UNIVERSIDADE ESTADUAL DE CAMPINAS
FACULDADE DE CIÊNCIAS MÉDICAS

ANITA BELLOTTO LEME NAGIB

A TECNOLOGIA PODE FAVORECER O TREINAMENTO DOS MÚSCULOS DO ASSOALHO PÉLVICO?

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Tese apresentada à Faculdade de Ciências Médicas da Universidade Estadual de Campinas como parte dos requisitos exigidos para a obtenção do título de Doutora em Ciências.

Thesis presented to the Faculty of Medical Sciences at the State University of Campinas as part of requirements for obtaining the title of Doctor in Sciences.

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COORIENTADOR: PROF. DR. CÁSSIO LUÍS ZANETTINI RICCETTO

ESTE EXEMPLAR CORRESPONDE À VERSÃO FINAL DA TESE DEFENDIDA PELA DISCENTE ANITA BELLOTTO LEME NAGIB E ORIENTADA PELA PROFA. DRA. SIMONE BOTELHO PEREIRA.

CAMPINAS

2020

Ficha Catalográfica

Ficha catalográfica
Universidade Estadual de Campinas
Biblioteca da Faculdade de Ciências Médicas
Maristella Soares dos Santos - CRB 8/8402

N134t

Nagib, Anita Bellotto Leme, 1976-
A tecnologia pode favorecer o treinamento dos músculos do assoalho pélvico? / Anita Bellotto Leme Nagib. – Campinas, SP : [s.n.], 2020.

Orientador: Simone Botelho Pereira.
Coorientador: Cássio Luís Zanettini Riccetto.
Tese (doutorado) – Universidade Estadual de Campinas, Faculdade de Ciências Médicas.

1. Aplicativos móveis. 2. Gameterapia. 3. Músculos do assoalho pélvico. 4. Treinamento dos músculos do assoalho pélvico. 5. Incontinência urinária. I. Pereira, Simone Botelho. II. Riccetto, Cassio Luís Zanettini. III. Universidade Estadual de Campinas. Faculdade de Ciências Médicas. IV. Título.

Informações para Biblioteca Digital

Título em outro idioma: Can technology favor training of pelvic floor muscles?
Palavras-chave em inglês:
Mobile app
Gametherapy
Pelvic floor muscle
Pelvic floor muscle training
Urinary incontinence
Área de concentração: Fisiopatologia Cirúrgica
Titulação: Doutora em Ciências
Banca examinadora:
Simone Botelho Pereira [Orientador]
Viviane Herrmann Rodrigues
Marcela Grigol Bardin
Maria Celina Martins Fozzatti
José Tadeu Nunes Tamanini
Data de defesa: 22-05-2020
Programa de Pós-Graduação: Ciências da Cirurgia

Identificação e informações acadêmicas do(a) aluno(a)
- ORCID do autor: https://orcid.org/0000-0002-6323-7860
- Currículo Lattes do autor: http://lattes.cnpq.br/2612956932108051

COMISSÃO EXAMINADORA DA DEFESA DE DOUTORADO

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A ata de defesa com as respectivas assinaturas dos membros encontra-se no SIGA/Sistema de Fluxo de Dissertação/Tese e na Secretaria do Programa De Pós-Graduação em Ciências da Cirurgia – FCM/UNICAMP.

Data de Defesa: 22/05/2020

Dedicatória

Aos meus pais, Enio e Rose, sempre tão presentes em minha vida, a quem dedico todas as minhas vitórias.

Ao meu esposo Fernando, companheiro de todos os momentos, pela compreensão e carinho ao longo da elaboração deste trabalho.

Ao meu filho João Fernando, presença diária de amor e motivação, por dar sentido à minha vida!

À minha irmã Elaine e minhas sobrinhas Fernanda e Gabriela, pela presença constante, pelo amor e amizade que sempre estiveram presentes.

Agradecimentos

Agradeço a Deus, por estar sempre do meu lado concebendo proteção e sabedoria, para vencer as dificuldades e os obstáculos da vida.

À Profa. Dra. Simone Botelho Pereira, amiga e orientadora, agradeço os tantos e inesquecíveis diálogos, a paciência, a coerência e a clareza em seus ensinamentos, que me acompanharam desde a graduação até o doutorado. Minha gratidão por essa orientação que ultrapassa todos os limites desta tese, bem como por todo o acolhimento, apoio e compreensão nos momentos em que necessitei me dedicar um pouco mais às demandas de minhas atribuições acadêmicas ou às necessidades da minha família. Agradeço, sobretudo, o privilégio de haver compartilhado de seus conhecimentos em um tema para o qual você tem contribuído imensamente.

Ao Prof. Dr. Cássio Luís Zanettini Riccetto, agradeço profundamente ter assumido a coorientação deste trabalho, tendo-me brindado com as ricas sugestões, sