idosos conseguiam realizar adequadamente todos os exercícios, orientaram os familiares a auxiliarem e estimularem a prática dos mesmos e ainda os encorajaram a telefonar em situações de problemas ou dúvidas. Já os participantes do GC foram informados que deveriam apenas continuar com suas atividades diárias e seguir as orientações relacionadas aos hábitos de vida.
Foram realizados treinamentos sistematizados de cinco assistentes (alunos do 3º ano do curso de graduação em Enfermagem), exclusivamente para a realização das avaliações e dez assistentes para o acompanhamento domiciliar dos idosos, sendo que cinco visitaram o GI e os outros cinco visitaram o GC. A distribuição da quantidade de idosos a serem avaliados e o número de domicílios a serem visitados, foi feita de forma equivalente entre os assistentes da pesquisa.

4.5 Metodologia das avaliações

As avaliações foram realizadas por um médico, um fisioterapeuta e cinco assistentes previamente treinados, os idosos receberam instruções verbais padronizadas sobre os procedimentos e foram avaliados individualmente em sala apropriada. Todo o processo avaliativo ocorreu uma semana antes e uma semana após o período da intervenção e os assistentes que realizaram exclusivamente as avaliações, assim como os pesquisadores

encarregados pelas análises dos dados, estavam cegos em relação a saber de qual grupo cada idoso tinha participado, evitando possíveis vieses.
Foi realizada avaliação física e clínica geral; coleta de dados socioeconômicos, demográficos, antropométricos, de comorbidades auto referidas, avaliação da qualidade do sono, sonolência excessiva diurna, qualidade de vida, risco de presença da síndrome da apneia obstrutiva do sono, mobilidade funcional e o nível de atividade física.

O desfecho primário foi a qualidade auto referida do sono, medida por meio do Índice de Qualidade do Sono de Pittsburgh (PSQI) validado para o Brasil[58]. O PSQI foi elaborado em 1989 por Buysse DJ[59]. e fornece uma medida de qualidade do sono padronizada, que discrimina os participantes em bons ou maus dormidores. É composto por sete componentes, cada qual pontuado em uma escala de zero a três. Os componentes são, respectivamente: qualidade subjetiva do sono; latência do sono; duração do sono; eficiência habitual do sono; alterações do sono; uso de medicações para o sono e disfunção diurna. Os escores dos sete componentes são somados para conferir uma pontuação global que varia de 0 a 21, sendo que as pontuações de 0-4 indicam boa qualidade do sono, de 5-10 indicam qualidade ruim e acima de 10 pontos indicam distúrbio do sono[58].

Em relação aos desfechos secundários, para avaliar a sonolência excessiva diurna foi utilizada a escala de sonolência de Epworth (ESE), que contem oito situações envolvendo atividades da vida diária em ocorrência de sonolência diurna. Os participantes foram orientados a classificar em um escore de 0 a 3 sobre a probabilidade de vir a sentir vontade de cochilar ou adormecer em cada uma das oito situações específicas, sendo que escores mais altos indicam maior chance de cochilar e escores acima de 10 sugerem diagnóstico de sonolência diurna excessiva[60].

Para avaliar o potencial risco de presença da síndrome da apneia obstrutiva do sono (SAOS) utilizou-se o Questionário Clínico de Berlin[61]. O instrumento inclui dez itens organizados em três categorias relativas como, ronco e apneia, (contendo 5 itens), sonolência diurna (4 itens), hipertensão arterial sistêmica e obesidade (1 item). As categorias 1 e 2 são consideradas positivas se a pontuação de cada uma for maior ou igual a dois pontos, já a categoria 3 é considerada positiva se a resposta à questão 10 for SIM ou se o índice de massa corporal (IMC) for superior a 30 kg/m². São considerados doentes de alto risco para SAOS, quando

duas ou mais categorias apresentarem pontuação positiva e, quando não apresentar nenhuma ou apenas uma categoria com pontuação positiva, o risco para SAOS é baixo.

O nível de atividade física foi avaliado por meio do Questionário Internacional de Atividade Física (IPAQ) adaptado para idosos[72]. É um instrumento que permite estimar o dispêndio energético semanal de atividades físicas relacionadas com o trabalho, transporte, tarefas domesticas e lazer, realizadas por, pelo menos 10 minutos contínuos, com intensidade moderada e/ou vigorosa, durante uma semana normal/habitual. Esta variável foi dicotomizada, sendo considerados inativos os que realizaram menos de 150 minutos semanais de atividades físicas moderadas e/ou vigorosas e ativos os que realizaram mais de 150 minutos semanais.

A mobilidade funcional foi avaliada por meio do *Timed Up and Go test* (TUG). O procedimento adotado seguiu o descrito no teste original, em que o participante inicia na posição sentado em uma cadeira com braços (altura do assento de 45 cm e dos braços de 65 cm), firme ao chão, com o dorso apoiado no encosto da cadeira, sendo orientado a levantar-se, percorrer uma distância de três metros à frente, fazer um giro de 180º em uma marcação feita no solo, retornar e sentar-se novamente, executando o mais rápido possível, porém de forma segura e confortável, minimizando a possibilidade de acidentes. Foi utilizado um cronômetro da marca Cassio® HS-70Wque era acionado a partir do comando verbal "já" no início do teste e interrompido quando o participante sentava-se novamente. Todos os idosos realizaram o teste duas vezes, sendo que na segunda o tempo de execução foi cronometrado[62].

Para avaliar a qualidade de vida foi utilizado o questionário do *World Health Organization Quality of Life Group-old* – (WHOQOL-OLD), que contém seis facetas de 4 itens cada, avaliados pela escala de *Likert* (1 a 5 pontos): Faceta I – "Funcionamento do Sensório"; Faceta II – "Autonomia"; Faceta III – "Atividades Passadas, Presentes e Futuras"; Faceta IV – "Participação Social"; Faceta V – "Morte e Morrer"; Faceta VI – "Intimidade". Cada uma das facetas possui 4 itens, portanto, para todas as facetas o escore dos valores possíveis pode oscilar de 4 a 20, sendo que os escores destas seis facetas ou os valores dos 24 itens podem ser combinados para produzir um escore "global" da qualidade de vida em idosos[73].

A capacidade cognitiva foi avaliada por meio do Mini-Exame do Estado Mental (MEEM), um instrumento composto por diversas questões tipicamente agrupadas em 7 categorias, cada uma

delas desenhada com o objetivo de avaliar “funções” cognitivas específicas: orientação para tempo (5 pontos), orientação para local (5 pontos), registro de 3 palavras (3 pontos), atenção e cálculo (5 pontos), lembrança das 3 palavras (3 pontos), linguagem (8 pontos), e capacidade construtiva visual (1 ponto). O escore do MMSE pode variar de um mínimo de 0 até um total máximo de 30 pontos. Os pontos de corte sugeridos são de 20 para analfabetos, 25 para idosos com um a quatro anos de estudo, 26,5 para cinco a oito anos de estudo, 28 para nove a onze anos de estudo e 29 para mais de onze anos de estudo[70].

Na avaliação das variáveis antropométricas, a massa corporal foi obtida utilizando-se uma balança da marca Welmy®, com capacidade de 150 quilogramas (Kg); a estatura, em metros (m), foi medida por meio de um estadiômetro vertical fixo à balança; para mensurar a circunferência do abdômen utilizou-se uma fita antropométrica da marca Cescorf® e o Índice de Massa Corporal (IMC) foi calculado a partir do peso em quilogramas dividido pela altura em metros ao quadrado.

4.6 Intervenção – programa de exercício físico domiciliar

O programa de exercício físico domiciliar, foi baseado nas recomendações do Colégio Americano de Medicina do Esporte para exercício e atividade física com idosos[11]. O programa foi constituído por uma combinação de exercícios aeróbios, de fortalecimento muscular, equilíbrio, coordenação e flexibilidade, priorizando exercícios que envolvem grandes grupos musculares, com duração de 12 semanas consecutivas, frequência mínima de 3 sessões semanais, tempo previsto de execução de 40 minutos e realização de 2 a 3 séries com 5 a 15 repetições para cada exercício, a uma taxa de esforço alvo de 13-15 ("um pouco difícil" para "difícil") na escala de esforço percebido de Borg de 6 a 20 pontos[74], podendo o exercício ser executado no turno de melhor conveniência para o idoso, sendo até três horas antes do horário de dormir. Os exercícios foram realizados, individualmente, no domicílio de cada participante, não tendo supervisão durante a sua execução, mas tendo orientações por meio de visitas domiciliares a cada quinze dias. Os participantes eram instruídos a aumentar a intensidade dos exercícios, utilizando como parâmetro a escala de Borg e de forma proporcional à sua capacidade de execução, avaliada pelos assistentes da pesquisa em cada uma das visitas.

Os exercícios foram realizados utilizando o peso do próprio corpo do participante e com a ajuda de alguns equipamentos de baixo custo (por exemplo, garrafas plásticas recicláveis para demarcar a sinalização do percurso, bastões e pesos de 1 e 2 Kg para execução dos exercícios resistidos), e foram constituídos da seguinte forma:

- Exercícios de aquecimento – Exercício ativo-livre dos membros superiores e inferiores e movimento de rotação dos ombros associado a exercícios respiratórios;
- Exercícios aeróbios – Deslocamento de um bastão, com as duas mãos, dos joelhos até acima da cabeça e retornando aos joelhos, e exercícios de deambulação com flexão alternada das coxas e aproximação do joelho à mão do lado oposto;
- Exercícios resistidos – Para os membros superiores: partindo da posição com o cotovelo estendido e a mão apoiada na coxa oposta, movimentar todo o membro em diagonal para cima e em seguida retornar a mão à coxa. Para os membros inferiores: exercício de agachamento, partindo da posição sentada em uma cadeira e com os braços cruzados à frente do corpo, levantar até a posição ortostática e em seguida retornar à posição sentada;
- Exercícios de equilíbrio e coordenação – Caminhar sobre uma linha reta e caminhar desviando de obstáculos enfileirados com distâncias progressivamente menores, sendo a distância inicial de 45cm. Quando possível, o exercício evoluía e a caminhada era realizada encostando o calcanhar de um pé nos dedos do outro pé (pé com pé).
  Obs.: Para garantir a segurança, estes exercícios foram realizados próximo a móveis fixos da casa, tornando possível apoiar-se quando necessário.
- Exercícios de alongamento – Partindo da posição sentada na cama e com os joelhos em extensão, tentar alcançar a ponta dos pés; partindo da posição sentada em uma cadeira e com os pés apoiados no solo, realizar rotação do tronco para um dos lados e elevação do membro superior, do mesmo lado, acima da cabeça, esticando o mais alto possível.

Durante o período de 12 semanas consecutivas, os participantes dos dois grupos receberam visitas domiciliares periódicas com o objetivo de continuar com as orientações em relação aos hábitos de vida e estimular a adesão ao programa, porém o GI, além das orientações sobre os hábitos de vida, recebeu acompanhamento específico em relação à prática dos exercícios e assistência à possíveis eventos adversos. Após o período de três meses, os participantes dos dois grupos foram reavaliados e com a finalização da pesquisa os idosos do GI foram

encorajados a continuar com os exercícios, já ao GC foi disponibilizado o acompanhamento dos exercícios domiciliares pelo mesmo período realizado com o GI.

A adesão ao exercício foi verificada por meio dos registros semanais preenchidos pelo próprio idoso, com auxílio de familiares e certificado pelos assistentes durante as visitas domiciliares.

4.7 Análise estatística

O cálculo do tamanho amostral baseado em estudo recente[75], demonstrou que seriam necessários 63 participantes por grupo, para obter um poder estatístico de 80% na detecção de diferença de 2 pontos com alfa de 5%, considerando-se um desvio-padrão estimado de 4 pontos.

Foi respeitado o princípio da análise por intenção de tratar e para os dados faltosos foi realizada a análise de sensibilidade, por meio da imputação simples, com o emprego da média das variáveis.

Para detectar se a randomização produziu grupos comparáveis, as características dos dois grupos foram comparadas, antes da intervenção, utilizando-se o teste t de Student para amostras independentes em relação às variáveis numéricas e o teste do qui-quadrado de Pearson para variáveis categóricas.

Para testar a normalidade dos dados foi feita a análise do histograma, média e mediana, desvio padrão, *skewness* e *kurtosis* e para confirmação utilizou-se o teste de normalidade Shapiro-Wilk. Devido à distribuição normal das variáveis utilizou-se estatística paramétrica, sendo realizadas as comparações intragrupo por meio da utilização do teste t de Student para amostras emparelhadas.

A análise de subgrupo dos extratos etários, que foi pré-especificada no protocolo do estudo, como foi realizada com mais de dois grupos que apresentaram distribuição paramétrica, utilizou-se a ANOVA a um fator.

O nível de significância estabelecido para todas as análises foi de $p < 0,05$ e os procedimentos estatísticos foram analisados e processados no programa *Statistical Package of the Social Sciences* (SPSS 21.0). IBM® SPSS versão 21 (IBM, Armonk, NY, EUA).

4.8 Considerações éticas

Este estudo tem aprovação do Comitê de Ética em Pesquisa Envolvendo Seres Humanos da Escola Bahiana de Medicina e Saúde Pública sob o protocolo 39072514.6.0000.5544. Os princípios éticos gerais foram acatados levando-se em conta que a pesquisa em qualquer área do conhecimento, envolvendo seres humanos, deve ser coerente com os princípios da ciência, obedecendo a resolução nº. 466/2012 da Comissão Nacional de Ética e Pesquisa (CONEP). Todos os participantes concordaram em participar e assinaram o termo de consentimento livre e esclarecido.

4.9 Registro dos protocolos dos ensaios clínicos

Considerando que os dois artigos principais, gerados por esta tese, correspondem a ensaios clínicos randomizados, ambos tiveram início com a criação dos protocolos de estudo e com o registro no Registro Brasileiro de Ensaios Clínicos – ReBEC (ensaiosclinicos.gov.br) com número de registro: RBR-3cqzfy e, em seguida, ambos os protocolos foram submetidos à publicação em revistas científicas internacionais, assim como apresentados na sessão seguinte.

5 RESULTADOS

Artigo 1. Efeito de um programa de exercício domiciliar sobre a qualidade do sono e a sonolência diurna de idosos da comunidade: protocolo de um ensaio clínico, randomizado, controlado e simples cego.

Este artigo refere-se ao protocolo dos objetivos principais do estudo, onde propõe, por meio de um ensaio clínico randomizado, controlado e simples cego, testar a hipótese de que a prática de exercícios físicos realizados no próprio domicílio pode melhora a qualidade do sono e a sonolência diurna de idosos da comunidade.

Este protocolo já foi aceito para publicação em 26 de fevereiro de 2018.

Artigo 2. Efeito de um programa de exercício domiciliar sobre a mobilidade funcional e qualidade de vida de idosos da comunidade: protocolo de um ensaio clínico, randomizado, controlado e simples cego.

Este artigo refere-se ao protocolo dos objetivos secundários do estudo, onde propõe, por meio de um ensaio clínico randomizado, controlado e simples cego, testar a hipótese de que a prática de exercícios físicos realizados no próprio domicílio pode melhora a mobilidade funcional e a qualidade de vida de idosos da comunidade.

Este protocolo foi submetido à revista Trials em 17 de novembro de 2017, já apresenta indicativo de aceite pela revista e está em processo de correção das revisões sugeridas pelos revisores técnicos da revista e possui o seguinte identificador de manuscrito: TRLS-D-17-00919.

Artigo 3. Associação da qualidade do sono com a sonolência excessiva diurna e qualidade de vida de idosos da comunidade.

Este artigo refere-se ao objetivo terciário do estudo. Em síntese, identificou-se, entre os 131 idosos da comunidade selecionados com pontuação do PSQI ≥ 5, que a má qualidade do sono noturno está associada à pior qualidade de vida e a presença de sintomas de sonolência excessiva diurna, porém não apresentou associação, de forma significativa, com a mobilidade funcional.

Este artigo foi publicado na revista Multidisciplinary Respiratory Medicine em 14 de março de 2018 e possui o seguinte identificador de manuscrito: MDRM-D-17-00039.

Artigo 4. Exercício físico domiciliar melhora a qualidade do sono e a sonolência excessiva diurna de idosos da comunidade: um ensaio clínico randomizado.

Este artigo apesenta os resultados referentes ao objetivo primário. Em resumo, o exercício físico realizado no domicílio com orientações periódicas é eficaz em melhorar a qualidade auto referida do sono e a redução da sonolência excessiva diurna de idosos sedentários da comunidade com distúrbios do sono, em variadas faixas etárias desta população.

Este artigo foi submetido à Multidisciplinar Respiratory Medicine em 25 de outubro de 2017 e publicado em 22 de novembro de 2017. Possui o seguinte identificador de manuscrito: MDRM-D-17-00049.

Artigo 5. Exercício físico domiciliar melhora a mobilidade funcional e a qualidade de vida de idosos da comunidade: um ensaio clínico randomizado.

Este artigo apesenta os resultados referentes ao objetivo secundário. Em resumo, o exercício físico realizado no domicílio com orientações periódicas é eficaz em melhorar a mobilidade funcional e a qualidade de vida de idosos sedentários da comunidade com distúrbios do sono.

Este artigo foi submetido ao The Journal of International Medical of Research em 31 de outubro de 2017 e aceito para publicação em 14 de fevereiro de 2018. Possui o seguinte identificador de manuscrito JIMR-17-1252.

5.1 Artigo 1 – The effect of home-based exercise in sleep quality and excessive daytime sleepiness in elderly people: A protocol of randomized controlled clinical trial. Home-based exercise and sleep in elderly people

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The effect of home-based exercise in sleep quality and excessive daytime sleepiness in elderly people: A protocol of randomized controlled clinical trial. Home-based exercise and sleep in elderly people

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ABSTRACT

Background: Sleep-disordered breathing is associated with significant morbidity and mortality, presenting a high prevalence in the general population and being considered today as an important public health problem worldwide, affecting about 45% of the world population. It is estimated that about from 50 to 75% of the elderly complain of difficulties in initiating or maintaining sleep. The regular practice of physical exercise of mild to moderate intensity is associated with improved sleep quality in the elderly and has increased its recommendation as one of the main non-pharmacological resources of preventive and therapeutic action. **Objectives:** To verify the effect of a semi-supervised home-based physical exercise program on sleep quality in a sedentary elderly population, which influences the improvement of self-reported sleep quality and the reduction of excessive daytime sleepiness in a sedentary elderly population. **Methods:** This protocol study of randomized, controlled, blinded clinical trial was designed, is being conducted and will be reported according to the guidelines of the CONSORT (Consolidated Standards of Reporting Trials) Statement, and is being conducted from July 2016 to December 2017, involving elderly people of both sexes, over 60 years old, living in Senhor do Bonfim. The home physical exercise program is based on the recommendations of the American College of Sports Medicine for exercise and physical activity for the elderly. **Results:** The first expected outcome is the improvement of self-reported sleep quality verified through the PSQI. The secondary outcomes are reduction in excessive daytime sleepiness among the sedentary elderly subjects undergoing the semi-supervised home-based physical exercise program, verified by the ESS, and the adherence of the subjects to the program. **Conclusions:** We hope that through this study, we can show that the regular practice of semi-supervised home exercises is effective in improving sleep quality and reducing excessive daytime sleepiness in sedentary elderly people and can be considered as a therapeutic, safe, easy-to-implement, and low-cost non-pharmacological resource.

Key words: Exercise Training; Sleep; Quality of Life; Aged;

INTRODUCTION

Sleep-disordered breathing is associated with significant morbidity and mortality, presenting a high prevalence in the general population and being considered today as an important public health problem worldwide, affecting about 45% of the world population[1]. In the study of Romano et al., the authors discuss the epidemiological and clinical characteristics of obstructive sleep apnoea (OSA), which has been shown to be a risk factor for serious health problems, such as hypertension, coronary artery disease, stroke, metabolic disorders, and excessive daytime sleepiness[2]. The first epidemiological study describing sleep disorders was published in 1993, and showed that the prevalence of OSA ranged from 2% to 3% in women and 4% to 5% in men[3].

Punjabi in 2008, in a study involving young adults, showed that OSA was present in 3–7% of males and 2–5% of females[4]. With the improvement of diagnostic means, a recent survey conducted on a representative population of Sao Paulo City showed that 24.8% of men and 9.6% of women had OSA[5]. The high prevalence of sleep-disordered breathing recorded in this population-based sample might be attributed to the

TRIAL REGISTRATION: This protocol study has been approved by the Research Ethics Committee of the Escola Baiana de Medicina e Saúde Pública (Brazil), process no 39072514.6.0000.5544, and was registered on ensaiosclinicos.gov.br Identificator number: RBR-3cqzfy.

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increased sensitivity of current recording techniques and scoring criteria.

A recent study, the HypnoLaus Sleep Cohort study, designed to assess the prevalence of sleep-disordered breathing using state-of-the-art polysomnographic recording techniques, showed that the prevalence of moderate to severe sleep-disordered breathing (≥15 events/h) was 23.4% (95% confidence interval, 20.9–26.0) in women and 49.7% (46.6–52.8) in men[6]. These results suggest that sleep-disordered breathing is highly prevalent with important public health outcomes, and that the definition and criteria of the gravity of the disorder should be revised.

It is estimated that about 50% of the elderly complain of difficulties in initiating or maintaining sleep. Sleep disturbances are commonly observed in this population because the aging process is associated with a growing prevalence of various comorbidities, considerable use of various medications, and psychosocial risk factors that compromise sleep and are associated with morbidity and mortality[7]. As most of the elderly present several factors from different domains that compromise their sleep, these complaints are more approached as a multifactorial geriatric health condition, causing the sleep disorders to be undiagnosed[8].

The regular practice of physical exercise of mild to moderate intensity is associated with improved sleep quality in the elderly and has increased its recommendation as one of the main non-pharmacological resources of preventive and therapeutic action[9,10]. However, although scientific evidence demonstrates the benefits of regular physical exercise in the health and quality of life of the elderly, there is little adherence to this strategy. This low adherence may be correlated with external factors such as difficulty in locomotion or non-adaptation to the environment where the exercises are performed[11].

Thus, our hypothesis is that the regular practice of home physical exercise is a safe, inexpensive, and easy-to-implement non-pharmacological therapeutic resource to improve sleep quality in the elderly.

STUDY OBJECTIVES

Primary Objective

- To verify the effect of a semi-supervised home-based physical exercise program on sleep quality in a sedentary elderly population.

Secondary Objective

- To verify the effect of excessive daytime sleepiness in sedentary elderly subjects of a semi-supervised home-based physical exercise program.
- To analyse the adherence of sedentary elderly subjects to the semi-supervised home-based physical exercise program.

METHODS

Study design and setting

This randomized, controlled, blinded clinical trial was designed, is being conducted and will be reported according to the guidelines of the CONSORT (Consolidated Standards of Reporting Trials) Statement[12], shown in Figure 1. The study will use a convenience sample, composed of elderly subjects of a community in the municipality of Senhor do Bonfim, north-west of Brazil.

Ethical and legal aspects

This study was approved by the Research Ethics Committee Involving Human Beings of the Bahian School of Medicine and Public Health (protocol 39072514.6.0000.5544) and registered on ensaiosclinicos.gov.br (identification number RBR-3cqzfy). All participants have agreed and signed the informed consent form to be part of the study.

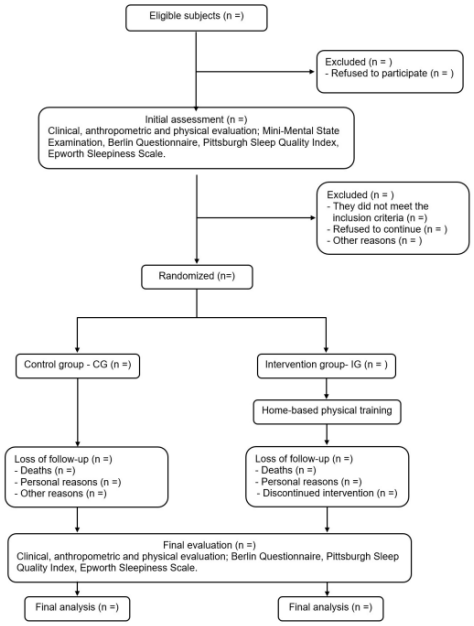

Figure 1. Flowchart of the study.

Subjects and recruitment procedure

The research is being conducted from July 2016 to December 2017, involving elderly people of both sexes, over 60 years old, living in Senhor do Bonfim. Recruitment is taking place consecutively from throughout the community, initially by disseminating the conduct of research in local newspapers, radios, religious centres, elderly meeting groups, senior residency, neighbourhood association, and the senior citizen project developed by the city hall. A telephone number is provided so that the interested subjects can contact the research team.

Eligibility criteria

The inclusion criteria for the survey are as follows: have not performed regular exercise for at least 3 months prior to the start of the study, having a score ≥5 on the Pittsburgh Sleep Quality Index (Brazilian Portuguese version; PSQI-BR)[13], and not presenting a high risk for OSA verified through the Berlin Questionnaire[14]. Participants are excluded based on the following: having a cognitive deficit according to the Mini-Mental State Examination[15], undergoing some treatment for sleep disorders (including the use of sleeping pills more than once a week), and having any clinical condition which contraindicates the performance of regular physical exercise, identified through a clinical and physiotherapeutic evaluation.

Randomization

After meeting the eligibility criteria, survey participants will receive a number in consecutive order of entry into the study and are randomly allocated to groups according to a random sequence generated by Research Randomizer. This randomization conceals the allocation to generate two groups: a control group (CG) and an intervention group (IG). All the elderly involved in the study participate in a 40-minute talk with explanations about the evaluation and intervention procedures.

The elderly of the IG will be informed to follow the guideline of home-based physical exercise program. To this end, they participate in theoretical-practical training for adequate accomplishment of the exercises and receive a booklet, developed by the researchers, that contains illustrative and written instructions on how to perform the exercises, besides a journal to register the frequency weekly.

The researchers, after making sure the subjects can perform all the exercises properly, guide the family members to help with and stimulate performance. Any change in the physical or mental condition of the subjects should be communicated by telephone to the research team. CG participants are informed that they should only continue their daily living activities.

Clinical evaluation

Evaluations are performed by a physician and previously trained physiotherapists. Research participants receive standardized verbal instructions on the procedures and are evaluated individually in the appropriate room. The entire evaluation process occurs before and after the intervention period. A clinical evaluation and a physical examination are performed, along with the collection of socioeconomic, demographic, and anthropometric data, and data on self-referred comorbidities, use of medications, sleep quality assessment, excessive daytime sleepiness, and OSA risk assessment.

Weight is measured with the subject wearing light clothing without shoes after emptying of the bladder, using a digital scale to the nearest 100 g. Height is measured without shoes, with a stadiometer to the nearest 0.5 cm (model 200/5; Welmy Industria e Comercio Ltda, Sao Paulo, Brazil). BMI is calculated by dividing weight (kg) by the square of height (m)[16].

Pittsburgh Sleep Quality Index (PSQI)

The PSQI, developed in 1989 by Buysse[17] and validated for the Portuguese language by Bertolazi[13], is used to verify sleep disorders and sleep quality by distinguishing good and bad sleepers. It consists of seven components, each punctuated on a scale of 0–3. The components are subjective sleep quality, sleep latency, duration of sleep, habitual sleep efficiency, sleep disorders, use of medications for sleep, and daytime dysfunction. The scores of these components are summed to give an overall score ranging from 0 to 21, with scores of 0–4 indicating good sleep quality, 5–10 poor sleep quality, and >10 sleep disturbance[13].

Epworth Sleepiness Scale

The Epworth Sleepiness Scale (ESS) is a self-administered scale that verifies the occurrence and intensity of excessive daytime sleepiness in eight situations of daily living. Participants are instructed to rate the likelihood of napping or falling a sleep in each of the eight specific situations on a score of 0–3, with 0: no chance of napping, 1: small chance of napping, 2: moderate chance of napping, and 3: strong chance of napping[18].

Berlin questionnaire

The Berlin Questionnaire is a self-administered test to identify patients at high risk for respiratory sleep disorders in a variety of populations, with recognized efficacy particularly in distinguishing individuals at high risk for OSA. This test consists of 10 items organized into three categories: snoring and apnoea (5 items), daytime sleepiness (4 items), and systemic arterial hypertension and obesity (1 item). All marked responses are considered positive. Scores for each category can be positive or negative. Patients with positive scores in two or more categories are considered at high risk for OSA[14].

INTERVENTION:

Physical Exercise Program at Home

The home physical exercise program is based on the recommendations of the American College of Sports Medicine for exercise and physical activity for the elderly[19]. The program

is a combination of aerobic exercises, muscle strengthening exercises, balance training, motor coordination exercises, and flexibility exercises, prioritizing exercises involving large muscle groups. The program lasts for 12 consecutive weeks, with a minimum frequency of 3 sessions per week and a planned execution time of approximately 40 min. During a session, two to three sets are performed with 5–15 repetitions for each exercise, at a target effort rate of 13–15 points ("a little difficult" to "difficult") on Borg's perceived exertion scale of 6–20[20].

The exercise program is performed individually at the home of each participant at his/her most convenient time, without direct supervision during its execution; however, on-site guidance is conducted through home visits every 15 days by a member of the research team. Participants are instructed to increase the intensity of the exercises, using Borg's scale as a parameter and in a manner proportional to their capacity of execution, evaluated by the research assistants in each of the visits.

The subjects perform the exercises using their own body weight and with the help of some low-cost equipment made by themselves (recyclable plastic bottles to demarcate the signage of the course, sticks and weights of 1 and 2 kg for performing the resistance exercises). The exercises performed are as follows:

- Warm-up exercises – Active free exercises of the upper and lower limbs, including extension, flexion, and rotation of the shoulders associated with breathing exercises.
- Aerobic exercises – Displacement of a stick with both hands, from the knees to above the head and returning to the knees, and exercises of ambulation with alternating flexion of the thighs and approaching the knee by hand on the opposite side.
- Resistance exercises – For the upper limbs: While standing with the elbow extended and the hand resting on the opposite thigh, the subject moves the whole hand diagonally upwards and then returns the hand to the thigh. For the lower limbs: For a squatting exercise, sitting on a chair with arms crossed in front of the body, the subject lifts to the orthostatic position and then returns to the sitting position.
- Balance and coordination exercises – The participant walks on a straight line and walks away from queued obstacles with progressively smaller distances. The exercise evolves as possible, and the walk is performed by placing the heel of one foot on the toes of the other foot (standing foot). Note: To ensure safety, these exercises are performed close to a fixed furniture in the house, making it possible to lean when needed.
- Stretching exercises – From a sitting position on bed and with the knees extended, the participant tries to reach the tip of the feet. From a sitting position on a chair and with the feet resting on the ground, the participant performs rotation of the trunk to one side and elevation of the upper limb, on the same side, above the head, stretching as high as possible.

During the period of the program (12 consecutive weeks), regular home visits are made to the participants of the two groups to clarify doubtsand encourage adherence to the program. The IG receives specific monitoring regarding the practice of the exercises and assistance to possible adverse events. After the 12-week period, the subjects in both groups are reassessed and encouraged to continue with the home program. Meanwhile, the subjects of the CG are followed up for the regular practice of the same home exercises performed by the IG participants in the same period. Adherence to the program is verified through weekly records that are filled in by the elderly with the help of his relatives and are also certified by the assistants during the home visits.

Statistical analysis

To detect whether randomization generated comparable groups, the characteristics of the two groups will be compared before the intervention using the Student's t-test for independent samples in relation to the numerical variables and the Pearson chi-square test for categorical variables. To test the normality of the data, a study of the histogram of the study, mean and median, standard deviation, skewness and kurtosis will be performed, and for its confirmation we will use the Shapiro-Wilk normality test. The significance level established for all analyzes will be $p < 0.05$ and all statistical procedures will be analyzed and processed in the Statistical Package of Social Sciences SPSS 21.0 (IBM® SPSS version 21, IBM, Armonk, NY).

Sample size

The calculation of sample size was based on a previous study by Chen et al. (21) that identified a significant improvement in overall sleep quality using the PSQI. Using a two-tailed alpha of 0.05 and 80% power to detect a moderate effect size of 0.63 (0.30–0.80), a sample size of 82 subjects was necessary to comprise our sample. Eight patients were added (20%) to each group to allow for possible sample loss.

Outcome measures

The first expected outcome is the improvement of self-reported sleep quality verified through the PSQI. The secondary outcomes are reduction in excessive daytime sleepiness among the sedentary elderly subjects undergoing the semi-supervised home-based physical exercise program, verified by the ESS, and the adherence of the subjects to the program.

Assessor blinding:

Researchers involved in the interpretation of clinical tests and the statistician responsible for data analysis will be blind to the composition of the study groups.

Data monitoring and quality control:

Systematic trainings exclusively for evaluations are carried out to 5 assistants, and 10 assistants are being used for home monitoring, 5 of whom are visiting the IG and the other 5 are visiting the CG. The research assistants ensure equal distribution of the number of subjects being evaluated and the number of homes being visited.

RESULTS

The results of this study are expected to show that sedentary elderly people with sleep disorders present a significant improvement in sleep quality and a reduction in excessive daytime sleepiness when participating in a semi-supervised physical exercise program. Such expected results are based on studies that have already demonstrated the effectiveness of physical exercise programs in improving sleep quality[9,22-24] and reducing excessive daytime sleepiness in the elderly[25].

DISCUSSION

However, most of these studies adopted professional supervision during the execution of exercise programs, as well as performance of the exercises in training and/or rehabilitation centres, which is a limiting factor for the participation of the elderly because they experience difficulties in relation to the transfer[24,26]. This study advocates a program of home physical exercise, supervised only every fortnight, easy to apply, and inexpensive. It has already been shown that physical exercise performed at home, besides being the preference of the elderly person, can present important health benefits[26-28], demonstrating greater adherence and continuity after the end of the proposed program[29].

Knowledge on the effects of home exercises on sleep quality of the elderly is still very incipient. A randomized trial similar to the one described here was conducted by Chen et al.[22] The trial involved 56 elderly people (mean age, 71.7 ± 8.1), where the IG performed the Baduanjin exercise program in their households and the CG did not perform any specific activity. The IG subjects received a videotape and an educational booklet with pictures of how to perform the exercises, were instructed to perform 30 min of exercise thrice a week for 12 weeks, and received a telephone follow-up twice a week. After the proposed period, a significant difference was observed in the PSQI scores between the groups of subjects.

A secondary outcome of this study is reduction in excessive daytime sleepiness, which is currently recognized as an important public health problem[28]. It would be expected that elderly people who practice physical exercise present a reduction in excessive daytime sleepiness, as observed in a study by Li et al.[25] using supervised Tai Chi exercises. Moreover, in a study by Chen et al.[24], the practice of Yoga resulted in a significant reduction in daytime sleepiness in elderly people, verified through ESS.

In a recent randomized, controlled trial study, Lu et al.[30], verified the effects of a 24-week Tai Ji Quan training program on sleep quality, quality of life, and physical performance among elderly Chinese women with knee osteoarthritis (OA). Subjects were randomly assigned to either a Tai Ji Quan group or a control group. Participants in the Tai Ji Quan group completed training sessions three times per week, while those in the control group had bi-weekly educational classes. The primary outcome was total score of the Pittsburgh Sleep Quality of Index (PSQI), and the secondary outcomes were seven subscales of the PSQI; physical component summary and mental component summary of the 36-item Short Form Health Survey (SF-36); Berg Balance Scale (BBS); and Timed Up and Go (TUG). Compared with the control group, participants in the Tai Ji Quan group had significantly improved primary outcome (PSQI score) and secondary outcomes, including three PSQI sub-scores (sleep latency, daytime total sleep, and SF- 36 PCS. The Tai Ji Quan group also had significant improvements compared to baseline in three PSQI sub-scores (sleep latency, sleep disturbance, sleep latency, BBS, and TUG). The authors concluded that Tai Ji Quan training is an effective treatment approach to improve sleep quality and quality of life in elderly Chinese women with knee OA.

One of the strengths of this study is that after random allocation of participants, both IG and CG periodically receive the same orientations and stimuli in relation to sleep hygiene measures, allowing them to present different behaviours only with regard to the practice of physical exercise, so that we can show differences between both groups. Some studies suggest that direct contact with the participants via telephone, Internet, or personal visit increases the adherence of elderly subjects to home exercise programs[29-32].

We hope that through this study, we can show that the regular practice of semi-supervised home exercises is effective in improving sleep quality and reducing excessive daytime sleepiness in sedentary elderly people and can be considered as a therapeutic, safe, easy-to-implement, and low-cost non-pharmacological resource.

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DESCRIPTION OF RISKS

There will be no risks for included patients.

AUTHORS CONTRIBUTIONS

GSB and AAC: conception and design of this study; AAC, GSB and, AAC: data acquisition, draft and revision of the study; JJU, ASS, NSFS, LVFO, GSB and AAC: analysis and interpretation of data, draft and revision of the study; RSBR: All authors: final approval of the version to submission.

CONFLICTS OF INTEREST

The authors declare that they have no competing interests.

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5.2 Artigo 2 - Effect of a home-based exercise program on functional mobility and quality of life in elderly people: protocol of a single blind, randomized, controlled trial.

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Effect of a home-based exercise program on functional mobility and quality of life in elderly people: protocol of a single blind, randomized, controlled trial.
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Effect of a home-based exercise program on functional mobility and quality of life in elderly people: protocol of a single blind, randomized, controlled trial.

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ABSTRACT

Background: Elderly people have high rates of functional decline, which compromises independence, self-confidence, and quality of life. Physical exercise lead to significant improvements in strength, balance, functional mobility, and quality of life. The purpose of this clinical trial will be to verify the effect of a progressive and semi-supervised, home-based exercise program on the functional mobility, and quality of life of sedentary elderly. **Methods/design:** This is a protocol of a consecutive single-center, single blind, randomized controlled trial. The design, conduct and report of this study followed the SPIRIT (Standard Protocol Items: Recommendations for Interventional Trials). Sedentary elderly persons will be evaluated, enrolled, and randomly allocated into two groups: intervention group, they will perform exercises in their own home; and control group, they will not perform exercises. The evaluations, which will occur at study enrolment and after three months of intervention, will be performed using the functional mobility test Timed Up & Go (TUG) test and application of a sociodemographic, and quality of life questionnaire (WHOQOL-OLD). In the statistical analysis, comparisons of mean and correlation analyses will be performed. The primary expected outcome is the improvement in functional mobility verified through the TUG test and the secondary is the improvement in quality of life, verified using the WHOQOL-OLD. **Discussion:** The lack of scientific evidence demonstrating the benefits of semi-supervised home exercise on functional mobility and quality of life in elderly people represents an obstacle to the development of guidelines for clinical practice and for policy makers. The World Health Organization highlighted the importance of musculoskeletal health programs for elderly people. The exercise program described in this protocol was designed to be viable, easy to implement, and inexpensive, and could be performed in elderly individuals' homes after receiving only guidelines and follow-up via periodic visits. Based on these facts, we hope this study will demonstrate that a well-structured, home-based exercise program can be effective in improving functional mobility and quality of life of sedentary elderly individuals, even without constant supervision during exercise. **Trial registration:** The study is registered at the website "ensaiosclinicos.gov.br - Identifier: RBR-3cqzfy".

Key Words: Aged, Motor Activity, Quality of life, Community.

BACKGROUND

Increased life expectancy is associated with biopsychosocial changes that occur naturally with advancing age[1]; among these changes, the decline in functional performance and fear of falls are some of the factors with the most influence on quality of life in elderly people[2,3]. The growing process of population aging has emerged as a clinical priority in the fields of public health and social assistance

policies[4], considering that old age and disability are among the main determinants of the use of public health services[5,6].

Elderly people in the community have high rates of functional decline and disability, progressively compromising their independence, self-confidence, and quality of life. These impairments are intensified by physical inactivity, which is linked to important negative outcomes in the general health of elderly people[7,8].

Some studies have demonstrated that the implementation of specific physical exercise programs produces significant improvements in muscle strength, balance, and functional mobility of elderly people, even in individuals of more advanced age, and that regular practice of these exercises produces positive effects on the quality of life in this population[7,9,10].

However, despite scientific evidence showing the benefits of physical exercise in this population, there is still low adherence to this strategy, possibly related to external factors such as difficulties in locomotion or non-adaptation to the environment where the exercises are performed, since the majority of studies use supervised exercise programs performed at physical training centres[11]. A recent study[12] showed that elderly people with a history of falls prefer to participate in exercise programs that can be performed at home or do not require transportation.

Considering that semi-supervised, home-based exercise is a safe, inexpensive, and easy to implement therapeutic resource, this study aims to test the hypothesis that the regular practice of a progressive physical exercise program performed at home improves functional mobility and quality of life in a population of sedentary elderly individuals. Our hypothesis is that regular practice of semi-supervised and progressive home exercise improves functional mobility and quality of life of sedentary community dwelling elderly individuals. The primary objective of the study is to verify the effect of a progressive and semi-supervised, home-based exercise program on the functional mobility of a population of sedentary elderly persons in the community. The secondary objectives are to analyse the effect of a progressive and semi-supervised, home-based exercise program on the quality of life of a sedentary elderly population in the community.

METHODS/DESIGN

Study design and setting

The design and conduct of this study followed the guidelines of The Standard Protocol Items "Recommendations for Intervention Trials (SPIRIT) guidelines[13], according to the flow chart of the study showed in Figure 1. This is a blind, randomized, controlled clinical trial, using a superiority test and 1:1 allocation ratio. The sample will be of convenience, composed of elderly individuals in a community in the city of Senhor do Bonfim - Ba, North West of Brazil.

Ethical and legal aspects

This study protocol was approved by the Research Ethics Committee of the Bahia School of Medicine and Public Health (Brazil), process no 39072514.6.0000.5544, and was registered on the website "ensaiosclinicos.gov.br Identifier: RBR-3cqzfy". All participants must agree and sign the informed consent form to participate in the study. Removal is permitted at any time without any loss.

Participants and recruitment procedure

The research will be conducted from December 2016 to July 2018, involving elderly people of both sexes, over 60 years old, living in the municipality of Senhor do Bonfim (BA), in the northeast region of Brazil. Recruitment will be consecutive, across the community, from December 2016 to December 2018. Initially, it will take place through the dissemination of the research study in local newspapers, radios, religious centres, elderly meeting groups, senior residency, neighbourhood associations, and the third age project developed by the municipal government. In this announcement will be provided a telephone so interested people will be able to contact the team of researchers.

Eligibility criteria

The inclusion criteria for the survey will be age ≥ 60 years old and not having performed regular exercise for at least three months prior to the start of the study. Participants with cognitive deficits will be excluded according to the Mental State Mini-Exam[14]; participants will also be excluded if they have any clinical condition that

contraindicates the performance of regular physical exercise, identified through a clinical and physiotherapeutic evaluation.

Randomization

After meeting the eligibility criteria, participants will receive a number in consecutive order of entry in the study; they will then be randomly allocated in a 1:1 ratio according to a random sequence generated by the *Research Randomizer* (www.randomizer.org). This will be a block randomization, with concealment of the allocation to generate two groups: a control group (CG) and an intervention group (IG). All elderly individuals involved in the study will participate in a 40-minute talk with explanations on the evaluation and intervention procedures and will receive educational leaflets containing guidelines on healthy habits related to food, hydration, and sleep hygiene.

Elderly individuals in the IG will be informed that they will follow the guidelines of healthy habits of life and a program of home physical exercise. For this program, they will participate in theoretical-practical training concerning adequate accomplishment of the exercises and will receive a booklet, developed by the researchers, that contains illustrative and written guidelines on the method of performing the exercises, and a diary to register the frequency of exercise on a weekly basis.

The researchers, after making sure that the participants will be able to properly perform all the proposed exercises, will guide the family members to help the participants and stimulate their practice. Any change in the physical or mental condition of the participants should be communicated by telephone to the research team. Participants in the CG will be informed that they should only continue their daily living activities and follow the guidelines of healthy living habits.

Clinical evaluation

A previously trained doctor and physiotherapist will perform all evaluations. Participants will receive standard verbal instructions on the procedures and will be evaluated individually in an appropriate room. Evaluations will be conducted before and after the intervention period. A clinical evaluation, physical examination, and evaluation of functional mobility and quality of life will be performed and

socioeconomic, demographic, anthropometric, and self-referenced morbidity data will be collected.

Weight will be measured while wearing light clothing and without shoes, after emptying of the bladder, using a digital scale to the nearest 100 g. Height will be measured without shoes, with a stadiometer to the nearest 0.5 cm (model 200/5; Welmy Industria e Comercio Ltda, Sao Paulo, Brazil). Body mass index will be calculated by dividing weight (kg) by the square of height (m)[15].

Functional mobility will be evaluated by the timed up and go (TUG) test, a simple test that evaluates the speed of execution in raising from a chair, walking three meters ahead, turning, walking back, and sitting in the chair again. According to the test, an execution time of less than 10 seconds suggests totally free and independent individuals. Individuals who perform the test between 10 and 19 seconds are considered independent, and those who perform the test in 20 to 29 seconds are in the so-called "grey zone", that is, demonstrating limited functional capacity and difficulties in tasks of daily living. Those who perform the test in 30 or more seconds tend to be totally dependent for many basic and instrumental activities of daily living[16].

Quality of life will be evaluated using the World Health Organization Quality of Life Group (WHOQOL-OLD), which contains six facets of 4 items each, evaluated by the Likert scale (1 to 5 points): Facet I **–** “Operation of Sensory”; Facet II **–** “Autonomy”; Facet III **–** “Past, Present, and Future Activities”; Facet IV **–** “Social Participation”; Facet V **–** “Death and Dying”; Facet VI **–** “Intimacy”. Each of the facets has 4 items; thus, for all facets the score of the possible values ranges from 4 to 20, and the scores of these six facets or the values of the 24 items can be combined to produce a "global" score of the quality of life[17].

INTERVENTION

Physical exercise program at home

The home exercise program will be based on the recommendations of the American College of Sports Medicine for exercise and physical activity of elderly people (3). The program consists of aerobic exercises, muscle strengthening exercises, balance

training, motor coordination, and flexibility, always prioritizing exercises involving large muscle groups. The protocol will last for 12 consecutive weeks, with a minimum frequency of 3 sessions per week and a planned execution time of 40 minutes. During each session, 2 to 3 sets will be performed with 5 to 15 repetitions for each exercise at a target effort rate of 13-15 ("a little difficult" to "difficult") on Borg's perceived exertion scale of 6 to 20 points[18].

The participant will perform the exercise program individually in their own home, without direct supervision during its execution, but with on-site guidance through home visits every 15 days by one of the members of the team. Participants will be instructed to increase the intensity of the exercises, using the Borg scale to evaluate intensity, and in a manner proportional to their execution capacity, evaluated by the research assistants at each of the visits.

The exercises will be carried out using the weight of the body itself and with the aid of some low-cost equipment (recyclable plastic bottles to demarcate the signage of the course, sticks and weights of 1 and 2 kg for performing the resistance exercises). The following are the exercises to be performed.

- Warm-up exercises - Active-free exercises of upper and lower limbs, including extension, flexion, and rotation of the shoulders associated with breathing exercises;
- Aerobic exercises - Displacement of a stick with both hands, from the knees to above the head and returning to the knees, and walking exercises with alternating thigh flexion and placing the hand on the opposite knee;
- Resistance exercises - For the upper limbs: starting from the position with the elbow extended and the hand resting on the opposite thigh, movement of the whole member diagonally upwards and then returning the hand to the thigh. For the lower limbs: squatting exercise, starting from the sitting position on a chair and with arms crossed in front of the body, lifting to the orthostatic position and then returning to the sitting position;
- Balance and coordination exercises - Walking on a straight line and walking while diverting from lined obstacles with progressively smaller distances. When

possible, the exercise will evolve and the walk will be performed by touching the heel of one foot to the toes of the other foot (foot with foot).

Note: To ensure safety, these exercises will be performed close to fixed furniture in the house, making it possible to lean when necessary.

- Stretching exercises - From the sitting position and with knees in extension, trying to reach the tip of the feet; from the sitting position on a chair and with the feet on the ground, performing rotation of the trunk to one side and elevation of the upper limb, on the same side, above the head, stretching as high as possible.

During the period of the proposed program (12 consecutive weeks), regular home visits will be made to the participants of the two groups in order to clarify doubts, guide healthy living habits, and encourage adherence to the program. The IG will receive, in addition to these guidelines, specific monitoring in relation to the practice of the exercises and assistance with possible adverse events. After the end of the proposed 12-week period, the researchers will reassess the participants in both groups and encourage them to continue with the home program. Those in the CG will be provided follow-up for the regular practice of home exercises for the same period performed by the IG participants. Adherence to the exercise will be verified through the weekly records that will be filled by the participants themselves, with the help of their relatives, and will be certified by the assistants during the home visits.

STATISTICAL ANALYSIS

The principle of intention-to-treat analysis will be respected. For missing data, we will perform a sensitivity analysis, through simple imputation, using the mean of the variables. To detect whether randomization generated comparable groups, the characteristics of the two groups will be compared prior to intervention using the Student's t-test for independent samples for numerical variables and the Pearson chi-square test for categorical variables. To test the normality of the data, an analysis of the study histogram, mean and median, standard deviation, skewness, and kurtosis will be performed and for its confirmation, we will use the Shapiro-Wilk normality test. With a normal distribution of variables, parametric statistics will be used, and intragroup comparisons will be made using the Student t-test for paired samples; the intergroup comparisons will be performed using the Student t-test for independent samples. If there is no normal distribution of the variables, the corresponding

nonparametric tests will be used. For the analysis of the groups by age, as will be done with more than two groups, we will use the one-way ANOVA for parametric distribution or Kruskal-Wallis for non-parametric analysis. The significance level established for all analyses will be $p < 0.05$ and all statistical procedures will be analysed and processed using the Statistical Package of the Social Sciences SPSS 21.0 software (IBM® SPSS version 21, IBM, Armonk, NY, USA).

Sample size

The sample size was calculated based on the main hypothesis. The calculation was based on the study performed by Lacroix et. Al[8] in which the group that performed unsupervised exercises obtained a pre/post-treatment reduction of 0.47 seconds at the time of execution of TUG during 12-week follow-up. This demonstrates that it would be necessary to include 63 participants per group, in order to obtain a statistical power of 80% with alpha of 5%, considering an estimated standard deviation of 0.84 in A and 1.02 in B. To allow 10% loss during follow-up, 70 participants will be recruited per group, i.e., 140 in total.

Outcome measures

Primary outcome

The first expected outcome is the improvement in functional mobility of elderly participants, verified through the TUG test.

Secondary outcome

The second expected outcome is the improvement in quality of life of elderly participants, verified using the WHOQOL-OLD.

Assessor blinding

Researchers involved in the interpretation of clinical tests and statistician responsible for data analysis will be blind to the composition of the study groups.

Data monitoring and quality control

Systematic training of five assistants will be carried out exclusively for evaluations, and training of ten assistants will be performed for home monitoring of elderly people, five of whom will visit the IG and five of whom will visit the CG. The distribution of the

number of participants to be evaluated and the number of domiciles to be visited will be done in an equivalent way among the research assistants. All data regarding the subjects involved in this study will be kept confidential, in accordance with the principle of confidentiality!

DISCUSSION

This is a study designed to verify whether a semi-supervised, home-based exercise program alters the functional mobility and quality of life of sedentary community elderly persons when compared to a control population. This hypothesis is based on research that has already demonstrated the efficacy of physical exercise programs in terms of functional mobility[7,19,20] and improving the quality of life of elderly people[8,9]. However, most of these studies adopted professional supervision during the execution of exercise programs, in addition to being performed in training and/or rehabilitation centres[21-23], which is characterized as a limiting factor for the participation of elderly people, as they may have difficulties with mobility and transfer[24].

The benefits of such programs depend on the degree of adhesion to exercise, which is influenced by the intensity of pleasure and satisfaction provided[24,25].

It has already been demonstrated in the literature that physical exercise performed at home, in addition to being the preference of elderly people, can provide important health benefits[7,22,26], leading to improved adherence and continuity of the exercises after the end of the proposed program[27].

One of the main characteristics of the present study is the focus on the practice of semi-supervised exercises. A strength of this study is that, after the random allocation of the participants, both groups will receive periodic home visits with the same frequency, aiming to provide the same orientation and stimuli in relation to healthy lifestyle habits. This allow the groups to acquire similar behaviours, differing only in terms of the practice of physical exercise, considering that previous studies suggest the frequent contact with the participants by phone calls, Internet, or personal visit increases adherence of elderly people to home exercise programs[8,26,27].

The lack of scientific evidence demonstrating the benefits of semi-supervised home exercise on functional mobility and quality of life in elderly people represents an obstacle to the development of guidelines for clinical practice and for policy makers. The World Health Organization highlighted the importance of musculoskeletal health programs for elderly people[28], and the exercise program described in this protocol was designed to be viable, easy to implement, and inexpensive, and could be performed in elderly individuals' homes after receiving only guidelines and follow-up via periodic visits. Based on these facts, we hope this study will demonstrate that a well-structured, home-based exercise program can be effective in improving functional mobility and quality of life of sedentary elderly individuals, even without constant supervision during exercise.

The results of this study should be interpreted considering some limitations. The inability to blind participants to the intervention may be mitigated by the fact that different assistants will accompany each group (CG and IG), minimizing the excitement bias applied by the IG assistants during home visits. Monitoring of the frequency of exercise completion will be self-referenced; in order to increase the reliability of this information, in addition to monitoring of the frequency register during home visits, family members will be recruited to assist in these annotations.

Trial status

The study is registered at the website "ensaiosclinicos.gov.br - Identifier: RBR-3cqzfy" and is currently recruiting participants. This phase is expected to end in March 2018.

Additional files:

Additional file 1: SPIRIT 2013 checklist: recommended items to address in a clinical trial protocol and related documents.
Additional file 2: Ethical approval file: ethical approval of participating centres involved. (pdf 176 kb)

Abbreviations

WHOQOL-OLD: World Health Organization Quality of Life for Older Adults; TUG: timed up and go; SPSS: Statistical Package of the Social Sciences.

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Availability of data and materials

The data of the subjects involved in this study and all documentation related to the informed consent and ethical approval of this protocol will be made available on request.

Authors' contributions

GSB[1], LVFO, and AAC provided the concept of the study, created the hypothesis,

and wrote the original proposal. GSB[1], EFO, AS and NSFJ obtained ethics approval. GSB[1], AACS and GSB[4] will be participated in the data collection and performed clinical evaluations. GSB[1], LVFO, and AAC prepared the drafted manuscript. GSB[4], LVFO, LTP, ASS, DPO, JJU, RFO and AAC were involved in the critical revision of the manuscript. GSB[1], AAC and LVFO co- lead investigators. GSB[1], AC, and LVFO wrote this protocol paper, with input from all co-authors. All the authors agree to be accountable for all aspects of the work in ensuring that questions related to the accuracy or integrity of any part of the work are appropriately investigated and resolved, and read and approved the final manuscript.

Competing interests

The authors declare that they have no competing interests.

Consent for publication

All subjects involved in this study gave permission for the publication of the data, while remaining anonymous. All authors agree with the final version of the study and agree with its publication.

Ethics approval and consent to participate

The study was approved by the Research Ethics Committee of the Bahia School of Medicine and Public Health, process 39072514.6.0000.5544 and, e study is registered at the website “ensaiosclinicos.gov.br - Identifier: RBR-3cqzfy”. All participants will sign an informed consent form before randomisation. All steps will be taken by the investigators if there is any recurring damage from participation in this study. The results of this protocol study will be published in peer-reviewed journals as well as national and international conferences. The data collected will also be made available in a public data repository.

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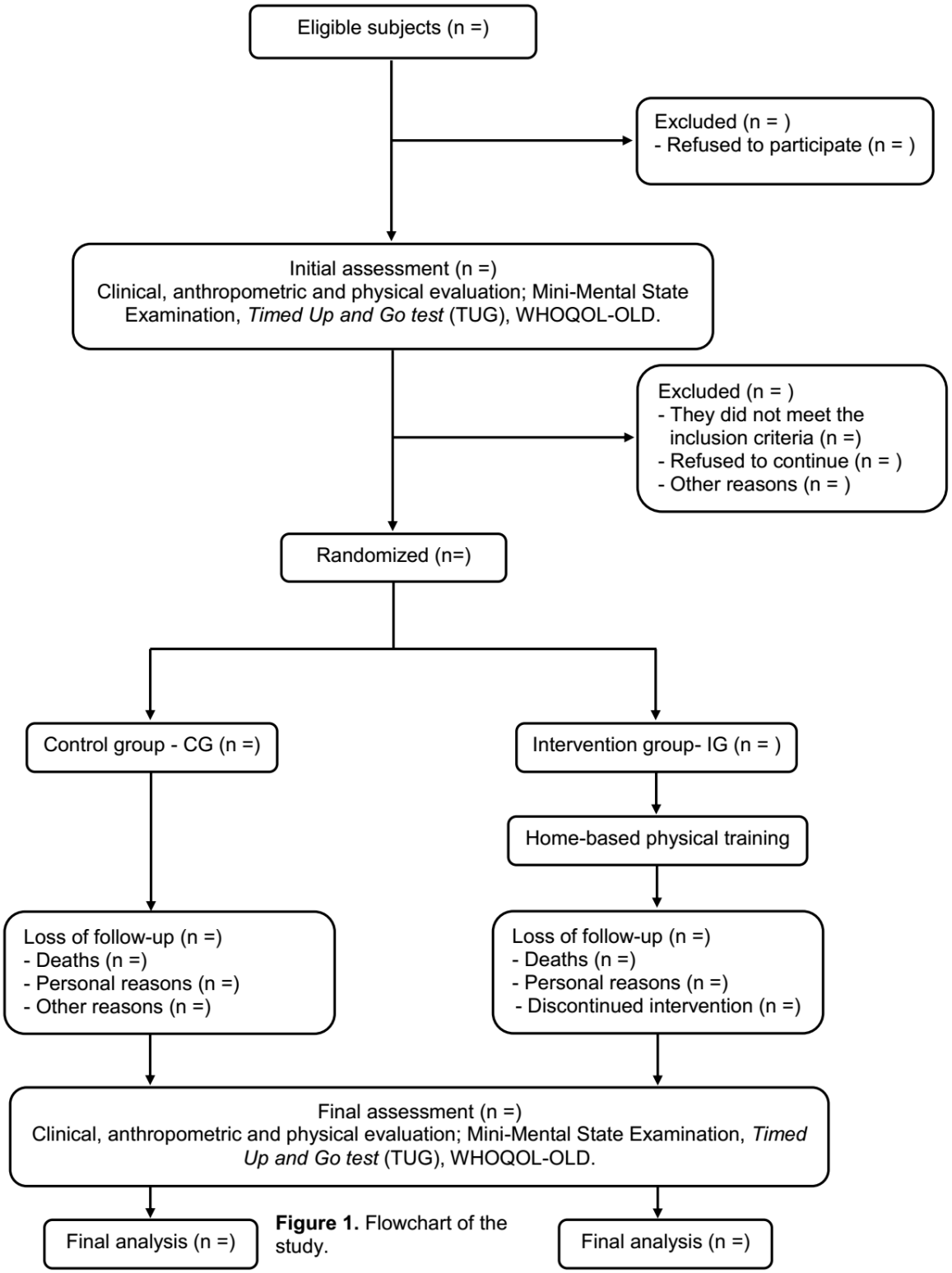

Figure 1. Flowchart of the study.

5.3 Artigo 3 - Association of Sleep Quality With Excessive Daytime Somnolence and Quality of Life of Elderlies of Community

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Association of sleep quality with excessive daytime somnolence and quality of life of elderlies of community

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Abstract

Background: The progressive increase in the elderly population contributes to the fact that studies on human aging have important attention of health professionals and government agents, since they present a great challenge regarding public health. Our objective is to characterize the profile of older people with poor sleep quality and analyze possible associations with excessive daytime somnolence, quality of life and functional mobility.

Methods: This is a cross-sectional descriptive study, involving elderlies of the community, with the questionnaires Pittsburgh Sleep Quality Index (PSQI), Epworth Sleepiness Scale, WHOQOL-OLD and application of the Timed Up and Go test - TUG. Descriptive statistics, Student's t test for paired samples and Pearson's correlation coefficient ($p \leq 0.05$) were used.

Results: We recruited 131 elderly people, predominantly female (87%); mean age 68 ± 7 years, low *per capita* income (84.8% ≤ 2 minimum wage), low education (86.3% ≤ 3 years of study), and mostly staying with relatives (67.9%), married (39.7%) or amassed (35.9%). Seventy-one percent of the sample is above normal weight, 90.1% of women have an abdominal circumference ≥ 80 cm and a high prevalence of chronic and psychosocial diseases was identified in the self-report, and the risk of obstructive sleep apnea in 38.2%. The mean PSQI, Epworth Sleepiness Scale, WHOQOL-OLD and TUG were equal to, respectively, 11.2 ± 3.2; 8.32 ± 2.2; 84.8 ± 10.2 and 8.97 ± 2. An association of sleep quality with excessive daytime somnolence and quality of life, while not with functional mobility, was observed.

Conclusion: The results of the present study allowed to identify a sleep quality associated with excessive daytime somnolence and quality of life and also to characterize the profile of elders with poor sleep quality.

Keywords: Elderly, Community, Sleep, Quality of life, Excessive daytime somnolence

Background

The elderly population has the highest growth rate in the world. In socioeconomic developing countries such as Brazil, population aging is a relatively new process and has occurred so rapidly that the more conservative projections indicate that by 2025 it will be the sixth country in the world in terms of the number of elderly people, corresponding to 15% of all the population contingent [1]. This progressive increase in the elderly population contributes to the fact that studies on human aging have important attention of health professionals and government agents, since they present a great challenge regarding public health [2].

The physiological aging is accompanied by alterations in the quality, quantity and architecture of the sleep, being able to lead to diverse diseases, originating considerable social and economic problems [3–6].

Studies using electroencephalography have shown that the cortical status of older people presents a tendency to alertness, associated with a low threshold to wake up in

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response to environmental stimuli and an increased sleep latency. Thus, a reduction in the ability of healthy elderly individuals to initiate and maintain sleep associated with an increase in stages 1 and 2 and a reduction of stage 3 of NREM sleep is observed, as well as a reduction of REM sleep [4, 6].

This reduction of slow-wave sleep may be a consequence of the loss of the predominance of parasympathetic activity, as evidenced by the reduction of heart rate variability during sleep in the elderly, and results in a decline in the secretion of human growth hormone, thus reducing restorative capacity [5, 7, 8].

Among the several diseases that affect the elderly, sleep disorders are among the most prevalent and they are associated with several comorbidities, which consist by a relevant factor of alterations in the perception of general health [9, 10]. An important epidemiological study with more than 9,000 participants has demonstrated that more than half of the elderly population had at least one complaint of sleep and that the poor quality of sleep would be associated with the presence of biopsychosocial deficiencies such as excessive daytime somnolence, cognitive deficit, depression, fatigue, increased risk of falls, limitations in daily life activities, reduced quality of life and increased incidence of cardiovascular morbidity and mortality [11].

According to the high prevalence of sleep disorders in the geriatric population, we highlight the necessity for information which may subsidize health services in the planning of care in relation to sleep quality and its health impacts in elderly. Therefore, the present study aimed to test the association of sleep quality with excessive daytime somnolence, quality of life and functional mobility of the elderly with poor sleep quality.

Methods

This is a descriptive, cross-sectional study with a quantitative approach on the profile of the elderly in the community with poor sleep quality, approved by the Research Ethics Committee of the Bahia School of Medicine and Public Health (EBMSP), with CAAE: 39072514.6.0000.5544. All participants in the study signed the Informed Consent Term. The design and conduct of this study followed the guidelines of the Reporting of Observational Studies in Epidemiology (STROBE).

The study was conducted with elderly residents in Senhor do Bonfim-BA, northeast region of Brazil, from July to November 2015. Recruitment occurred throughout the community, through the dissemination of study in local newspapers, radios, religious centers, groups of elderly meeting, senior residence, neighborhood association and in the third age project developed by the city hall, and in the announcement the phone number was provided for interested parties in order to contact the researchers. The inclusion criteria were 60 years old or older and score ≥ 5 in the Pittsburgh Sleep Quality Index (PSQI) [12]. Participants with a cognitive decline according to the Mental State Mini-Exam [13] and those who were performing some treatment for sleep disorders were excluded from the study.

A questionnaire was applied covering socioeconomic and demographic variables, as well as questions regarding self-reported morbidities and life habits.

Sleep quality was assessed using the Pittsburgh Sleep Quality Index (PSQI) validated for using in Brazil [12]. The PSQI was developed in 1989 and provides a measure of quality of standardized sleep, which discriminates the participants in good or bad sleepers. It consists of seven components, each scored on a scale of zero to three. The components are, respectively; sleep subjective quality; sleep latency; duration of sleep; habitual sleep efficiency; sleep disturbances; using medications for sleep and daytime dysfunction. The scores of the seven components are added together to give an overall score ranging from 0 to 21, with scores of 0–4 indicating good quality of sleep, 5–10 poor quality and above 10 sleep disorder [14].

Excessive daytime somnolence was assessed using the Epworth Sleepiness Scale (ESS), validated for Brazil. The scale presents eight situations involving activities of daily living in the occurrence of daytime sleepiness. The participants were instructed to rate on a score from 0 to 3 about the probability of feeling slumber or falling asleep in each of the eight specific situations, in which the higher scores indicate a greater chance of sleeping and scores above 10 suggesting a diagnosis of excessive daytime somnolence [15].

To evaluate the potential risk of Obstructive Sleep Apnea (OSA), the Berlin Clinical Questionnaire was used. The instrument includes ten items organized in three categories: snoring and apnea (containing 5 items), daytime somnolence (4 items), systemic arterial hypertension and obesity (1 item). The categories 1 and 2 are considered positive if the score of each is greater than or equal to two points, while category 3 is considered positive if the answer to question 10 is YES or if the body mass index (BMI) is greater than 30 kg/m^2. Patients are considered to be at high risk for OSA, when two or more categories present a positive score and, when there is none or only one category with a positive score, the risk for OSA is low [16].

In evaluating the anthropometric variables such as body weight and height, a balance with estadiometer was used (mechanical anthropometric scale, 150 kg - Welmy®, Sao Paulo, Brazil) properly calibrated; to measure the waist circumference, a tape measure was used and the Body Mass Index (BMI) was calculated from the weight in kilograms divided by the height in meters squared.

The level of physical activity was evaluated through the International Questionnaire of Physical Activity (IPAQ)

adapted for the elderly [17]. It is an instrument which allows estimating the weekly energy expenditure of physical activities related to work, transportation, domestic tasks and leisure, carried out continuously for at least 10 min with moderate and/or vigorous intensity during a normal/usual week. For the present study, the last variable was dichotomized, and it was considered inactive that participant who executed less than 150 min per week of moderate and/or vigorous and active that participant who executed physical activities for more than 150 min per week.

Functional mobility was assessed using the *Timed Up and Go test* (TUG), a simple test which evaluates the execution speed in getting up from a chair with arms, to walk three meters forward, to turn around, to walk back and to sit on the chair again. The execution time less than 10 s suggests totally free and independent individual; those who perform the test between 10 and 19 s are considered independent, from 20 to 29 s those who are in a so-called "gray zone", which is, they demonstrate difficulties for tasks of daily living and limited functional capacity. Those who present a time score of 30 or more seconds tend to be totally dependent on many basic and instrumental activities of daily living [18].

To evaluate the quality of life used the WHOQOL-OLD containing six facets each of 4 items, which was evaluated by *Likert scale* (1 to 5 points): Facet I - "Sensory Operation"; Facet II - "Autonomy"; Facet III - " Past, Present and Future Activities"; Facet IV - "Social Participation"; Facet V - "Death and Dying"; Facet VI - "Intimacy". Each of the facets has 4 items, thus for all facets the score of the possible values may range from 4 to 20, and the scores of these six facets or the values of the 24 items may be combined to produce a "global" score of the quality of life in the elderly and the higher the score the better the quality of life [19].

The data were tested for normality *(Kolmogorov-Smirnov test)* were subjected to a descriptive analysis by the absolute frequencies and percentages for categorical variables and measures of central tendency and dispersion for numerical variables. It was used the Student's T test for comparison of means, and the graphical representation of the box diagram *(boxplot)* to demonstrate the behavior of continuous variables between groups. The Pearson correlation coefficient (r) was also used to analyze the association of PSQI with the following variables: ESE, TUG and WHOQOL-OLD. For decision criteria, it was adopted the significance level of 5% ($p \leq 0.05$) and statistical procedures were processed and analyzed in *Statistical Package of the Social Sciences* (SPSS) for Windows®, version 21.

Results

One hundred and ninety-one potential participants were recruited from the community. Twenty-eight refused to participate in the study and 32 were excluded according to the eligibility criteria, which left only 131 participants, which represented 80.4% of the sample. A summary of participants' flow over the course of the study is presented in Fig. 1.

Table 1 shows the predominance of females (87%); with a mean age of 68 ± 7 years, the majority being between 60 and 69 years of age. This is a population predominantly low income *per capita* (84.8% ≤ 2 minimum wage), low education (86.3% ≤ 3 years of study) and, mostly living with relatives (67.9%), married (39.7%) or cohabiting (35.9%). Regarding anthropometry, 47.3% of the elderly were overweight and 23.7% were obese, which is associated with the fact that 90.1% of the women had abdominal circumference ≥ 80 cm.

Among the self-reported morbidities, anxiety (58%), arthrosis (37.4%), systemic arterial hypertension (33.6%), diabetes (26%) and chronic pain were the most prevalent (38.9%). Regarding lifestyle habits, 90.1% of the elderly reported not smoking, and out of these non-smokers, 12.2% reported smoking in the past. Most participants did not report alcohol consumption and presented a level of physical activity considered active (> 150 min/week), according to the IPAQ (Table 2).

Data regarding sleep quality, daytime somnolence symptoms, quality of life and functional mobility (TUG) are described in Table 3.

From the 131 elderlies with poor sleep quality, 76 (58%) had sleep disorder (PSQI score > 10 points), 40 (30.5%) had excessive daytime somnolence assessed by ESS, and 50 (38.2%) were considered to be at high risk for OSA because they presented positive scores in two or more categories of the Berlin Clinical Questionnaire. The average nightly sleep time was 5.7 ± 0.94 h and 55 elderlies (42%) reported waking up at night to go to the bathroom. In Table 4 we can see the comparison of baseline characteristics by Pittsburgh Sleep Quality Index.

Table 5 and Table 6 show the comparison of the questionnaire scores according to the gender and BMI of the subjects involved in this study.

After dividing the sample into two groups with different PSQI scores (5 to 10 versus > 10 points) and performing Student's t-test to compare ESS means between groups ($p < 0.01$), it was represented, in the Fig. 2, the ESS score distribution for each group using the boxplot graph, with a median 7 (4–13) for the group (5 to 10), median 9 (4–14) the group (> 10). The correlation of the PSQI score with ESS was moderate and statistically significant ($r = 0.4$ and < 0.001).

By using the same groups of the PSQI (5 to 10 versus > 10 points), and after carrying out the Student's t test to compare the WHOQOL-OLD means between the groups ($p < 0.01$), it was represented in Fig. 3, the WHOQOL-OLD score for each group, with a median of 85 (63–111) for the subgroup (5 to 10) and a median of 84 (62–104) for the subgroup (> 10). An association

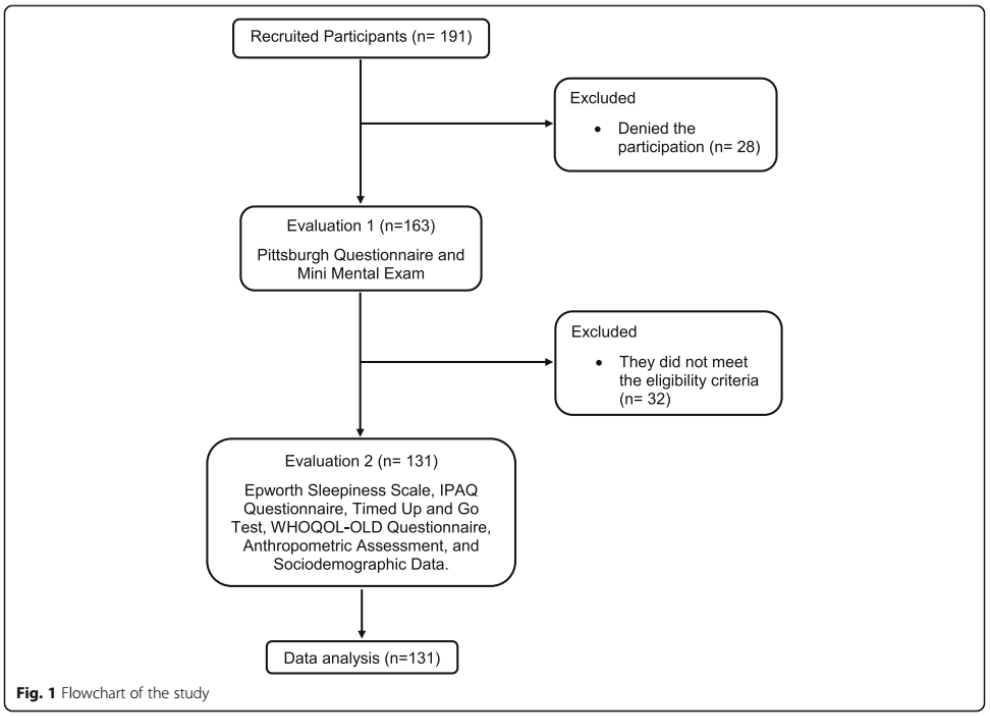

Fig. 1 Flowchart of the study

between PSQI and WHOQOL-OLD scores ($r = -0.285$ and $p < 0.01$) was identified.

Regarding the TUG, the PSQI group (5 to 10) had a median 8.5 (5–14) and the group with PSQI (> 10) had a median 8.9 (5.7–14), no difference between groups and a weak association were found, with no statistical significance between TUG and IPAQ ($r = -0.13$ and $p = 0.89$).

Discussion

In the sample of patients in the present study, we observed the predominance of female gender (87%), reflecting the greater longevity of women in history and worldwide. The great number of females in old age is associated with several aspects, such as less exposure to occupational risk factors, lower prevalence of smoking and alcoholism, greater attention to health and self-care, and greater frequency of using the health services [20, 21].

There was a preponderance of 60 to 69 years of age (51.9%), with a mean age 68 ± 7 years, converging with international [22] and national studies [23], positively qualifying the external validity of the present study. This preeminence of age at the lower limit is evidence of the recent aging of the Brazilian population, unlike the developed countries, where the elderly is aged 80 and over [24].

In the present study, 75.6% of the elderly have low educational level, reflecting the intense socioeconomic inequality experienced in the country [25, 26]. In addition, a low economic status was identified, with 44.3% presenting a family income below 1 minimum wage, converging with epidemiological profile studies conducted in Brazilian cities [26]. Despite these socioeconomic and demographic characteristics, it was possible to properly apply the questionnaires and extract important information by analyzing the results, encouraging further studies.

In the anthropometric analysis, the BMI indicates that 47.3% are overweight and 23.7% are obese, which is, 71% of the interviewed elderly are overweight considered adequate [27]. These weight changes associated with the fact that 90.1% of the women present waist circumference ≥ 80 cm, present a high risk of cardiovascular diseases [28] and the Obstructive Sleep Apnea Syndrome, possibly related to pharyngeal narrowing by fat deposition in its walls or the parapharyngeal structures [29]. On the other hand, growing evidence indicates that short sleep duration, as presented in the present study, avoiding a possible selection bias, the PSQI, ESS, WHOQOL-old, Berlin Questionnaire and IPAQ questionnaire scores were compared according to the gender and also according to

Table 1 Sociodemographic and anthropometric characteristics of the interviewed elderly

	Total ($n = 131$)	
Variables	N	%
Gender		
Female	114	87
Male	17	13
Age (years)		
60 to 69	68	51.9
70 to 70	48	36.6
≥ 80	15	11.5
Education		
Illiterate	14	10.7
1 to 3 years	99	75.6
4 to 7 years	15	10.7
8 years or more	3	2.3
Monthly income per capita		
< 1 MW	58	44.3
1 to 2 MW	53	40.5
> 2 to 3 MW	12	9.2
> 3 MW	8	6.1
Family composition		
Live alone	42	32.1
Live with relatives	89	67.9
Marital status		
Single	11	8.4
Married	52	39.7
Widowed	8	6.1
Cohabiting	47	35.9
Divorced	13	9.9
BMI (Kg/m^2)		
Low weight (< 18.5)	4	3.1
Normal (18.5 to 24.9)	34	26.0
Overweight (25.0 to 29.9)	62	47.3
Obese (≥ 30)	31	23.7
Waist Circumference (cm)		
Women		
Increased risk[a] (WC ≥ 80 cm)	118	90.1
Men		
Increased risk[a] (WC ≥ 94 cm)	2	1.5

MW minimum wage during the study (in real) = R$ 788.00, *BMI* Body mass index, *WC* Waist Circumference
[a]Risk for cardiovascular disease

Table 2 Self-reported morbidities, life habits and physical activity level of the interviewed elderly

	Total ($n = 131$)	
Variables	N	%
Morbidities		
Diabetes	34	26.0
Systemic arterial hypertension	44	33.6
Urinary incontinence	32	24.4
Stroke	6	4.6
Respiratory disease	14	10.7
Arthritis	24	18.3
Arthrosis	49	37.4
Fibromyalgia	6	4.6
Depression	29	22.1
Anxiety	77	58.8
Chronic pain	51	38.9
Smoking		
Yes	13	9.9
No	118	90.1
Ex-smokers	14	12.2
Alcohol use		
Yes	17	13.0
No	114	87.0
Physical Activity Level – IPAQ		
Inactive (< 150 min/week)	17	13
Active (> 150 min/week)	114	87

the BMI of the subjects involved in the study. No significant difference was observed.

Where the average nightly sleep time was 5.7 ± 0.94 h, it is considered a risk factor for the development of obesity and its subsequent complications [30, 31]. Sleep loss may lead to metabolic and endocrine disorders, including reduced glucose tolerance and changes in appetite-regulating hormones, such as the ghrelin, a hunger-promoting hormone which increases with sleep restriction, while leptin is the hormone which contributes to satiety is reduced [29, 30].

Associated with the growing process of population aging, functional changes occur which are characteristic of this age group, predisposing to the appearance of pathologies classified as chronic non-transmissible [32]. The present study found a high frequency of elderly patients with self-reported chronic and psychosocial disorders,

Table 3 Mean values and standard deviation for the PSQI, ESE, WHOQOL-OLD, and TUG performance time in the elderly community ($n = 131$)

Variables	Mean ± SD	Variation
Sleep Quality (PSQI)	11.2 ± 5.6	5–18
Excessive daytime somnolence (ESS)	8.3± 2.2	4–14
Quality of life (WHOQOL-OLD)	84.8 ± 10	62–111
Functional mobility (TUG)	9.0 ± 2.0	5–14

Table 4 Comparison of baseline characteristics by Pittsburgh Sleep Quality Index

Variables	5 a 10	> 10	*p*
Gender (% women)	50	64	0.26
Age (years)	71.2 ± 6.2	69.8 ± 7.5	0.07
BMI (Kg/m^2)	27.3 ± 4.2	27.2 ± 4.1	0.95
Waist Circumference (cm)	92.8 ± 10.6	92.4 ± 10.3	0.82
Self-reported morbidities (n)	1.73 ± 1.2	1.82 ± 1.7	0.74
Per capita income (% ≤ 2 minimum wages)	43	55	0.95
Education (% ≤ 3 years of study)	45	62	0.28
Housing (% live with relatives)	42	47	0.08

highlighting the anxiety, followed by chronic pain, osteoarthritis, hypertension, and diabetes, as observed in epidemiological studies on aging [33, 34]. The chronic and psychosocial diseases are negatively associated with self-perception of health, quality of life and sleep quality of the elderly [32]. This panorama points to the real necessity to strengthen the health promotion actions.

Regarding lifestyle habits, few elderly people reported smoking and alcohol consumption, which may be explained by the predominance of females in the sample, considering that women devote more attention to health and self-care [20, 21]. According to the IPAQ, most of participants were considered active, diverging from other studies in which the level of physical activity is presented inversely proportional to income and education [33, 34].

In evaluating the quality of nocturnal sleep, the sample showed an overall average score 11.2 ± 5.6 in the PSQI, classified as sleep disorder. This result is similar to that presented by other studies [35, 36]. Among the problems related to nocturnal sleep, we highlight the high risk of OSA in 38.2% of the sample, corroborating the important epidemiological study where it was found that the incidence of OSA is proportional to age, female gender and low socioeconomic class and presents important interference in sleep quality [37]. It is worth noting the necessity to wake up to go to the bathroom, reported by 42%, which may also interfere with sleep quality [38].

Table 5 Comparison of the questionnaires scores according to gender

Variables	Female	Male	*p*
PSQI	11.2 ± 3.3	11.6 ± 2.5	0.6
ESS	8.3 ± 2.2	8.2 ± 1.9	0.8
WHOQOL-old	84.4 ± 10.4	83.9 ± 10.6	0.8
BQ (% high risk)	38	34	0.2
IPAQ (% actives)	85	90	0.1

PSQI Pittsburgh Sleep Quality Index, *ESS* Epworth Sleepiness Scale, *BQ* Berlin Questionnaire, *IPAQ* International Physical Activity Questionnaire

Table 6 Comparison of the questionnaire scores according to Body Mass Index

Questionnaires	Normal weight	Overweight	Obese	*p*
PSQI	11.21 ± 3.7	11.18 ± 3	11.34 ± 3	0.97
ESS	7.94 ± 2.4	8.37 ± 2.2	8.66 ± 2.1	0.43
BQ (% high risk)	37	36	38	0.13
IPAQ (% actives)	89	87	86	0.24

PSQI Pittsburgh Sleep Quality Index, *ESS* Epworth Sleepiness Scale, *BQ* Berlin Questionnaire, *IPAQ* International Physical Activity Questionnaire

As for excessive daytime sleepiness, 40 elderly participants (30.5%) had a score ≥ 10 in ESS, however the mean score of the sample was 8.32 ± 2.2, which is not indicative of excessive daytime somnolence, converging with previous studies [36, 39]. Excessive diurnal somnolence reverberates in the life of the elderly predisposing to naps that, when prolonged, may be harmful because they interfere in the duration and quality of nocturnal sleep [38]. In the present study, the daytime somnolence is directly associated with worse perception of nocturnal sleep quality, corroborating previous investigations [40, 41]. The nocturnal sleep restriction, identified in our sample through PSQI (nocturnal sleep duration 5.7 ± 0.94), may result in a sensation of physical and mental fatigue during the day, predisposing to excessive daytime sleepiness [42].

The quality of life of the interviewed elderly was considered good, with a mean score in the WHOQOL-OLD 84.8 ± 10, similar to that found in another study which has compared the quality of life among the young and very old elders and obtained a total score 84.1 ± 11.5 and 83.3 ± 12.3, considered as good quality of life for both groups [43]. In the present study, it was found that the deterioration of sleep quality presents a significant but weak association, with the deterioration in the perception of quality of life, in consonance with results presented in other studies [44].

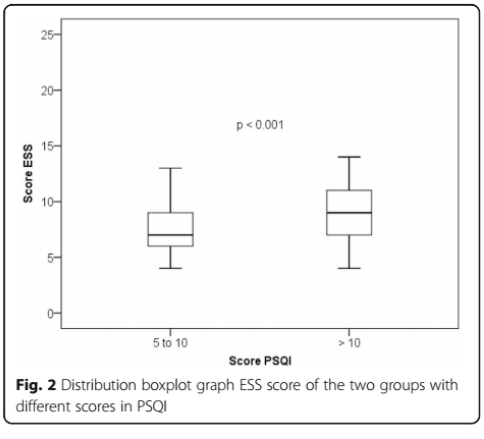

Fig. 2 Distribution boxplot graph ESS score of the two groups with different scores in PSQI

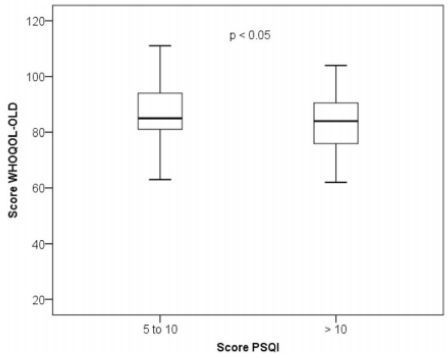

Fig. 3 Distribution boxplot graph of WHOQOL-OLD score in relation to two subgroups with different scores in PSQI

Sleep deprivation may adversely affect the quality of life of elderly by altering proprioception, neuromuscular reaction time and postural control, reducing independence and autonomy [45]; increasing pain sensitivity [46]; triggering neurobehavioral impairments such as decline in attention and memory and it may be a risk factor for the development of stress, anxiety and depression [47].

To move from sitting to standing position is an activity considered to be complex and most performed in the daily life of the elderly, and it is important in the evaluation of functional decline, which occurs proportionally as the age advances [48]. Functional mobility was assessed through the TUG and obtained a mean score 8.9 ± 2, suggestive of totally unrestricted, independent elderly and classified as low risk for falls [18]. According to the results presented, it is possible to hypothesize that sleep disturbance is not associated with changes in functional mobility and risk of falls in the elderly, diverging from previous studies that obtained this association [49], however, we cannot exclude the possibility of type II statistical error. These aspects may be evaluated in future studies specially designed for this purpose.

The study presents some limitations that must be considered. The cross-sectional design shows the reverse causality bias, since it is not possible to obtain information regarding the natural history of the diseases and/or events; the study recruitment was directed at older adults in the general community who presented self-reported sleep complaints but the results may be more clinically significant if the recruitment is performed in the elderly with clinical diagnosis of sleep disturbance through polysomnography or polygraphy; The questionnaires were used in the elderly in different degrees of education, which may interfere in the quality of the answers, but all the subjects who presented difficulties in answering the questionnaires were assisted; only the elderly with a PSQI score ≥ 5 were studied, and the elderly with good sleep quality were not studied.

Conclusion

Among the elderly in the community selected with PSQI scores ≥5, the poor quality of nocturnal sleep is associated with worse quality of life and the presence of symptoms of excessive daytime somnolence, however not significantly influencing functional mobility.

Abbreviations

BMI: Body mass index; ESS: Epworth Sleepiness Scale; IPAQ: International Questionnaire of Physical Activity; OSA: Obstructive Sleep Apnea; PSQI: Pittsburgh Sleep Quality Index; STROBE: Reporting of Observational Studies in Epidemiology; TUG: Timed Up and Go test; WHOQOL-OLD: World Health Organization Quality of Life for Older Adults

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Availability of data and materials

All data and materials are available upon request.

Authors' contributions

GSB[1], LVFO, and AAC provided the concept of the study, created the hypothesis, and wrote the original proposal. GSB[1], ASS, GSBFG, AACS and FWRC obtained ethics approval. GSB[1], AACS, GSBFG and GSB[4] will be participated in the data collection and performed clinical evaluations. GSB[1], LVFO, and AAC prepared the drafted manuscript. GSB[4], LVFO, FWRC, CFD and GSB[1] were involved in the critical revision of the manuscript. GSB[1], AAC and LVFO co- lead investigators. GSB[1], AAC, and LVFO wrote this protocol paper, with input from all co-authors. All authors read and approved the final manuscript.

Ethics approval and consent to participate

The study was approved by the Research Ethics Committee of the Bahia School of Medicine and Public Health, process 39,072,514.6.0000.5544. All participants signed an informed consent form. The results of this protocol study will be published in peer-reviewed journals as well as national and international conferences. The data collected will also be made available according demand.

Consent for publication

All patients give their consent for publication in the consent form. However, every attempt will be made to ensure the patients' anonymity.

Competing interests

The authors declare that they have no competing interests.

Publisher's Note

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5.4 Artigo 4 - Home exercise improves the quality of sleep and daytime sleepiness of elderlies: a randomized controlled trial

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RESEARCH ARTICLE Open Access

Home exercise improves the quality of sleep and daytime sleepiness of elderlies: a randomized controlled trial

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Abstract

Background: Aging causes physiological changes which affect the quality of sleep. Supervised physical exercise is an important therapeutic resource to improve the sleep of the elderlies, however there is a low adherence to those type of programs, so it is necessary to implement an exercise program which is feasible and effective. The study aimed to test the hypothesis that a semi-supervised home exercise program, improves sleep quality and daytime sleepiness of elderlies of the community who present poor sleep quality.

Methods: This was a randomized controlled trial study, conducted from May to September 2017, in Northeastern Brazil, with elderlies of the community aging 60 years old or older, sedentary, with lower scores or equal to 5 at the Pittsburgh Sleep Quality Index (PSQI) and without cognitive decline. From one hundred ninety-one potential participants twenty-eight refused to participate, therefore, one hundred thirty-one (mean age 68 ± 7 years), and 88% female, were randomly assigned to an intervention group - IG (home exercise and sleep hygiene, $n = 65$) and a control group - CG (sleep hygiene only, $n = 66$). Sleep assessment tools were used: PSQI, Epworth sleepiness scale (ESS) and clinical questionnaire of Berlin. The level of physical activity has been assessed by means of International Physical Activity Questionnaire adapted for the elderly (IPAQ) and Mini-Mental State Examination for cognitive decline. All participants were assessed before and after the 12-week intervention period and, also, the assessors were blind.

Results: The IG showed significant improvement in quality of sleep with a mean reduction of 4.9 ± 2.7 points in the overall PSQI ($p < 0.01$) and in all its 7 components of evaluation ($p < 0.05$), and improvement of secondary endpoint, daytime sleepiness, a decline of 2.8 ± 2.2 points in the ESS ($p < 0.01$).

Conclusion: Our results suggest that semi-supervised home exercise is effective in improving the quality of sleep and self-referred daytime sleepiness of sedentary elderlies of the community who presented sleep disorders.

Trial registration: Ensaiosclinicos.gov.br process number: RBR-3cqzfy.

Keywords: Community elderly, Exercise, Sleep

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Background

The natural process of human aging causes important organic changes, resulting in mental and physical alterations which involve quality of life of the elderlies [1, 2]. Among the main health problems observed in elderly population, with the incidence increasing proportionally with age, sleep disorders are among the most prevalent, and more than 50% of the elderlies complain about their sleep quality [3–6].

For this specific population, the pharmacologic therapeutic approach still is the most commonly used to treat sleep disorders [7]. However, the frequent use of sleeping pills alter sleep architecture and they are associated to several adverse effects such as sedation, excessive drowsiness daytime, increased risk of falling and higher functional dependency [7, 8], which usually are frequently observed in elderlies [9]. Therefore, alternative strategies are needed to improve the quality of sleep in this population. The physical exercise of mild to moderate intensity, presents positive results in the sleep quality of elderlies and it is recommended as one of the key features of preventive and therapeutic non-pharmacologic intervention [10, 11]. However, despite scientific evidence demonstrating the benefits of physical exercise in health and quality of life, yet there is little adhesion to this strategy by the elderlies [12].

The difficulty in the transfer to the location of the exercises, schedule conflict with household tasks, conditioning difference between participants and the limited supply of free programs associated to the low economic power of this population, are possible explanations for the low adhesion [13, 14]. These difficulties presented by the majority of the elderlies in supervised exercises, associated with the benefits of their practice, encourage the development of other feasible programs which allow greater adherence. In a recent systematic review, the authors concluded that home-based exercise programs show better adherence when compared to group programs [15]. However, according to our knowledge, a single reference was located on the practice of semi-supervised home exercise and quality of sleep of elderlies [16].

In view of the foregoing and considering this knowledge gap, the present study aimed to test the hypothesis that an alternative program of activities, through physical exercise performed at home, semi-supervised, easy to perform and low cost, improves the perception of sleep quality, and excessive daytime sleepiness of sedentary elderly people in the community who present sleep disorders.

Methods

Study design

It is an analytical, experimental, randomized, controlled, single blind study conducted according to the CONSORT stands for Consolidated Standards of Reporting Trials [17].

Participants

The study involved elderly aged 60 years or older, living in the city of Senhor do Bonfim - BA in the Brazil Northeastern region, in the period from May to September 2017. The recruitment occurred throughout the community, initially through local newspapers, radio, religious centers, encounter groups of elderlies, senior residence, association neighborhoods and in the senior project developed by the municipal government. Inclusion criteria were: absence of regular exercise in the last three months before the beginning of the study and score more than or equal to 5 in the Sleep Quality Index Pittsburgh (PSQI-BR) [18]. We excluded the subjects presenting cognitive decline according to the Mini-Mental State Examination [19] or performing treatment for sleep disorders (including the use of sleep medications) or presenting any clinical condition that would contraindicate the performance of physical activity, identified through a medical and physiotherapic evaluation.

The study was approved by the Ethics Committee on Research Involving Human Subjects of Bahia School of Medicine and Public Health and all participants agreed to participate and signed the free and informed consent. This trial is registered in ensaiosclinicos.gov.br (identifier: RBR-3cqzfy).

After meeting the eligibility criteria, the subjects were identified in consecutive order of entry into the study and were then randomly allocated according to a sequence of random numbers generated by the Research Randomizer (https://www.randomizer.org/). This randomization was of the closed type, with concealment of the allocation, generating two groups, being one the control group (CG) and the other the intervention group (IG).

All the elderlies involved in the present study participated in a 40-min presentation with explanations about the experimental procedure and they received educational leaflets containing guidelines on life habits related to feeding, hydration and sleep hygiene. The IG participants were informed that they should follow lifestyle guidelines and conduct a home physical exercise program. For that, they participated in a theoretical-practical training aimed at the adequate accomplishment of the proposed exercises and received a primer developed by the researchers, with illustrated and written guidelines on the accomplishment of the exercises, as well as a journal to record the weekly frequency of its accomplishment. The researchers, after making sure that the subjects could perform all the exercises adequately, guided the family members to help and stimulate the practice and encouraged the elderlies to call in situations of problems or doubts. The participants of the CG were

informed that they should only continue with their activities of daily living and follow the guidelines related to their habits of life.

Previously, before the beginning of the study, there were systematic trainings of assistants, five students of the physiotherapy course, exclusively for the evaluation, and ten other assistants, also students of the physiotherapy course, for home monitoring of the elderlies, five visited the subjects of the IG and the other five visited the elderlies of the CG. The distribution of the number of subjects to be evaluated and the number of domiciles to be visited was done in an equivalent way among the research assistants.

Evaluation protocol and procedures

Assessments

The evaluations were performed before and after the intervention period, by a doctor, a physiotherapist and the assistants, in which, the elderly received standard verbal instructions regarding the procedures and they were evaluated individually in an appropriate room. The researchers in charge of the data analysis were blinded to groups of subjects, avoiding possible biases.

A general physical and clinical evaluation was performed, with collection of socioeconomic, demographic, anthropometric, and self-referenced morbidities data. The quality of sleep, excessive daytime sleepiness, the risk of obstructive sleep apnea syndrome and the level of physical activity were also evaluated.

The primary endpoint of the present study was the quality of self-reported sleep, verified through the Pittsburgh Sleep Quality Index (PSQI). The PSQI was developed in 1989 by Buysse DJ [20] and validated for the Brazilian population [18]. This instrument allows an assessment of the quality of sleep, categorizing the subjects in good or bad sleepers.

The secondary endpoint was presence of excessive daytime sleepiness recorded using the Epworth Sleepiness Scale (ESS), validated in Brazil [21].

In order to assess the potential risk of the presence of obstructive sleep apnea (OSA) we used the Berlin clinical questionnaire [22]. This instrument considers a high risk for OSA, when two or more categories present positive score and when it shows none or only one category with a positive score the risk for OSA is low.

In the evaluation of the anthropometric variables, Body Mass Index (BMI) was calculated from the weight in kilograms divided by the height in squared meter.

The level of physical activity was assessed using the International Physical Activity Questionnaire (IPAQ) adapted for the elderly [23]. It is an instrument that allows estimating the weekly energy expenditure of physical activities related to labor, transportation, domestic tasks and leisure, performed for at least 10 continuous minutes with moderate and/or vigorous intensity during a normal/usual week. This variable was dichotomized, and those who performed less than 150 min per week of moderate and/or vigorous physical activity were considered non-active and active those who performed more than 150 min per week.

Intervention

The home exercise program was based on American College of Sports Medicine recommendations for exercise and physical activity with the elderly [24]. The exercise program was composed by a combination of aerobic exercises, muscle strengthening, balance, coordination and flexibility, prioritizing exercises involving large muscle groups. The protocol lasted 12 consecutive weeks, with minimum frequency of three weekly sessions, predicted time of 40 min and performing 2–3 sets with 5–15 repetitions for each exercise, a target effort rate of 13–15 ("a bit difficult" to "difficult") in the range of perceived exertion Borg 6–20 points [25], being the exercise performed in the convenience turn chosen for the elderly. The exercises were performed individually at home by each participant, having no supervision during implementation; however, receiving guidance through home visits every 15 days. The subjects were instructed to increase exercise intensity, using as parameter the Borg range and proportional form for their implementation capacity, assessed by research assistants in each visit.

The exercises were conducted by using the subject's own weight body and with the help of some low-cost equipment (e.g., recyclable plastic bottles to demarcate the signaling route rods and weights of 1 and 2 kg for implementing the resistance exercises). The protocol was performed as follow:

- Warm up exercises - Free-active exercises involving upper and lower limbs and movements of rotation of the shoulders associated with breathing exercises;
- Aerobic exercises - Displacement of a stick with both hands, starting from the knees up over the head and returning to the knees. Ambulation exercises with alternating bending of the thighs and approaching the knees to the hands on the opposite side;
- Endurance Exercises - Upper limbs departing from the position with the extended elbow and the hand resting on the opposite thigh, moving the whole limb diagonally upward and then returning the hand to the thigh. For the lower limbs, squatting exercises, starting from the sitting position on a chair and with arms crossed in front of the body, lifting to the orthostatic position and then returning to the sitting position;

- Balance and coordination exercises - Walk on a straight line on the ground and walk from queued obstacles with progressively smaller distances. When possible, the exercise evolved and the walk was performed by placing the heel of one foot on the toes of the other foot (standing foot).

Note: To ensure safety, these exercises were performed close to fixed furniture in the house, making it possible to lean when needed.

- Stretching Exercises - Starting from a sitting position on the bed or a chair, with your knees in extension trying to reach the tip of the feet; from the sitting position in a chair and with the feet resting on the ground, perform the rotation of the trunk to one side and elevation of the upper limb, on the same side, above the head, stretching as high as possible.

During the period of 12 consecutive weeks, the subjects of both groups received periodic home visits with the purpose of continuing with the guidelines on lifestyle and encouraging the adherence to the program; however the IG, in addition to guidelines on habits of life, received specific follow up regarding exercise practice and assistance to possible adverse events. After three months, the participants of both groups were re-evaluated and at the end of protocol the elderlies of the IG were encouraged to continue with the exercises, while the CG was made available the follow up of the home exercises for the same period performed with the IG.

The adherence to the exercise was verified through the weekly records filled out by the subjects themselves, with the help of family members and certified by the assistants during the home visits.

Statistical analysis

The sample size calculation based on recent studies [16] demonstrated that it would take 63 participants per group to obtain a statistical power of 80% in the detection of 2-point difference with 5% alpha, considering a standard deviation estimated 4 points. The principle of intention-to-treat analysis was respected and for the missing data the sensitivity analysis was performed through simple imputation using the mean of the variables. To detect if randomization produced comparable groups, the characteristics of both groups were compared before the intervention using the Student's t-test for independent samples in relation to the numerical variables and the Pearson chi-square test for categorical variables. To test the normality of the data, the histogram, mean and median, standard deviation, skewness and kurtosis were analyzed and the Shapiro-Wilk normality test was used for confirmation. Due to the normal distribution of variables, parametric statistics were used, and intra-group comparisons were performed using Student's t-test for paired samples.

A subgroup analysis of extracts of age was prespecified in the study protocol, as it was done with more than two groups that had parametric distribution, we used one-way ANOVA. The significance level set to for the analyses was set at $p < 0.05$ and statistical procedures were analyzed and processed in the Statistical Package of Social Sciences (SPSS 21.0). IBM SPSS version 21 (IBM, Armonk, NY).

Results

One hundred and ninety-one potential elderlies candidates were screened by phone. 28 elderlies refused to participate in the examination, therefore 163 elderlies were enrolled in the study, of which 32 were excluded according to the eligibility criteria. 131 subjects were randomized elected, and thus constituted the IG with 65 participants and the CG with 66 subjects. During the study, there were follow up losses of 2 participants of the CG and 4 of the IG, allowing to 125 elderlies to conclude the follow up. A summary of the randomization, participant flow, and follow up losses during the trial are shown in Fig. 1.

The patients involved in the present study showed a predominance of females (88%); mean age 68 ± 7 years and a mean BMI of 27.3 ± 4, indicative of pre-obesity. The socioeconomic profile showed a predominance of low income in relation to the monthly minimum wage (84.8% ≤ 2 minimum wage) and low schooling (86.3% ≤ 3 years of study). 87% of the elderlies presented a level of physical activity considered active (IPAQ > 150 min per week).

Most of the subjects lived with their families (88%), were nonsmokers (91%), non users of alcoholic beverages (88%) and presented as main self-reported morbidities anxiety, arthrosis, hypertension and diabetes. 38.2% of the subjects are considered to be at high risk for OSA because they present a positive score in two or more categories of the Berlin Clinical Questionnaire. The mean PSQI score was 11.2 ± 3.2 and ESS score was 8.6 ± 2.8. The Table 1 presents the characteristics of the two groups, at baseline, with no statistically significant difference.

The exercise average frequency over the entire 12-week period was 4 ± 0.6 days per week, with a minimum of 3 days per week performed by 3 participants and a maximum of 6 days per week performed by 1 participant. All participants of the IG had 100% adherence to the exercises and there was no report on any type of njury related to the intervention program.

Figure 2 shows an analysis of the overall quality of sleep improvement, by comparing the global PSQI score before and after the intervention in each group, demonstrating

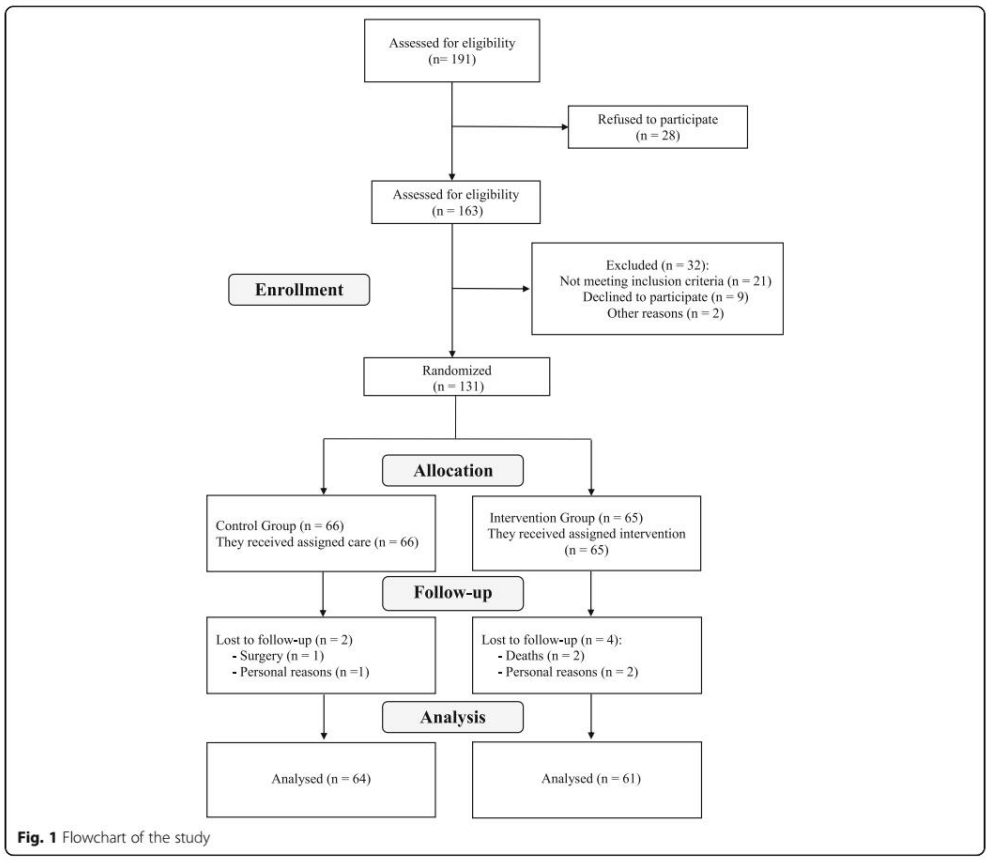

Fig. 1 Flowchart of the study

that the improvement of sleep quality was statistically significant only in the IG with a mean reduction of 4.9 ± 2.7 points ($p < 0.001$) compared to 0.7 ± 2.8 in the CG ($p = 0.061$). Subgroup analysis by ANOVA, performed in the IG, showed that the improvement in overall sleep quality did not present a significant difference when comparing the ages 60 to 69, 70 to79 and ≥80-year-old, $p = 0.15$.

Table 2 shows the sleep evaluation components constituting the PSQI, demonstrating that only the GI showed statistically significant improvements in all components.

The evaluation of the presence of daytime sleepiness in the groups, through ESS before and after the intervention, in each group, found that only the IG presented a statistically significant reduction, with a mean variation of 2.8 ± 2.2 points ($p < 0.001$) compared to 0.14 ± 2.3 ($p = 0.63$) in the CG (Fig. 3).

Discussion

The results of the present study showed that sedentary elderlies who present sleep disorders while participating in a semi-supervised home physical exercise program presented significant improvement in sleep quality and reduction of self-reported excessive daytime sleepiness, verified in a non-objective way through questionnaires, being consistent with the hypotheses of the study and configuring a clinically relevant change.

Our results are consistent with previous studies which demonstrated the efficacy of physical exercise programs in sleep quality and in the reduction of daytime sleepiness in the elderlies [10, 11, 26, 27]. However, these studies used exercise programs with professional supervision during their execution, in addition to being performed in training and/or rehabilitation centers, which is a limiting factor for

Table 1 Baseline characteristics by group

Variables	Control group ($n = 64$)	Intervention group ($n = 61$)	p
Age (years)	69.9 ± 6.7	69.8 ± 7.4	0.76
Gender (% women)	84.4	91.8	0.23
BMI (Kg/m^2)	27.7 ± 4.7	27.6 ± 4.1	0.75
Waist Circumference (cm)	93 ± 10	93 ± 10	0.76
Number of self-reported morbidities	1.9 ± 1.4	1.8 ± 1.5	0.63
Per capita income (% ≤ 2 minimum wages)	82.3	85.7	0.86
Education (% ≤ 3 years of study)	75	75.9	0.54
Housing (% live with relatives)	67	71	0.85
Pittsburgh Sleep Quality Index	11.4 ± 3	11 ± 3.4	0.55
Epworth Sleepiness Scale	8.5 ± 3	8.7 ± 3	0.14
Berlin Questionnaire (% high risk)	37	39	0.23
Physical Activity – IPAQ (% actives)	88	85	0.34

Data mean ± standard deviation or in (%); n = number of participants who completed the follow up. No significant difference was detected between groups ($p > 0.05$)

the participation of the elderlies, as they present difficulties in relation to the transfer [14, 28, 29].

However, in the present study, a home physical exercise program was applied, with only one-week supervision, easy to apply and low cost, which proved to be safe and feasible, since no injuries related to training were observed as well as high frequency rates (mean of 4 ± 0.6 days per week) and small loss of follow up (4.5%).

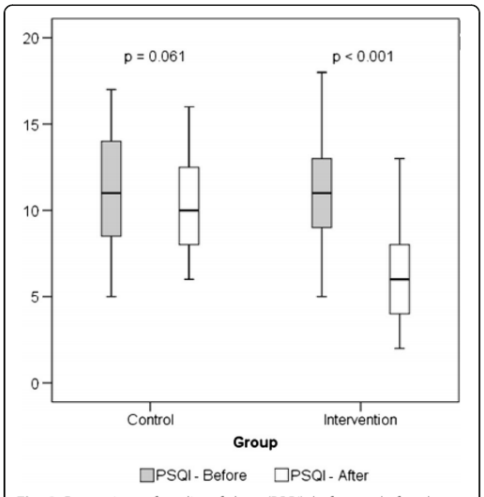

Fig. 2 Comparison of quality of sleep (PSQI), before and after the intervention, in each group. T-test for paired samples

It has already been demonstrated in the literature that physical exercise performed at home may result in important health benefits for the elderly and, because it is appreciated by the elderly [29], there is still greater adherence and continuity after the end of the program [15, 30].

However, the knowledge regarding the effects of home exercises on sleep quality of the elderly is still very incipient. In the present study, the elderly who participated in the home exercise program during the 12-week period showed significant improvement over the primary endpoint, self-reported quality of sleep, represented by a reduction of 4.9 points in the overall PSQI score (Fig. 2). The significant reduction in all components of PSQI assessment, especially in relation to sleep latency, sleep duration and habitual sleep efficiency (Table 2), characterizes a relevant clinical improvement, being the results consistent with the study performed by Chen et al. [16]. The authors used a similar methodology to demonstrate the effectiveness of home physical exercise, by practicing the "Baduanjin" exercise technique in the self-reported quality of sleep. In that study, 56 elderly people (mean age 71.7 ± 8.1) were randomized, and the IG performed the "Baduajin" exercise in their households and the CG did not perform any specific activity. The IG received a videotape, an educational booklet with pictures about the performance of the exercises, and they were instructed to perform 30 min of exercise 3 times a week for 12 weeks and received telephone follow up twice a week. After this period, the IG showed a statistically significant improvement when compared to the CG in relation to the overall PSQI score and in 5 of the 7 evaluation components, similar to the results found in the present study.

The secondary endpoint, excessive daytime sleepiness, recognized as an important public health problem [31], was evaluated through the ESS demonstrating that the elderlies who practiced physical exercise presented a significant reduction of excessive daytime sleepiness, when compared to the CG, in which the reduction was not significant (Fig. 3), being consistent with the results of other studies which used supervised exercises of Yoga [27] and Tai Chi [32], which also demonstrated a significant reduction of excessive daytime sleepiness in the exercise group, using of the same rating scale.

The analysis of variance performed in the age subgroups has showed a significant improvement in sleep quality, however there was no significant difference, demonstrating that the home exercise program was effective in the different age groups of the elderly involved in the present study.

One of the strengths of our study is that, after random allocation of subjects, both groups were periodically

Table 2 Delta of mean PSQI components related to pre- and post-intervention for each group and *p* of the difference

Variables	Group	Basal moment	After 12 weeks of intervention	Delta	*p**
Subjective sleep quality	CG	1.9 ± 0.7	1.8 ± 0.6	0.1	0.16
	IG	1.8 ± 0.7	1.1 ± 0.6	0.7	< 0.01
Sleep latency	CG	2.0 ± 0.9	1.7 ± 0.8	0.2	0.08
	IG	1.9 ± 1.0	1 ± 0.9	0.9	<0.01
Duration of the sleep	CG	1.9 ± 0.9	1.6 ± 0.8	0.3	0.11
	IG	2.1 ± 1	1.2 ± 0.8	0.8	<0.01
Usual sleep efficiency	CG	2 ± 0.9	1.6 ± 1.1	0.4	0.06
	IG	1.6 ± 1.0	0.7 ± 0.9	0.9	<0.01
Sleep Disorders	CG	2 ± 0.6	1.9 ± 0.7	0.1	0.41
	IG	1.9 ± 0.6	1.2 ± 0.5	0.6	<0.01
Use of sleeping medicines	CG	0.3 ± 0.4	0.2 ± 0.4	0.0	0.32
	IG	0.2 ± 0.4	0.1 ± 0.3	0.1	0.04
Dysfunction during the day	CG	1.6 ± 1.2	1.7 ± 1	−0.1	0.57
	IG	1.7 ± 1.1	1.1 ± 0.8	0.6	<0.01

Data mean ± standard deviation
*t-test for non-paired samples ($p < 0.05$)

given the same orientations and stimuli in relation to life habits such as feeding, hydration and sleep hygiene. These positive results presented in our study are also related to the fact that, in addition to the program being carried out at home and composed of dynamic and easy to be performed physical exercises, the elderlies received visits every fortnight and then they were encouraged and oriented, by the research assistants and their relatives, in relation to practice of the exercises, contributing to the high rate of adherence and small loss of the participants.

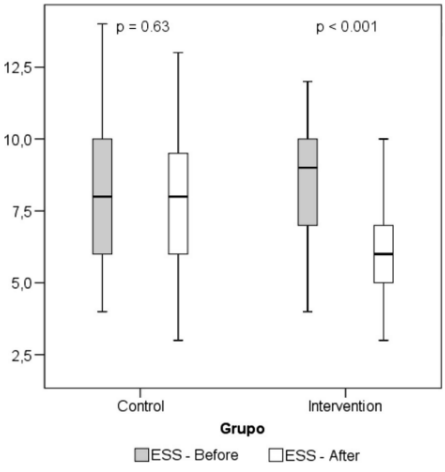

Fig. 3 Comparison of improving excessive daytime sleepiness (ESS), before and after the intervention in each group. T test for paired samples

We also highlight the lack of reports of adverse events during the exercise period.

Previous studies have suggested that a direct contact with participants via phone, internet or personal visits increases the adherence to home exercise programs [29, 30]. Follow up losses did not interfere in the results, since they occurred at random, their characteristics are homogeneous both in terms of quantity and quality of losses, since they corresponded to less than 10% of the total sample and presented reasons similar in both groups, besides the characteristics of those who remained in the study are comparable to those who did not remain.

All these results should be interpreted taking into account some limitations of the present study. Firstly, recruitment was performed with elderlies of the community with self-reported sleep disorders, however the results may be more clinically reliable if the participants are clinically diagnosed for the disorders. There is a predominance of females in the sample, which is justified by the feminization of the elderly population [33, 34] and the prevalence of sleep disorders in the female elderly [35], however the randomization generated equivalent distribution between groups. The inability to blind participants in relation to the intervention may have been tempered by the fact that each group (CG and IG) was accompanied by different assistants, minimizing the excitement bias applied by the IG assistants during home visits. The monitoring of the frequency of the exercises was self-reported, however to increase the reliability of that information, in addition to monitoring the frequency register during visits, family members were recruited to assist in collecting information. The quality of sleep was measured in a non-objective instrument, by

means of validated questionnaire, that represented as perceived by the individual.

Future studies are needed to evaluate the effects of semi-supervised home-based exercise programs with long follow up periods and using objective strategies for assessing sleep quality, and to monitor and to quantify treatment efficacy, making outcomes clinically more reliable.

Conclusions

The results of the present study suggest that the regular practice of semi-supervised physical exercises at home is effective in improving the self-reported quality of sleep and the reduction of daytime sleepiness in sedentary elderly people with sleep disorders in various age groups of the elderly population. Therefore, it may be considered as a therapeutic, non-pharmacological, easy-to-implement and safe resource for improving the quality of sleep of the elderlies.

Abbreviations

BMI: body mass index; ESS: Epworth Sleepiness Scale; IPAQ: International Questionnaire of Physical Activity; OSA: Obstructive Sleep Apnea; PSQI: Pittsburgh Sleep Quality Index

Acknowledgments

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Availability of data and materials

All data and materials are available upon request.

Authors' contributions

GSB[1], LVFO, CFD and AAC provided the concept of the study, created the hypothesis, and wrote the original proposal. GSB[1], AACS and GSB[3] obtained ethics approval. GSB[1], AACS, GSBFG and GSB[3] participated in the data collection and performed clinical evaluations. GSB[1], LVFO, and AAC prepared the drafted manuscript. GSB[3], LVFO, CFD and GSB[1] were involved in the critical revision of the manuscript. GSB[1], AAC and LVFO co- lead investigators. GSB[1], AAC, CFD and LVFO wrote this final version of this paper, with input from all co-authors. All authors read and approved the final manuscript.

Ethics approval and consent to participate

The study was approved by the Research Ethics Committee of the Bahia School of Medicine and Public Health, process 39,072,514.6.0000.5544. All participants sign an informed consent form. The results of this study will be published in peer-reviewed journals as well as national and international conferences. The data collected will also be made available according demand.

Consent for publication

All patients give their consent for publication in the consent form. However, every attempt will be made to ensure the patients' anonymity.

Competing interests

All the authors declare that they have no competing interests.

Publisher's Note

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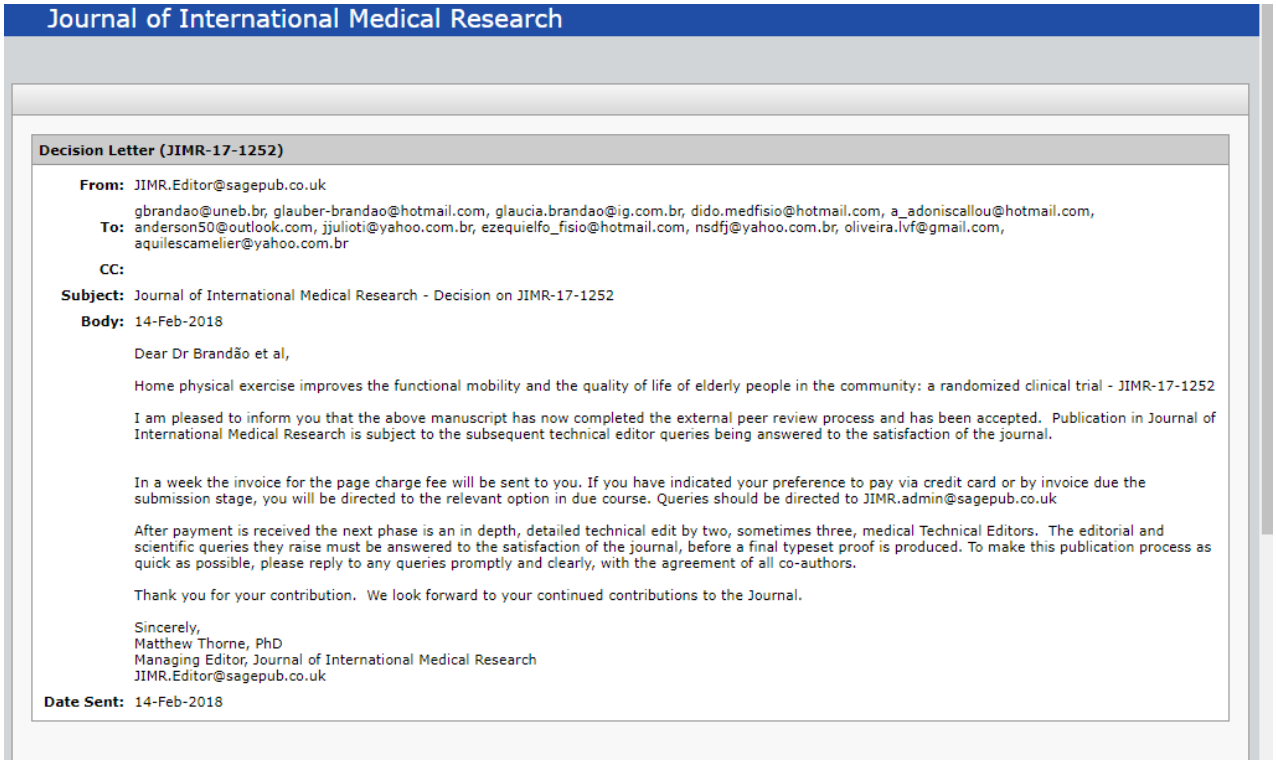
5.5 Artigo 5 - Home physical exercise improves the functional mobility and the quality of life of elderly people in the community: a randomized clinical trial



Journal of International Medical Research

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Dear Dr Brandão et al,

Home physical exercise improves the functional mobility and the quality of life of elderly people in the community: a randomized clinical trial - JIMR-17-1252

I am pleased to inform you that the above manuscript has now completed the external peer review process and has been accepted. Publication in Journal of International Medical Research is subject to the subsequent technical editor queries being answered to the satisfaction of the journal.

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Date Sent: 14-Feb-2018

Original Research

Home physical exercise improves the functional mobility and the quality of life of elderly people in the community: a randomized clinical trial

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Abstract

Objective: to test the hypothesis that a semi-supervised home physical exercise program improves the functional mobility and quality of life (QoL) of elderly in the community. **Methods:** This is a randomized controlled trial, conducted in the northeast region of Brazil, with elderly people in the community, aged 60 years or older, sedentary and without cognitive decline. One hundred and thirty - one elderly (mean age 68 ± 7 years), 88% female, were randomly assigned to an intervention group - IG (home physical exercise and sleep hygiene, n = 65) and a control group - CG (sleep hygiene only, n = 66). Were applied the International Questionnaire on Physical Activity adapted for the elderly; mental state mini-exam; the Timed Up and Go test (TUG) and World Health Organization questionnaire Quality of Life Group-old (WHOQOL-OLD). All the subjects were assessed before and after the 12-week intervention period. **Results:** The IG showed a significant improvement in functional mobility, with a mean reduction in TUG execution time of 2 ± 1 seconds ($p < 0.01$) and improvement in the QOL, with an increase of 5.4 ± 9.5 points ($p < 0.01$) in WHOQOL-OLD. **Conclusion:** Semi-supervised physical home exercise is effective in improving the functional mobility and the QOL of sedentary elderly in the community.

Trail Registration: Registro Brasileiro de Ensaios Clínicos (REBEC) Identifier: RBR-3cqzfy

Keywords: Elderly; Exercise; Functional Mobility; Quality of Life; Community.

INTRODUCTION

Increased life expectancy is associated with biopsychosocial changes that occurs naturally with advancing age.[1] The decline in functional performance and the fear of falling are among the factors which most influence the quality of life (QOL) of elderly.[2,3] This growing population process aging emerges as a clinical priority, becoming a challenge for the development of health specific resources and social assistance policies,[4] considering old age and disability are among the main determinants of the use of services public health.[5,6]

Elderly people in the community have considerable functional decline and disabilities, progressively compromising independence, self-confidence and QOL, and these commitments are intensified by physical inactivity, which is linked to important negative results in the general health of them.[7,8] Some studies have shown the use of specific physical exercise programs present significant improvements in the strength, balance and functional mobility of elderly, even at more advanced ages, also the regular practice of these exercises provides them positive results in the QOL.[7,9,10]

Although the evidence shows the benefits of physical exercise, there is still low adherence to this strategy, and this reduced adherence may be related to factors such as locomotion difficulties and poor functional mobility or non-adaptation to the environment where the exercises are performed. It has been shown in others studies so far, the use programs of supervised exercise and performed in physical training centers.[11]

A recent study[12] indicated elderly people with a history of falls prefer to participate in exercise programs that can be performed at home or do not require transportation. Considering semi-supervised physical home exercise is a safe therapeutic resource, low cost and easy to implement. The purpose of the present study was to test the hypothesis that regular practice of a progressive physical exercise program performed at home improves the functional mobility and quality of life in a sedentary elderly population in the community.

METHODS

Study design and subjects

This is an experimental, analytical, randomized, controlled, single-blind trial, conducted between May to September 2017. Eligible subjects were elderly subjects aged 60 years or older residing in the municipality of Senhor do Bonfim-Ba, in the northeast region of Brazil. Recruitment took place throughout the community. The inclusion criteria were aged $\geq$ 60 years and have not exercised regularly for at least three months prior to the start of the study. Participants with cognitive impairment were excluded according to the Mental State Mini-

Exam[13] and who presented any clinical condition that contraindicated the performance of regular physical exercise, identified through a clinical and physiotherapeutic evaluation. This study has been approved by the Research Ethics Committee Involving Human Beings of the Bahian School of Medicine and Public Health and registered in Registro Brasileiro de Ensaios Clínicos (REBEC) (Identifier: RBR-3cqzfy). All participants agreed to participate and signed the free and informed consent form.

After completing the eligibility criteria, the subjects received consecutive numbering in the study and were then randomly allocated according to a sequence of random numbers generated by the Research Randomizer (www.randomizer.org). This randomization was of the closed type, with concealment of the allocation and generated two groups, being a control group (CG) and an intervention group (IG). All the subjects participated in a 40-minute lecture to explain about the experimental procedure and received educational leaflets containing guidelines on life habits related to feeding, hydration and sleep hygiene. IG participants were informed they should follow lifestyle guidelines and conduct a home physical exercise program. They participated in a theoretical-practical training of the adequate accomplishment of the proposed exercises and received a primer developed by the researchers, with illustrative and written guidelines on the practice of the exercises, as well as a diary to record the weekly frequency of activities.

The researchers, after making sure the elderly were able to perform all the exercises adequately, guided the family members to help and stimulate their practice and encouraged them to call in problems or doubts situations. The participants of the CG were informed they should only continue with their daily activities and follow the orientations related to life habits. Systematized training of five assistants was carried out, exclusively for evaluations, and ten assistants were used for home monitoring of elderly, five of them visited the IG and the other five visited the CG.

ASSESSMENTS

The evaluations were performed by a physician, a physiotherapist, and assistants. The subjects received standardized verbal instructions on the procedures and were evaluated individually in an appropriate room. The whole evaluation process occurred before and after the intervention period and the assistants who exclusively performed the evaluations, as well as the researchers in charge of the data analyzes, was blind in relation to knowing which group each elderly person had participated, avoiding possible biases. A physical and general clinical evaluation was performed with collection of socioeconomic, demographic, anthropometric

data, self-referred comorbidities, sleep quality evaluation, daytime sleepiness, risk of obstructive sleep apnea syndrome, functional mobility and level of physical activity.

In the evaluation of the anthropometric variables, the body mass was obtained using a Welmy® (Welmy, São Paulo, Brazil) brand scale, with a capacity of 150 kilograms (kg); the height, in meters (m), was measured by means of a vertical stadiometer fixed to the scale; to measure the circumference of the abdomen was used an anthropometric tape of the brand Cescorf® (Cescorf Equipamentos para Esporte Ltda., Porto Alegre, Brazil) and the body mass index (BMI) was calculated from the weight in kilograms divided by the height in meters squared. The level of physical activity was assessed through the International Questionnaire of Physical Activity (IPAQ) adapted for the elderly.[14] It is an instrument that allows estimating the weekly energy expenditure of physical activities related to work, transportation, domestic tasks and leisure, carried out for at least 10 continuous minutes, with moderate and / or vigorous intensity during a normal / usual week. This variable was dichotomized, and those who performed less than 150 minutes per week of moderate and / or vigorous and active physical activity were those who performed more than 150 minutes per week.

Functional mobility was assessed using the Timed Up and Go test (TUG). The procedure followed was described in the original test, where the participant starts in the sitting position in a chair with arms (height of the seat of 45 cm and arms of 65 cm), firm to the floor, with the back resting on the backrest of the chair, being guided to stand up, walk a distance of three meters ahead, make a 180º turn in a marking made in the ground, return and sit again, running as fast as possible, but safely and comfortably, minimizing the possibility of accidents. A Cassio® HS-70W (Casio Computer LTDA, São Paulo, Brazil) chronometer was used from the verbal command "already" at the beginning of the test and stopped when the participant sat down again. All the subjects performed the test twice, and in the second the execution time was timed.[15]

To evaluate the QOL, was applied the World Health Organization questionnaire Quality of Life Group-old (WHOQOL-OLD), which contains six facets of 4 items each, evaluated by the Likert scale (1 to 5 points): Facet I - "Operation of Sensory"; Facet II - "Autonomy"; Facet III - "Past Activities, Gifts and Future"; Facet IV - "Social Participation"; Facet V - "Death and Dying"; Fact VI - "Intimacy". Each of the facets has 4 items, so for all facets the score of the possible values can range from 4 to 20, and the scores of these six facets or the values of the 24 items can be combined to produce a "global" quality of life in the elderly.[16]

INTERVENTION

HOUSING PHYSICAL EXERCISE PROGRAM

The home physical exercise program was based on the recommendations of the American College of Sports Medicine for exercise and physical activity with the elderly.[17] The program consisted of a combination of aerobic exercises, muscle strengthening, balance, coordination and flexibility, prioritizing exercises involving large muscle groups, lasting 12 consecutive weeks, minimum frequency of 3 sessions per week, 40 minutes of execution time and performing 2 to 3 sets with 5 to 15 repetitions for each exercise at a target stress rate of 13-15 ("a little difficult" to "difficult") on the Borg perceived exertion scale of 6 to 20 points,[18] and the exercise can be performed in the most convenient shift for the elderly.

The exercises were carried out individually at each participant's home, not supervised during their execution, but had guidelines through home visits every fifteen days. Subjects were instructed to increase exercise intensity using the Borg scale as a parameter and in proportion to their ability to perform, as assessed by the research assistants at each visit. This exercises were performed using the weight of the participant's own body and with the help of some low-cost equipment (for example, recyclable plastic bottles to demarcate the signaling of the course, sticks and weights of 1 and 2 kg for performing the resisted exercises) , and were constituted as follows:

- Warm-up exercises - Active-free exercise of the upper and lower limbs and shoulder rotation associated with breathing exercises;
- Aerobic exercises - Displacement of a walking stick with two hands, from the knees to above the head and returning to the knees, and walking exercises with alternating flexion of the thighs and approaching the knee by hand on the opposite side;
- Resisted exercises - For the upper limbs: from the position with the elbow extended and the hand resting on the opposite thigh, move the whole diagonally upwards and then return the hand to the thigh. For the lower limbs: squatting exercise, starting from the position sitting in a chair and with arms crossed in front of the body, lift to the orthostatic position and then return to the sitting position;
- Balance and coordination exercises - Walk on a straight line and walk away from lined obstacles with progressively smaller distances. When possible, the exercise evolved and the walk was performed by placing the heel of one foot on the toes of the other foot (standing foot).

- Note: To ensure safety, these exercises were performed close to fixed furniture in the house, making it possible to lean when needed.
- Stretching Exercises - From the sitting position on the bed and with their knees in extension, try to reach the tip of the feet; from the sitting position in a chair and with the feet resting on the ground, perform rotation of the trunk to one side and elevation of the upper limb, on the same side, above the head, stretching as high as possible.

During the period of 12 consecutive weeks, subjects from both groups received periodic home visits to continue living guidelines and encourage adherence to the program, but the IG, as well as guidelines on lifestyle habits , received specific follow-up regarding exercise practice and assistance to possible adverse events.

After the three-month period, the participants of the two groups were re-evaluated and with the completion of the research the elderly of the IG were encouraged to continue with the exercises, while the CG was made available the follow-up of the home exercises for the same period performed with the GI. Adherence to the exercise was verified through the weekly records filled out by the elderly themselves, with the help of family members and certified by the assistants during home visits.

STATISTICAL ANALYSIS

The sample size calculation based on recent studies[8] demonstrated it would take 63 participants per group to achieve a statistical power of 80% in the detection of 2-point difference with 5% alpha, considering a standard deviation estimated 4 points. The principle of intention-to-treat analysis was considered and the sensitivity analysis was performed through simple imputation using the mean of the variables. To test the data normality, the histogram, mean and median, standard deviation, skewness and kurtosis were analyzed and the Shapiro-Wilk normality test was used for confirmation. Due to the normal distribution of the variables, parametric statistics were used, and the intragroup comparisons were made through the Student test for paired samples. The analysis of subgroups of age groups, which was pre-specified in the study protocol, as it was done with more than two groups that presented parametric distribution, one-way ANOVA was used, followed by the one-way ANOVA. Tukey's multiple comparison test. The significance level established for all analyzes was $p < 0.05$ and statistical procedures were analyzed and processed in the Statistical Package of the Social Sciences (SPSS 21.0). IBM® SPSS version 21 (IBM, Armonk, NY, USA).

RESULTS

One hundred and ninety-one potential participants were screened over the phone. Of this total, 28 refused to participate in the in-depth analysis, with 163 enrolled in the study, of which 32 were excluded according to the eligibility criteria. The 131 elect were randomized, thus constituting the IG with 65 participants and the CG with 66. During the study there were follow-up losses of 2 participants of the CG and 4 of the IG, and it was concluded with 125 elderly. The flowchart of the study are shown in Figure 1.

The sample was predominantly female (88%); with mean age 68 ± 7 years; anthropometric data indicative of pre-obesity, with a mean BMI of 27.3 ± 4; socioeconomic profile with low income preeminence (78% ≤ 2 SM) and low schooling (76% ≤ 3 years of study); level of physical activity considered active, with 87% of the elderly presenting IPAQ> 150 minutes per week and mean TUG of 9 ± 2. Most of them lived with their relatives (88%), not being smokers (91%), not consuming beverages (88%) and had as their main self-reported morbidities anxiety, arthrosis, hypertension and diabetes. Table 1 presents the characteristics of the two groups, at the initial moment of the study, with no statistically significant difference.

Table 1. Baseline characteristics of subjects by group

Variables	Control Group (n = 64)	Intervention Group (n = 61)
Age (years)	69.9 ± 6.7	69.8 ± 7.4
Gender (% women)	84.4	91.8
BMI (Kg/m^2)	27.7±4.7	27.6±4.1
Waist Circumference (cm)	93±10	93±10
Number of self-reported morbidities	1.9±1.4	1.8±1.5
Per capita income (% ≤ 2 minimum wages)	82.3	85.7
Education (% ≤ 3 years of study)	75	75.9
Housing (% live with relatives)	67	71
Timed Up and Go test (TUG)	9 ± 2	9,1 ± 2
Physical Activity – IPAQ (% actives)	88	85

Note: BMI= Body mass index; IPAQ= International Physical Activity Questionnaire; Data mean ± standard deviation or in (%); n = number of participants who completed the follow-up. No significant difference was detected between groups (p > 0.05).

The average exercise frequency over the entire 12-week period was 4 ± 0.6 days per week, with a minimum of 3 days per week performed by 3 participants and a maximum of 6 days

per week performed by 1 participant. All IG subjects had 100% adherence to the exercises and there was no report on any type of injury related to the intervention program developed. Figure 2 presents an analysis of the improvement in functional mobility, by altering the TUG execution time between the moments before and after the intervention, in each group, demonstrating the improvement in mobility was statistically significant only in the IG, changing from 9.1 ± 2 for 7.1 ± 1, with a mean reduction of 2 ± 1 seconds ($p < 0.01$), compared with the CG who presented a change from 9 ± 2 to 8.7 ± 2, reducing only 0.2 ± 0.7 ($p = 0.7$).

Figure 3 presents the influence of home physical exercise on the quality of life of the elderly, by altering the global WHOQOL-OLD score between the moments before and after the intervention, in each group studied, noting that only the IG presented improvement in the quality of life, with a variation of the score of 85 ± 10 at the initial time of the study to 90.4 ± 9 after application of the intervention, obtaining an increase of 5.4 ± 9.5 points ($p < 0.01$) compared to the CG that varied from 84, 3 ± 10 for 83.7 ± 10, with a decrease of 0.6 ± 8.8 ($p = 0.6$).

Table 2 presents the mean and standard deviation data for each of the 6 quality-of-life aspects of the WHOQOL-OLD, both before and after the intervention in each of the studied groups, demonstrating that IG improved statistically significant in the autonomy facets; present, past and future activities; social participation and death and dying, with no significant improvement in sensory functioning and intimacy being identified. CG did not show significant improvement in any of the facets. Subgroup analysis by means of ANOVA, performed in the IG, showed that the improvement in quality of life and functional mobility did not present a significant difference when comparing the 60 to 69, 70 to 79 and ≥ 80 age groups, with $p > 0.05$ for both analyzes.

Table 2. Mean score of WHOQOL-OLD before and after the intervention, for each group studied. T test for samples in pairs.

Facets	Groups	Basal moment	After 12 weeks of intervention	p*
1- Sensory functioning	**CG**	14,1 ± 0.8	14.2 ± 0.8	0,57
	IG	14,3 ± 0.4	14,6 ± 0.4	0,27
2- Autonomy	**CG**	13.6 ± 0,4	13.5 ± 0,4	0,40
	IG	13.8 ± 0,5	15.2 ± 0,9	<0,01
3- Present, past and future activities	**CG**	13.5 ± 0.4	13.4 ± 0.5	0,20
	IG	13.6 ± 0,4	14.1 ± 0,5	<0,01
4- Social participation	**CG**	14,8 ± 1,5	14,6 ± 1,5	0,19
	IG	14,9 ± 1,5	15,4 ± 1,7	0,01
5- Death and Dying	**CG**	12,6 ± 1,2	12,8 ± 1,2	0,09
	IG	12,5 ± 1	13,4 ± 1	<0,01
6- Intimacy	**CG**	14,5 ± 1,7	14,4 ± 1,6	0,70
	IG	14,6 ± 1,5	14,9 ± 1,1	0,06

DISCUSSION

The results of this research reveal that sedentary elderly, when participating in a semi-supervised physical home exercise program, presented a statistically significant improvement in functional mobility and quality of life when compared to a control group, being consistent with the hypotheses of the research and setting a clinically relevant evolution. The natural aging process causes morphological and functional deteriorations that progressively compromise the functional mobility and quality of life of the elderly,[1-3] but these physiological changes can be minimized by regular physical exercise.[2,3,19-22] It was used a semi-supervised exercise program, completely performed in the elderly's household and only with visits to guidelines every fortnight, which proved to be safe and feasible, since there were no injuries related to training and we obtained a high frequency rate (mean of 4 ± 0.6 days per week) and small loss of follow-up (4.5%).

The results are consistent with previous researches that have demonstrated the efficacy of physical exercise programs in functional mobility[7,19-22] and in the quality of life of the elderly.[2,8,9,22] Most of these studies have analyzed the effect of supervised exercise programs performed at training and / or rehabilitation centers, others have conducted a comparative analysis of the benefits of supervised versus unsupervised exercise and have observed trends

indicating supervised exercise is most effective;[23-25] however, recent studies have shown the elderly have a preference for home-based programs,[7,26,27] providing more satisfaction and, as a consequence, greater adherence and continuity after the end of the program, which may have a positive impact on the results in the medium and long term.[8,19,28] Whereas, the knowledge regarding the effects of home exercises on the elderly is still incipient.

In the present study, the subjects who performed the home exercise program during the period of 12 consecutive weeks showed a significant improvement in the primary endpoint, functional mobility, constituting an important evolution of the functional capacity, being consistent with previous studies[7,8,10,19] which, through similar methodologies, obtained equivalent results.

In the study conducted by Nelson et al.,[7] 72 elderly (mean age of 77.8 ± 5.3) were randomly assigned to a group that performed physical exercise at home or to a control group with nutritional education at home. The exercise group performed the program for 6 months, where each participant received a booklet with exercises guidelines, adjustable weight anklets, training at the beginning of the program on proper exercise performance and periodic follow-up visits. They concluded that minimally supervised home-based exercises can be safe and improve the functional performance of the elderly, similar to the results found in this study. The practice of physical exercise improves the functional mobility of the elderly, increasing their level of physical activity[7,29] and giving them the ability to safely carry out activities of daily living such as bathing, dressing and performing household activities , minimizing the risk of falls and increasing autonomy,[7,8,30] which provides a higher quality of life for this population.[2,9,22,31] A recent systematic review[32] demonstrated evidence of a strong association between physical exercise and the quality of life of the elderly, but it was not possible to sustain the existence of the causal relationship, since most of the studies presented significant associations used transversal designs, making inferences impossible about causality.

It was verified semi-supervised home physical exercise resulted in a statistically significant improvement in overall quality of life when compared to CG, converging with results from previous studies obtained similar results, but with the use of supervised exercises.[22] It was also observed a significant improvement in the quality of life in the IG, in four of the six facets of the WHOQOL-OLD, corroborating with previous study.[33] It is important to highlight the great improvement obtained in the autonomy facet, which may be related to a relevant improvement in functional mobility, identified by the reduction. The analysis of variance performed in the age extracts showed no statistically significant difference between the subgroups studied, demonstrating the home exercise program is effective in improving the

functional mobility and the quality of life of the elderly in different age groups, obtaining equivalent results between elderly and very old.

One of the strengths of the study is that, after the random allocation of the participants, both groups were periodically given the same orientations and stimuli in relation to the habits of life regarding feeding, hydration and hygiene of the sleep, contributing for the groups to present behaviors different only in relation to the practice of physical exercise, allowing the improvement in the functional mobility and quality of life presented by the IG is due only to the practice of the home exercises. These positive results presented are also related to the fact that, in addition, to the program being carried out in the home and composed of dynamic and easy-to-perform exercises, the elderly received visits every fortnight and were encouraged and research assistants and relatives regarding their practice, contributing to the high rate of adherence and little loss of follow-up of the participants to the program, which was fomented by the inexistence of reports on adverse events during the period of execution of the exercises. Follow-up losses did not interfere in the results of the investigation, since they occurred at random, that is, their characteristics are homogeneous both in terms of quantity and quality of losses, since they corresponded to less than 10% of the total sample and presented reasons similar in both sample segments, and the characteristics of those who remained in the study are comparable to those who did not remain.

The results of this study should be interpreted considering some limitations. First, there is a preponderance of females in the sample, which is justified by the feminization of the elderly population,[35,36] but randomization generated equivalent distribution among the groups. The inability to blind participants in relation to the intervention may have been tempered by the fact that each group (CG and IG) was accompanied by different assistants, minimizing the excitement bias applied by the assistants to the GI during home visits. The monitoring of the frequency of the exercises was self-reported, but in order to increase the reliability of this information, besides monitoring the frequency register during the visits, family members were recruited to assist in these annotations. Future studies need to evaluate the effects of semi-supervised home exercise programs with long follow-up periods, making the results clinically more reliable.

CONCLUSION

The results suggest semi-supervised home physical exercise is effective in improving the functional mobility and the quality of life of the community's sedentary elderly. Therefore, it

can be considered as a therapeutic, non-pharmacological, low cost, easy implementation and safe resource.

Declaration of conflicting interests

All the authors declare that they have no competing interests.

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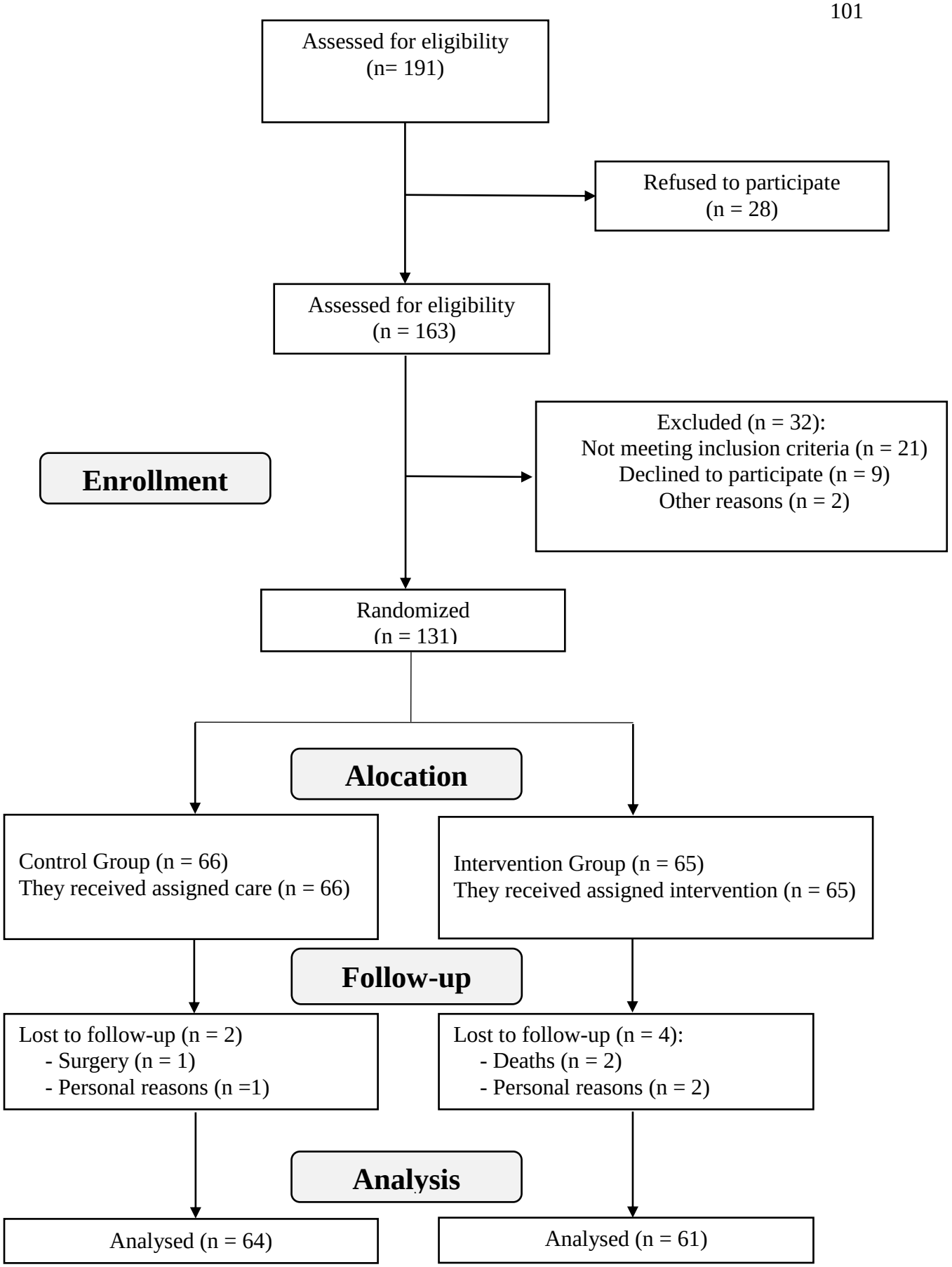

Figure 1. Flowchart of the study.

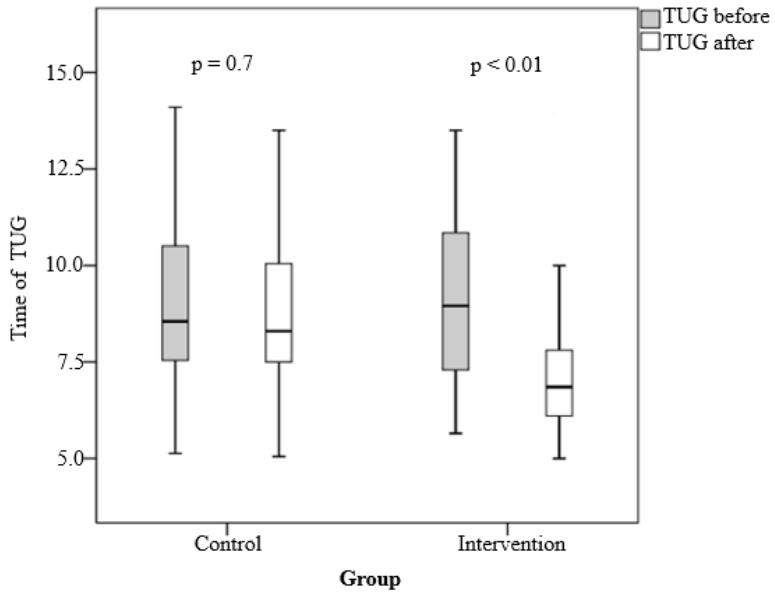

Figure 2. Comparison of the TUG execution time, between the moments before and after the intervention, in each group studied. Control group n= 66; Intervention group n= 65. T-test for paired samples.

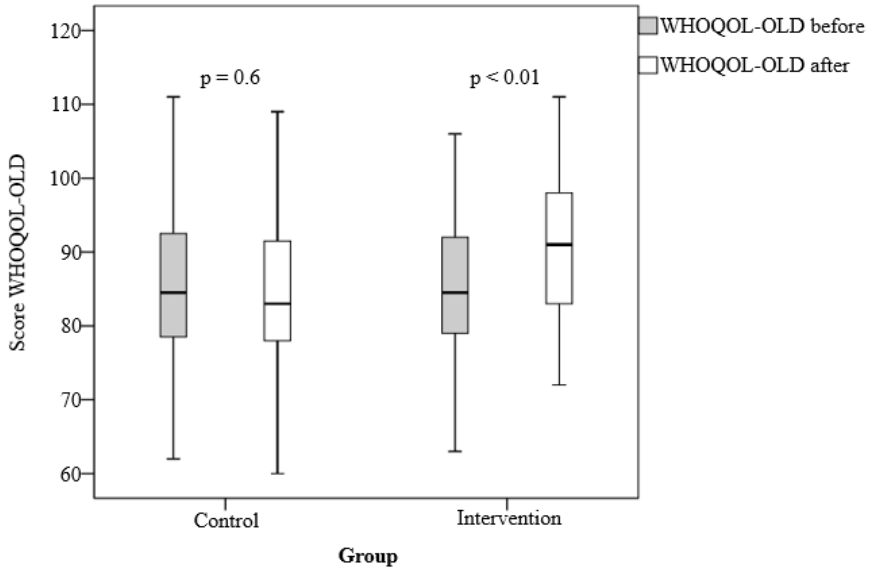

Figure 3. Comparison of the overall WHOQOL-OLD score, between the moments before and after the intervention, in each group studied. T test for samples in pairs.

6 DISCUSSÃO

Os artigos apresentados na seção “Resultados” deste trabalho podem ser considerados partes de um único trabalho, já que versam sobre um mesmo tema. Assim, essa discussão será desenvolvida de forma conjunta, enfocando as evidências provenientes das análises realizadas. De forma complementar, os itens da discussão dos referidos artigos fornecem uma explanação específica de cada estudo.

Inicialmente foi realizada uma análise descritiva dos 131 idosos que participaram desse estudo e em seguida foi testada a associação da qualidade do sono com a sonolência excessiva diurna, a qualidade de vida e a mobilidade funcional. Observou-se predominância do sexo feminino (87%), refletindo a maior longevidade das mulheres em todos os momentos da história e em todos os lugares do mundo[78]. Esta feminização da velhice está associada a diversos aspectos, destacando-se a menor exposição a fatores de risco ocupacional, melhores hábitos de vida, maior atenção à saúde e ao autocuidado e maior frequência da utilização dos serviços de saúde por parte das mulheres[78,79]. Houve preponderância da faixa etária de 60 a 69 anos (51,9%), com média de idade de 68 ± 7 anos, convergindo com trabalhos de âmbito internacional[80] e nacional[81]. A baixa escolaridade apresentada (75,6% ≤ 3 anos de estudo) reflete a intensa desigualdade socioeconômica vivenciada no país[82,83] e está associada ao baixo estado econômico, com 44,3% apresentando renda familiar per capta inferior a 1 salário mínimo, convergindo com um estudo de perfil epidemiológico[83].

A maioria dos idosos entrevistados (71%) está acima do peso e 90,1% das mulheres apresentam circunferência abdominal ≥ 80cm, o que configura elevado risco de doenças cardiovasculares[84] e da Síndrome da Apneia Obstrutiva do Sono[85]. Porém, é importante ressaltar que a relação inversa também é possível, ou seja, a curta duração do sono, assim como apresentado neste estudo, é considerada um fator de risco para o desenvolvimento da obesidade e suas subsequentes complicações[86,87].

A amostra apresentou escore médio global do PSQI de 11,2 ± 5,6 configurando como distúrbio do sono e demonstrou, por meio de análise de correlação, que a sonolência excessiva diurna está diretamente associada a pior percepção da qualidade do sono noturno, corroborando com investigações prévias[88,89]. Uma vez que esta restrição do sono noturno, identificada em nossa amostra por meio do PSQI (duração do sono noturno 5,7 ± 0,94 horas),

pode resultar em sensação de fadiga física e mental durante o dia, predispondo à sonolência excessiva diurna[90].

A qualidade de vida dos idosos entrevistados foi considerada boa, com escore médio no WHOQOL-OLD de 84,8 ± 10 e constatou-se que a deterioração da qualidade do sono apresenta associação significativa com a piora na percepção da qualidade de vida, em consonância com resultados apresentados em outros trabalhos[91-93].

O exercício físico proporciona importantes benefícios para a saúde do idoso e quando realizado no próprio domicílio, por ser uma preferência dos idosos[94], ainda obtém maior adesão e continuidade após o término do programa[15,95]. Porém, considerando que o conhecimento referente aos efeitos de exercícios domiciliares em idosos ainda é muito incipiente, em nosso estudo utilizamos um programa de exercício semisupervisionado, completamente realizado no domicílio do idoso e apenas com visitas para orientações a cada quinze dias, o que mostrou-se seguro e exequível, pois não ocorreram lesões relacionadas ao treinamento e ainda obtivemos elevada taxa de frequência (média de 4 ± 0,6 dias por semana) e pequena perda de seguimento do grupo intervenção (6,1%).

O programa domiciliar de exercício físico, realizado pelos idosos do grupo intervenção por um período de 12 semanas, proporcionou melhora significativa da qualidade do sono e da sonolência diurna. Os idosos do GI apresentaram redução de 4,9 pontos no escore global do PSQI e em todos os seus componentes de avaliação, o que caracteriza uma relevante melhora clínica, sendo resultados consistentes com um trabalho anterior[8] que utilizou metodologia semelhante para demonstrar a eficácia do exercício físico domiciliar, por meio da prática do exercício Baduanjin, na qualidade auto referida do sono e constatou que o GI apresentou melhora estatisticamente significativa, quando comparado ao GC, em relação ao escore global do PSQI e em 5 dos 7 componentes de avaliação.

Em relação à sonolência excessiva diurna, reconhecida como um importante problema de saúde pública[96], foi demonstrado que os idosos que praticaram exercício físico domiciliar apresentaram redução significativa da sonolência diurna, sendo consistente com os resultados de outros estudos que utilizaram exercícios supervisionados de Yoga[97] e Tai Chi[98] e também demonstraram redução significativa da sonolência diurna dos idosos do grupo exercício, com a utilização da mesma escala de avaliação.

O envelhecimento compromete progressivamente a mobilidade funcional e a qualidade de vida dos idosos[5,11,99], no entanto, estas alterações fisiológicas podem ser minimizadas com a prática de exercício físico[5,11,14,76,100,101]. Nossos resultados são consistentes com pesquisas anteriores que tem demonstrado a eficácia dos programas de exercício físico na mobilidade funcional[14,100-103] e na qualidade de vida de idosos[5,95,101,103]. Porém, a maioria destes trabalhos analisaram o efeito de programas de exercícios supervisionados e realizados em centros de treinamento e/ou reabilitação, outros realizaram análise comparativa dos benefícios do exercício supervisionado versus não supervisionado e verificaram tendências indicando que o supervisionado é mais eficaz[95,104-106], entretanto estudos recentes demonstraram que idosos tem preferência pelos programas domiciliares[96,102,107]. Os idosos do nosso estudo, ao praticarem exercícios domiciliares durante 12 semanas consecutivas, apresentaram melhora da mobilidade funcional, podendo repercutir com aumento do nível de atividade física, proporcionando maior capacidade de realizar, com segurança, as atividades da vida diária, como tomar banho, vestir-se e executar as atividades domésticas, minimizando o risco de quedas e aumentando a autoconfiança e a autonomia[95,102,108], gerando como consequência maior qualidade de vida para esta população, assim como demonstrado em nosso resultados, onde foi constatado melhora significativa da qualidade de vida global e em quatro das seis facetas do WHOQOL-OLD, corroborando com estudos anteriores[5,101,103,109]. É importante destacar a grande melhoria obtida na faceta referente à autonomia, que pode estar relacionada a relevante evolução na mobilidade funcional, identificada pela redução no tempo de realização do TUG[29,100,102].

A análise de variância realizada nos extratos etários, demonstrou não haver diferença estatisticamente significativa entre os subgrupos estudados, demonstrando que o programa de exercício domiciliar semisupervisionado é eficaz em melhorar todas as variáveis estudadas: qualidade do sono, sonolência excessiva diurna, mobilidade funcional e a qualidade de vida de idosos em variadas faixas etárias, obtendo resultados equivalentes entre idosos jovens e muito idosos.

Um dos pontos fortes do presente estudo é que, após a alocação aleatória dos participantes, ambos os grupos estudados receberam periodicamente as mesmas orientações e estímulos em relação aos hábitos de vida referentes à alimentação, hidratação e higiene do sono, contribuindo para que os grupos apresentassem comportamentos diferentes apenas em relação à prática de exercício físico, permitindo que a melhora na mobilidade funcional e qualidade de

vida apresentada pelo GI seja decorrente apenas da prática dos exercícios domiciliares. Estes resultados positivos apresentados em nosso estudo estão também relacionados ao fato de que, além do programa ser realizado no próprio domicílio e composto por exercícios dinâmicos e de fácil execução, os idosos recebiam visitas a cada quinze dias e assim eram encorajados e orientados, pelos assistentes da pesquisa e os familiares, em relação à prática dos mesmos, contribuindo com a elevada taxa de adesão e pequena perda de seguimento dos participantes ao programa, que foi fomentada pela inexistência de relatos sobre eventos adversos durante o período de execução dos exercícios. Trabalhos anteriores[94,95] sugerem que o contato ocasional direto com os participantes via telefone, internet ou visita pessoal aumenta a adesão de idosos aos programas de exercícios domiciliares.

As perdas de seguimento não interferiram nos resultados da investigação, pois ocorreram de forma aleatória, ou seja, suas características são homogêneas tanto em relação à quantidade como a qualidade das perdas, já que corresponderam a menos de 10% do total da amostra e apresentaram razões semelhantes em ambos os seguimentos amostrais, além de que as características das pessoas que permaneceram no estudo são comparáveis às que não permaneceram.

Os resultados deste estudo devem ser interpretados considerando algumas limitações. Primeiramente, há preponderância do sexo feminino na amostra, o que é justificável pela feminização da população idosa[78,79], porém a randomização gerou distribuição equivalente entre os grupos. A impossibilidade de cegar os participantes em relação à intervenção pode ter sido amenizada pelo fato de que cadagrupos (GC e GI) foi acompanhado por assistentes diferentes, minimizando o viés de empolgação aplicado pelos assistentes ao GI durante as visitas domiciliares. A monitorização da frequência de realização dos exercícios foi autorreferida, porém para aumentar a confiabilidade desta informação, além do acompanhamento do registro das frequências durante as visitas, membros da família foram recrutados para auxiliar nestas anotações. A qualidade do sono, apesar de ter sido avaliada por um instrumento validado e amplamente aceito na comunidade científica, mas trata-se de uma medida realizada por meio da autoavaliação, tornando os resultados potencialmente propensos ao viés de memória.

7 CONCLUSÕES

1. Constata-se, entre os idosos da comunidade selecionados com pontuação do PSQI ≥ 5, predominância do sexo feminino, na faixa etária de 60 a 69, com baixa classe socioeconômica e de escolaridade e morando com familiares. Além de apresentarem, em sua maioria, risco aumentado de doenças cardiovasculares e metabólicas, sonolência diurna, boa mobilidade funcional, boa qualidade de vida e nível de atividade física considerado ativo.

2. Identificou-se que a má qualidade do sono noturno está associada à pior qualidade de vida e a presença de sintomas de sonolência excessiva diurna, porém não influenciando de forma significativa na mobilidade funcional.

3. Os nossos resultados sugerem que o exercício físico domiciliar semisupervisionado, é eficaz em melhorar a qualidade autorreferida do sono e a redução da sonolência excessiva diurna de idosos sedentários da comunidade com distúrbios do sono, além de melhorar a mobilidade funcional e a qualidade de vida desta população em variadas faixas etárias. Portanto, pode ser considerado como um importante recurso terapêutico, não farmacológico, de fácil implementação e seguro para idosos da comunidade.

8 PERSPECTIVAS DE ESTUDOS FUTUROS

Futuras pesquisas poderão advir de algumas estratégias: 1. Análises adicionais no atual banco de dados; 2. Análises de acompanhamento dos participantes em momento futuro; 3. Outros potenciais estudos. Assim, podemos enumerar algumas perspectivas:

1. Correlacionar qualidade do sono com a presença de doenças crônicas (atual banco de dados).

2. Correlacionar condição socioeconômica com qualidade do sono e qualidade de vida (atual banco de dados).

3. Analisar a associação da presença do alto risco da Síndrome de Apnéia Obstrutiva do sono com a qualidade do sono de idosos da comunidade (atual banco de dados).

4. Analisar a continuidade da prática de exercício físico domiciliar após o termino do período de acompanhamento do programa (novas análises).

5. Analisar os efeitos do exercício físico domiciliar na qualidade do sono de idosos da comunidade, por meio da polissonografia ou da poligrafia (novo estudo).

6. Analisar os efeitos do exercício físico domiciliar em idosos da comunidade a longo prazo e com maior número de participantes (novo estudo).

7. Lançamento da cartilha em evento institucional (Universidade do Estado da Bahia) para a população de idosos.

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APÊNDICES

Apêndice A - Termo de consentimento livre e esclarecido

TERMO DE CONSENTIMENTO LIVRE E ESCLARECIDO

Esta pesquisa seguirá os Critérios da Ética em Pesquisa com Seres Humanos conforme Resolução nº 466/2012 do Conselho Nacional de Saúde.

I – DADOS DE IDENTIFICAÇÃO DO PARTICIPANTE DA PESQUISA

Nome:_____

Endereço:_____

Bairro:_____ Cidade_____ CEP_____

Telefone:_____ Data de nascimento: ___/____/___

Sexo: M ( ) F ( ) Telefone: (__)_____-_____ RG nº_____ CPF nº_____

O (A) Senhor (a) está sendo convidado (a) a participar, como voluntário (a), da pesquisa intitulada "Efeitos de um programa de exercício físico domiciliar, não supervisionado e orientado, na qualidade do sono de idosos", de responsabilidade do pesquisador Glauber Sá Brandão. O presente estudo ocorrerá no período de abril a outubro de 2015 e terá como objetivo medir a influência de um programa de exercício físico, não supervisionado e orientado, na qualidade do sono de idosos. Sua participação nesta pesquisa consistirá em, inicialmente, passar por uma avaliação clínica geral, avaliação da qualidade de vida e da qualidade do sono respondendo a questionários específicos, além da avaliação da capacidade funcional (capacidade de realizar as atividades da vida diária) por meio de um teste que consta de levantar-se de uma cadeira e andar um percurso em linha reta por 3 metros, com passos seguros, retornar em direção à cadeira e sentar-se novamente na mesma. A avaliação do sono será complementada por um exame denominado de polissonografia domiciliar (nível III). Este exame é realizado com um aparelho portátil e em sua própria casa, o aparelho possui canais (cabos) que serão afixados, por meio de adesivos, ao corpo do participante, sendo um canal na abertura do nariz para medir a quantidade de respirações por minuto, outro no tórax para medir as movimentações torácicas por minuto e outro em um dos dedos da mão que vai calcular a porcentagem de oxigênio que tem circulando no sangue e a frequência de batimentos cardíacos por minuto. Após a avaliação, todos os participantes assistirão a uma apresentação de como realizar adequadamente alguns exercícios físicos, além de receber uma

cartilha com orientações e ilustrações de como realizar estes exercícios em casa. O (A) senhor (a) será orientado (a) e estimulado (a) a realizar estes exercícios em sua casa durante três meses, e após este período será realizada nova avaliação clínica, avaliação da qualidade de vida, da qualidade do sono e da capacidade funcional. Sua participação é voluntária e não apresenta gratificação financeira. A qualquer momento, o (a) senhor (a) poderá desistir de participar e retirar seu consentimento. Sua recusa não trará nenhum prejuízo em sua relação com o pesquisador ou com a instituição. Conforme o que estabelece a Resolução 466/2012 CNS/MS caso se sinta prejudicado (a) terá direito a tratamento e acompanhamento por uma equipe de saúde. As informações obtidas por meio desta pesquisa serão confidencias e asseguramos o sigilo de sua identidade. Ao concordar, o (a) senhor (a) receberá uma cópia deste termo onde consta o telefone e endereço do pesquisador responsável pela pesquisa, podendo tirar dúvidas do projeto e de sua participação, agora ou a qualquer momento.

Todo o procedimento será orientado por um professor/pesquisador, Fisioterapeuta, com especialidade e mestrado em áreas relacionadas ao exercício físico e com experiência, e ainda acompanhado por seis monitoras pesquisadoras, que constituem a equipe executora do projeto. Os exercícios são de fácil execução e utilizam apenas o peso do próprio corpo. Sendo assim, a metodologia dos testes, das avaliações e dos exercícios apresentam apenas riscos mínimos, que estão relacionados à possibilidade de quedas durante a realização de caminhadas e movimentos como rodar o corpo para fazer as curvas, além da possibilidade de constrangimento durante a aplicação dos questionários. Porém, apesar de toda a segurança apresentada, para reduzir ainda mais o risco de quedas, será feita análise cuidadosa do piso antes da realização dos testes e dos exercícios, além de cuidadosas orientações, de forma oral e escrita, em relação à execução dos mesmos, porém caso ocorra algum imprevisto, será prestado suporte necessário a sua recuperação, garantindo a integridade da saúde física e mental.

Em relação aos possíveis benefícios da pesquisa, este trabalho se constituirá em uma importante fonte de informações à comunidade acadêmica, científica e à prática clínica dos profissionais da saúde que trabalham com a terceira idade, além dos benefícios diretos aos participantes da pesquisa por considerar que o exercício físico é um importante recurso na promoção da qualidade de vida, da qualidade do sono e na melhoria da capacidade de realização das atividades da vida diária das pessoas na terceira idade. E, após a finalização do projeto, serão disponibilizadas, aos participantes que tenham interesse, orientações para a continuação da prática dos exercícios.

V – INFORMAÇÕES DOS RESPONSÁVEIS PELO ACOMPANHAMENTO DA PESQUISA, PARA CONTATO EM CASO DE DÚVIDAS.

Pesquisador responsável: Glauber Sá Brandão

Tel: (74) 8824-7858

E-mail: gbrandao@uneb.br

Endereço: Departamento de Educação, Campus-VII, Rodovia Lomanto Junior, Km 125, Br 407, Senhor do Bonfim/BA, CEP: 48970-000.

Comitê de Ética em Pesquisa em Seres Humanos – CEP/BAHIANA, – Avenida Don João VII, nº 275, Brotas, pavilhão II, 2º andar, próximo à pós-graduação, Salvador/BA, CEP 40290-000.

VI – CONSENTIMENTO PÓS-ESCLARECIDO:

Declaro que, após ter sido convenientemente esclarecido pelo pesquisador e ter entendido o que me foi explicado, consinto em participar do presente Protocolo de Pesquisa. Consinto, também, que os resultados obtidos sejam apresentados e publicados em eventos e artigos científicos desde que a minha identificação não seja realizada.

Senhor do Bonfim, _____de _____ de 2014.

Assinatura do(a) participante _____

Impressão digital (polegar direito)

Assinatura do Pesquisador: _____

Apêndice B - Ficha de controle da frequência dos exercícios

FICHA CONTROLE DA FREQUÊNCIA DOS EXERCÍCIOS

Título da pesquisa: Efeitos de um programa de exercício físico domiciliar, não supervisionado e orientado, na qualidade do sono de idosos.
Nome do

Participante:_____

Idade: _____ Sexo: ( ) M ( ) F

Endereço: _____

Data do início do exercício físico: _____

ORIENTAÇÃO: Em cada semana marque os dias que fez exercício e escreva o turno

(Manhã, Tarde ou Noite) – evitando exercitar-se próximo (até 3h antes) do horário de dormir

SEMANAS	SEGUNDA	TERÇA	QUARTA	QUINTA	SEXTA	SABADO	DOMINGO	NÃO REALIZOU
1ª								
2ª								
3ª								
4ª								
5ª								
6ª								
7ª								
8ª								
9ª								
10ª								
11ª								
12ª								

Condições de moradia:

_____

_____

Histórico:

_____

_____

Queixas:

_____

_____

Observações:

_____

_____

_____

Apêndice C - Ficha de avaliação dos participantes

PROJETO: EFEITO DO EXERCÍCIO FÍSICO DOMICILIAR, NÃO SUPERVISIONADO E ORIENTADO, NA QUALIDADE DO SONO DE IDOSOS
PESQUISADOR RESPONSÁVEL: GLAUBER SÁ BRANDÃO

Data:___/___/_____

▪IDENTIFICAÇÃO:

Nome: _____

Idade: _____

Sexo: ( )M ( )F RG: _____ Tel: (__) _____

Endereço do participante: _____

_____

• DADOS SOCIODEMOGRÁFICOS

Estado Civil: ( )Solteiro(a) ( )Casado(a) ( )Companheiro(a) ( )Viúvo(a) ( )Divorciado(a) ( ) Separado(a)

Escolaridade: ( )Analf. ( )Fund – 1º ao 9º ano ( )Méd – 1º ao 3º colegial

( )Sup – graduação, mestrado ou doutorado

Anos de estudo: ( ) Nenhum ( )1 a 2 ( )3 a 4 ( )≥ 5

Raça (conforme declaração da participante)**:** _____

Religião (conforme declaração da participante)**:** _____

Arranjo domiciliar: ( )Mora sizinho(a) ( )Cônjuge/Companheiro ( )Filho(a) não casado(a) ( )Filho(a) casado(a) ( )Irmãos(ãs) ( )Netos(as) ( )Sobrinhos(as)

Número de pessoas no domicílio: ( )1 a 2 ( )3 a 4 ( )≥ 5

Ocupação: _____

Renda *per capta*: ( )< 1 SM[1] ( )1 a 2 SM ( )> 2 a 3 SM ( )> 3 SM

[1]. SM = Salário Mínimo

• MORBIDADES AUTOREFERIDA:

Doenças:

( )Artrite/reumatismo/artrose ( )Osteoporose ( )Incontinência urinária ( )Diabetes

( )Fibromialgia ( ) Ansiedade ( )Câncer ( )AVE/derrame ( )Dor crônica ( )Depressão

( )Distúrbios do equilíbrio

OBSERVAÇÕS: _____

_____

_____

- **HÁBITOS DE VIDA**

Tabagismo: ( ) Fumante ( ) Ex-fumante ( ) Nunca fumou

Etilismo: ( )Não ( )Sim

Quantidade:_____Frequência:_____

Tipo de bebida:_____

- **DOENÇAS CARDIOVASCULARES, PULMONARES E METABÓLICA:**

_____

_____

Descrever as doenças do coração, vasculares e metabólicas que limitem ou contraindiquem a realização dos exercícios

- **DOENÇAS NEUROLÓGICAS, PSIQUICAS E DO EQUILÍBRIO**

_____

_____

- **MEDICAÇÕES UTILIZADAS:**

Anotar a prescrição médica: o nome das medicações, a dose, a forma e intervalo da administração.

_____

_____

Atenção aos medicamentos que interferem na qualidade do sono, como os utilizados para emagrecer, antidepressivos, anticonvulcivantes, antipsicóticos e antihipertensivos

- **CIRURGIAS:**

( )Não ( ) Sim

Tipo de cirurgia e há quanto tempo?

_____

_____

Obs.: cirurgia a menos de três meses é critério de exclusão do estudo

- **DADOS ANTROPOMÉTRICOS:**

Peso (Kg)	Altura (m)	IMC (Kg/m^2)	Circunf Abd	Circunf Coxa	Circunf Panturrilha

Circunferência adequada, na perna esquerda, para idosos ≥ 31 cm

- **AVALIAÇÃO DA QUALIDADE DE VIDA**

Questionário de qualidade de vida (WHOQOL-OLD)

Escore total:_____

- **AVALIAÇÃO DA CAPACIDADE FUNCIONAL**

Timed up and go (TUG)

Tempo gasto:_____

- **AVALIAÇÃO DO NÍVEL DE ATIVIDADE FÍSICA**

Questionário internacional de atividade física adaptado para idosos (IPAQ)

Escore total:_____

- **AVALIAÇÃO DO SONO**

ÍNDICE DE QUALIDADE DO SONO DE PITTSBURGH (PSQI-BR)

Escore total:_____

ESCALA DE SONOLENCIA DE EPWORTH

Escore total:_____

QUESTIONÁRIO CLÍNICO DE BERLIN

Escore total:_____

OBSERVAÇÕES:

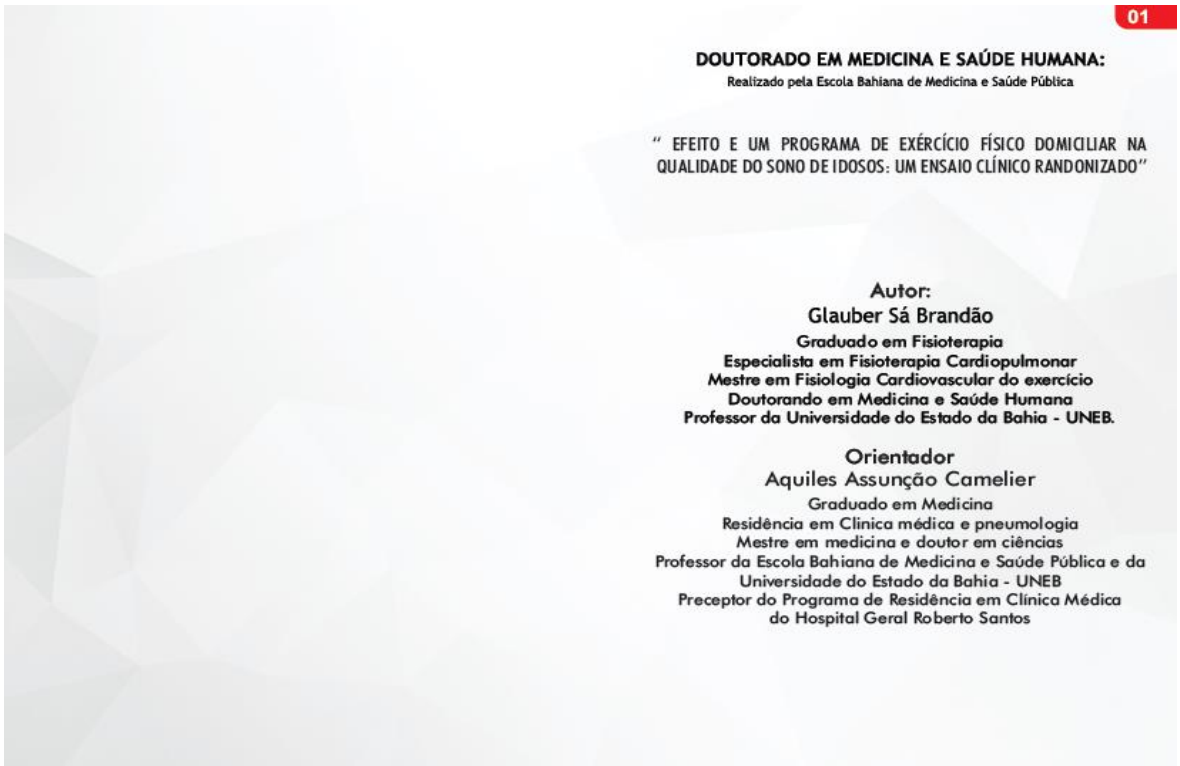
_____

_____

_____

AVALIADOR:_____

Apêndice D - Cartilha de exercício físico domiciliar e semisupervisionado para idosos



02

DICAS IMPORTANTES:

Escolha um horário de sua preferência e tente fazer os exercícios sempre no mesmo horário;

Procure realizar os exercícios todos os dias;

Respire durante os exercícios (Nunca prenda a respiração);

Não faça os exercícios quando não estiver sentindo-se bem;

Mantenha uma boa postura e procure seguir corretamente as instruções de cada exercício (não tenha pressa);

O grau de esforço dos exercícios deve ser de "um pouco difícil" para "difícil" (não podendo ser muito fácil nem muito difícil).

03

RODANDO OS OMBROS

Posição: Sentado

1. Faça um circulo com os ombros: Movimente-os para frente, para cima, para trás e para baixo;
2. No momento que os ombros estiverem subindo puxe o ar pelo nariz e tente encostá-los, o mais próximo possível, nas orelhas;
3. Gire os ombros para trás, ainda segurando o ar;
4. Ao descer os ombros, solte o ar pelo nariz;
5. Em seguida retornar a posição inicial.

TEMPO: Faça 5 vezes para FRENTE, descanse e repita 5 vezes para TRÁS.

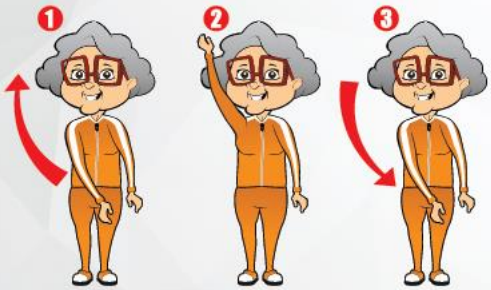
04

FORTALECENDO OS OMBROS

1. **Posição inicial:** Em pé com a mão direita na coxa esquerda;
2. **Movimento:** Movimente o braço em diagonal, para cima e para o lado (esticando a mão o mais alto possível);
3. Em seguida retornar a posição inicial.

TEMPO: Faça 10 vezes com o braço direito, descanse e faça 10 vezes com o braço esquerdo. Repita mais 10 vezes com cada um dos braços.

Progressão: Quando o movimento estiver fácil, faça o exercício segurando pesos de 1 a 2kg, mantendo o esforço entre "um pouco difícil" e "difícil".



05

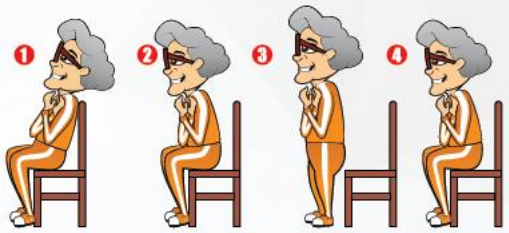
LEVANTANDO SEM A AJUDA DAS MÃOS

COLOQUE A CADEIRA BEM APOIADA NA PAREDE

1. **Posição inicial:** Mantenha seus pés firmes e próximo aos pés da cadeira Sente com o bumbum próximo a ponta do assento da cadeira, cruze os braços na frente do corpo;
2. **Movimento:** Levante da cadeira sem ajuda das mãos;
3. Fique em pé;
4. Logo em seguida sente novamente sem ajuda das mãos.

TEMPO: Faça 5 vezes, descanse e faça mais 5 vezes.

Progressão: Quando estiver fácil, faça o exercício segurando pesos de 1 a 2kg junto ao tórax, mantendo o esforço entre "um pouco difícil" e "difícil".



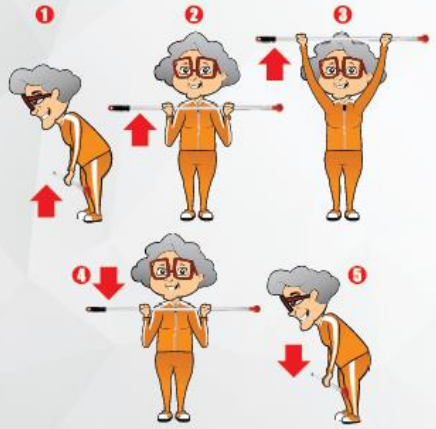
06

JOGANDO PARA CIMA

1. **Posição inicial:** Em pé, com os pés um pouco afastados e segurando um cabo de vassoura na altura do joelho;
2. **Movimento:** Movimente o cabo de vassoura até a altura do peito;
3. Em seguida coloque-o acima da cabeça;
4. Retorne o cabo de vassoura ao peito;
5. E depois ao joelho novamente.

TEMPO: Faça 5 vezes, descanse e faça mais 5 vezes

Progressão: Quando estiver fácil, aumente o número de repetições, mantendo o esforço entre "um pouco difícil" e "difícil".



07

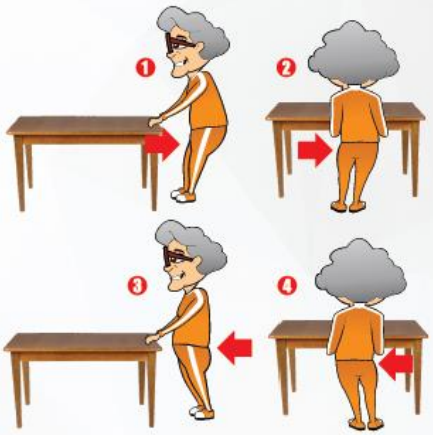
MEXENDO O QUADRIL

Posição: Em pé

1. **Movimento:** Faça um grande círculo com o quadril movimentando para trás;
2. Para o lado direito;
3. Para frente;
4. E para o lado esquerdo.

TEMPO: Faça 10 vezes. Repetir girando para o outro lado.

Progressão: Quando estiver fácil, faça o movimento com as mãos no quadril e depois com os pés juntos.



08

PÉ COM PÉ

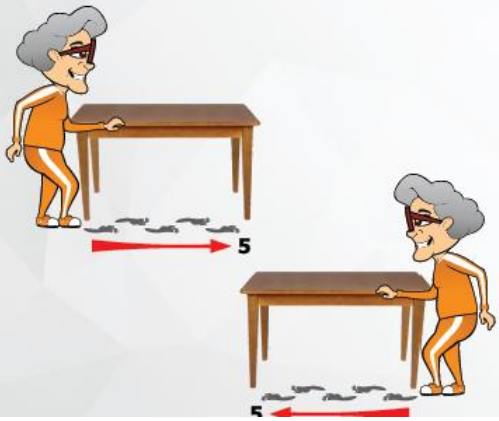
SEGURE COM UMA DAS MÃOS EM UM APOIO FIRME: BARRA, PIA DA COZINHA, MESA, BATENTE DA JANELA.

Movimento: Ande em linha reta, cinco passos para frente pé com pé (encostando o calcanhar nos dedos do outro pé);

Vire e volte andando para a outra direção;

Realize novamente o exercício.

Progressão: Quando estiver fácil, faça o exercício sem segurar em apoios



09

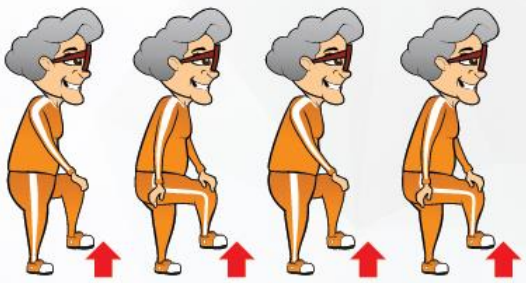
CAMINHAR LEVANTANDO OS JOELHOS

Posição inicial: Em pé com os braços esticados ao longo do corpo;

Movimento: Ao caminhar você deve levantar o joelho esquerdo e tocá-lo com a mão direita e em seguida levantar o joelho direito e tocá-lo com a mão esquerda;

Continuar caminhando e fazendo este movimento por 5 vezes, descansar e fazer mais 5 vezes.

Progressão: Quando estiver fácil, aumente o número de repetições para 10, depois para 15 e assim por diante, mantendo o esforço entre "um pouco difícil" e "difícil".



10

ESTICANDO PERNAS E COLUNA

Posição: Sentado na cama

1. **Movimento:** Estique os joelhos e force a ponta dos pés em sua direção;
2. Quando você sentir as pernas bem esticadas;
3. Incline o tronco para frente.

TEMPO: Realizar 2 vezes mantendo na posição por **20 segundos.**
Obs.: Não prender a respiração.
(Continuar respirando durante o exercício)

Progressão: Quando estiver fácil, tente inclinar mais o tronco e permanecer mais de 20 segundos, mantendo o esforço entre "um pouco difícil" e "difícil".

11

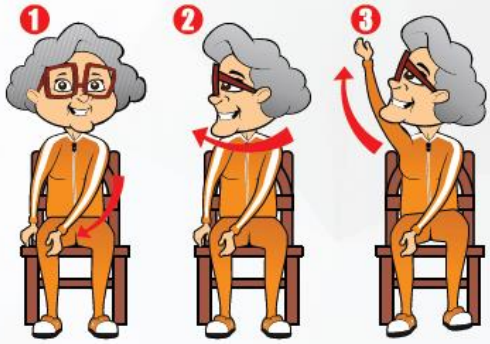
ALCANÇANDO AS ESTRELAS

Posição: Sentado

1. Estique seu braço esquerdo até apoiar sua mão no joelho direito;
2. Gire sua cabeça e tronco para a direita como se quisesse olhar para trás;
3. Estique o braço direito para cima como se fosse alcançar a mão no teto.

Tente alcançar o mais alto que você puder de forma que seu bumbum do lado esquerdo levante um pouco do acento.

TEMPO: Faça 10 vezes. Repetir do outro lado.



12

DESVIANDO DE OBSTÁCULOS

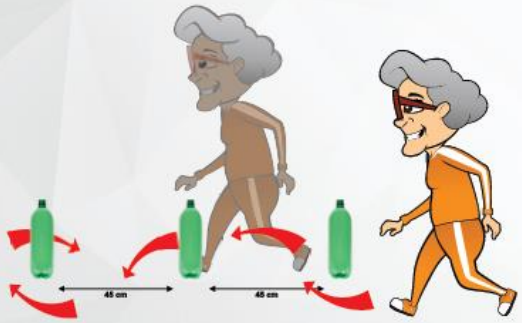
Utilizar 3 garrafas de refrigerante de 2 litros (de plástico) ou algo semelhante;

Colocar as garrafas em fila com uma distância de 45 cm entre elas (distância de uma garrafa e meia);

Caminhar desviando das garrafas (vá até o final e volte duas vezes).

TEMPO: Vá até o final e volte duas vezes, descanse e repita mais duas vezes.

Progressão: Quando estiver fácil, caminhar encostando o calcanhar com os dedos do outro pé e depois reduzir a distância entre as garrafas de 5 cm em 5 cm.



13

LEMBRETE:

A prática destes exercícios, com frequência de pelo menos três vezes por semana, tem como objetivo possibilitar à você:

Realizar suas atividades diárias com mais facilidade e independência;

Diminuir as dores do corpo;

Sentir mais disposição;

Melhorar a qualidade do sono;

Melhorar a qualidade de vida.

ANEXOS

Anexo A – Parecer Consubstanciado do CEP

ESCOLA BAHIANA DE MEDICINA E SAÚDE PUBLICA / FUNDAÇÃO BAHIANA

PARECER CONSUBSTANCIADO DO CEP

DADOS DO PROJETO DE PESQUISA

Título da Pesquisa: EFEITOS DE UM PROGRAMA DE EXERCÍCIO FÍSICO DOMICILIAR, NÃO SUPERVISIONADO E ORIENTADO, NA QUALIDADE DO SONO DE IDOSOS: UM ENSAIO CLÍNICO RANDOMIZADO.

Pesquisador: Glauber Sá Brandão

Área Temática:

Versão: 2

CAAE: 39072514.6.0000.5544

Instituição Proponente: Fundação Bahiana para Desenvolvimento das Ciências - FUNDECI

Patrocinador Principal: Financiamento Próprio

DADOS DO PARECER

Número do Parecer: 979.606

Data da Relatoria: 25/02/2015

Apresentação do Projeto:

Conforme o Pesquisador Responsável: A população idosa é a que apresenta o maior índice de crescimento em todo o mundo. No Brasil o crescimento desta população tem ocorrido de forma tão acelerada que as projeções mais conservadoras indicam que em 2025 seremos o sexto pais do mundo em número de idosos, correspondendo a 15% de todo o contingente populacional. Associado ao envelhecimento humano ocorrem alterações orgânicas importantes que implicam na qualidade de vida dos idosos, dentre estas alterações destacam-se os distúrbios do sono. A prática de exercício físico de intensidade leve a moderada apresenta resultados positivos na melhoria da qualidade do sono de idosos. Este estudo tem como objetivo avaliar o impacto de um programa de exercício físico domiciliar, não supervisionado e orientado, na qualidade do sono de idosos. Trata-se de um estudo experimental do tipo ensaio clínico randomizado, controlado composto por idosos com 60 anos ou mais, que apresentem alterações na qualidade do sono e que sejam residentes na zona urbana da cidade de Senhor do Bonfim-Ba. Os participantes serão recrutados por meio de divulgação em jornais locais, rádios, igrejas, grupo de idosos, residência sênior e associação de bairros. Inicialmente será realizada uma avaliação clínica, preenchimento dos instrumentos de avaliação do sono, validados para a língua portuguesa, que são o Índice de Qualidade do Sono de Pittsburgh (PSQI), escala deonolência Epwort e o Questionário Clínico de

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Berlin. Aqueles que apresentarem alterações da qualidade do sono de acordo com os instrumentos citados serão submetidos à polissonografia domiciliar (nível III), e serão ainda submetidos a avaliação da capacidade funcional por meio do teste Timed up and go e avaliação do nível de atividade física por meio do Questionário Internacional de Atividade Física (IPAQ) adaptado para idosos. Em seguida os participantes selecionados serão divididos em dois grupos, um grupo denominado de Grupo Experimental (GE) que realizará exercícios não supervisionados e orientados em seus domicílios e outro denominado de Grupo Controle (GC) que não realizará exercícios. Ambos os grupos receberão orientações em relação à higiene do sono e acompanhamento do ponto de vista clínico. A pesquisa será encaminhada a um Comitê de Ética para análise e todos os idosos assinarão o TCLE para participação no estudo. Foi realizado o cálculo do tamanho amostral utilizando o software Winpepi, obtendo como resultado um total de 50 participantes, sendo 25 para cada grupo.

Objetivo da Pesquisa:

Objetivo Primário:

1. Avaliar o impacto de um programa de exercício físico domiciliar, não supervisionado e orientado, na qualidade do sono de idosos por meio do Índice de Qualidade do Sono de Pittsburgh (PSQI)

Objetivo Secundário:

1. Avaliar o efeito de um programa de exercício físico domiciliar, não supervisionado e orientado no índice de apneia e hipopnéia (IAH) e no tempo total de sono por meio da polissonografia domiciliar nível III;
2.Quantificar o efeito programa de exercício físico domiciliar, não supervisionado e orientado na sonolência diurna de idosos por meio da escala de sonolência de Epwort;
3. Identificar a influencia de um programa domiciliar de exercício físico, não supervisionado e orientado na capacidade funcional de idosos por meio do teste Timed Up and Go (TUG);
4. Quantificar o ganho de massa muscular adquirido por meio do programa de exercício físico domiciliar, não supervisionado e orientado, utilizando como referência a circunferência da panturrilha;
5.Avaliar os efeitos do programa de exercício físico domiciliar, não supervisionado e orientado na qualidade de vida dos idosos por meio do Whoqol Bref;
6.Correlacionar a qualidade do sono de idosos com as variáveis antropométricas e sociodemográficas.

Avaliação dos Riscos e Benefícios:

Apesar dos exercícios serem realizados de forma não supervisionada, mas serão exercícios de fácil execução e que utilizam, em sua maioria, o peso do próprio corpo, além de serem orientados periodicamente, sendo assim, considera-se apenas um risco mínimo de risco de quedas durante a realização de caminhadas e movimentos como rodar o corpo para fazer as curvas, este será minimizado por meio de orientações de segurança aos idosos no dia da apresentação, análise cuidadosa do piso onde serão realizadas as avaliações e também recomendações detalhadas na cartilha que será entregue aos mesmos. Em relação à aplicação dos instrumentos de coleta de dados, todos serão realizados com a supervisão de pelo menos dois pesquisadores que acompanharão a execução dos mesmos. Caso necessário, será disponibilizado todo o suporte apropriado por parte da equipe executora da pesquisa, garantindo integridade à saúde física e mental de todos os participantes da pesquisa.

Em relação à aplicação dos instrumentos de coleta de dados, todos serão realizados com a supervisão de pelo menos dois pesquisadores que acompanharão a execução dos mesmos. Caso necessário, será disponibilizado todo o suporte apropriado por parte da equipe executora da pesquisa, garantindo integridade à saúde física e mental de todos os participantes da pesquisa.

Benefícios: Ainda existem poucas pesquisas sobre a influencia do exercício físico domiciliar não supervisionado e orientado sobre a saúde dos idosos, principalmente correlacionando seus efeitos com a qualidade do sono e qualidade de vida dos mesmos, associado ao fato de que idosos apresentam, com o passar dos anos, declínio progressivo do funcionamento de seus sistemas orgânicos e consequentemente da sua independência e autonomia, gerando fragilidade e sensação de insegurança para sair de casa. Sendo assim, a realização deste trabalho se constituirá em importante fonte de informações à comunidade acadêmico-científica, à prática clínica dos profissionais da saúde que trabalham com a terceira idade e às políticas públicas de saúde devido ao baixo custo e a flexibilidade organizacional apresentada por este programa em relação à prática de exercício físico, tornando-o uma alternativa ou um complemento a outras formas de exercício físico e estilo de vida ativo para idosos. Considera-se ainda os benefícios diretos que são esperados na saúde dos idosos participantes deste projeto de pesquisa. E, após a finalização do projeto, serão disponibilizadas, aos participantes que tenham interesse, orientações para a continuação da prática dos exercícios.

Comentários e Considerações sobre a Pesquisa:

Será realizado um ensaio clínico randomizado, controlado composto por idosos com 60 anos ou mais, que apresentem alterações na qualidade do sono e que sejam residentes na zona urbana da

cidade de Senhor do Bonfim-Ba. Os participantes serão recrutados por meio de divulgação em jornais locais, rádios, igrejas, grupo de idosos, residência sênior e associação de bairros. Inicialmente será realizada uma avaliação clínica, preenchimento dos instrumentos de avaliação do sono,validados para a língua portuguesa, que são o Índice de Qualidade do Sono de Pittsburgh (PSQI), escala de sonolência Epwort e o Questionário Clínico de Berlin. Aqueles que apresentarem alterações da qualidade do sono de acordo com os instrumentos citados serão submetidos à polissonografia domiciliar (nível III), e serão ainda submetidos a avaliação da capacidade funcional por meio do teste Timed up and go e avaliação do nível de atividade física por meio do Questionário Internacional de Atividade Física (IPAQ) adaptado para idosos . Em seguida os participantes selecionados serão divididos em dois grupos, um grupo denominado de Grupo Experimental (GE) que realizará exercícios não supervisionados e orientados em seus domicílios eoutro denominado de Grupo Controle (GC) que não realizará exercícios. Ambos os grupos receberão orientações em relação à higiene do sono e acompanhamento do ponto de vista clínico. O programa de exercício domiciliar proposto foi baseado nas recomendações do Colégio Americano de Medicina do Esporte para exercício e atividade física com idosos , terá duração mínima de 12 semanas, frequência mínima de 3 sessões semanais. Inicialmente será agendado um encontro com todos os participantes do GE para a realização de um treinamento teórico-prático da adequada realização dos exercícios propostos e para a distribuição de uma cartilha com orientações sobre a realização dos exercícios e os possíveis benefícios dos mesmos, além de outro encontro com os dois grupos para orientações sobre higiene do sono. A primeira semana de execução dos exercícios será utilizada apenas como período de adaptação dos participantes ao programa, não sendo contabilizada como parte dos três meses propostos. No primeiro mês os participantes do GE receberão visitas domiciliares semanais, e no período restante será realizada uma visita a cada quinze dias, até completarem o mínimo de 36 sessões de exercícios. Ao finalizar o programa, os participantes dos dois grupos serão recrutados para uma nova avaliação e em seguida os participantes do GE serão encorajados a continuar com os exercícios, já ao GC será disponibilizado o acompanhamento dos exercícios domiciliares, não supervisionado e orientado, pelo mesmo período realizado com o GE.
O Pesquisador Responsável esclarece o número de participantes da pesquisa 50 (25 por grupo).

Considerações sobre os Termos de apresentação obrigatória:

termos obrigatórios de acordo com as pendências do protocolo de pesquisa :

1. Carta de anuência do responsável pelo polissonografia.

3. Cronograma contempla as etapas da pesquisa;

4. Orçamento encontra-se adequado;
5. TCLE conforme a Resolução 466/12.

Recomendações:

Conclusões ou Pendências e Lista de Inadequações:

O Pesquisador Responsável atendeu as pendências do protocolo de pesquisa.

Situação do Parecer:

Aprovado

Necessita Apreciação da CONEP:

Não

Considerações Finais a critério do CEP:

Atenção : o não cumprimento à Res. 466/12 do CNS abaixo transcrita implicará na impossibilidade de avaliação de novos projetos deste pesquisador. Tendo sido sanadas as pendências anteriormente assinaladas e, estando de acordo com a Res. 466/12 do CNS o projeto encontra-se exequível.

XI ¿ DO PESQUISADOR RESPONSÁVEL

XI.1 - A responsabilidade do pesquisador é indelegável e indeclinável e compreende os aspectos éticos e legais.

XI.2 - Cabe ao pesquisador: a) e b) (...)

c) desenvolver o projeto conforme delineado;

d) elaborar e apresentar os relatórios parciais e final;

e) apresentar dados solicitados pelo CEP ou pela CONEP a qualquer momento;

f) manter os dados da pesquisa em arquivo, físico ou digital, sob sua guarda e responsabilidade, por um período de 5 anos após o término da pesquisa;

g) encaminhar os resultados da pesquisa para publicação, com os devidos créditos aos pesquisadores associados e ao pessoal técnico integrante do projeto; e

h) justificar fundamentadamente, perante o CEP ou a CONEP, interrupção do projeto ou a não publicação dos resultados

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Plataforma Brasil

Continuação do Parecer: 979.606

SALVADOR, 10 de Março de 2015

ESCOLA BAHIANA DE MEDICINA E SAÚDE PÚBLICA
BAHIANA

Assinado por:
CRISTIANE MARIA CARVALHO COSTA DIAS
(Coordenador)

Cristiane Maria Carvalho Costa Dias
Vice-Coordenadora do CEP
Comitê de Ética em Pesquisa em Seres Humanos

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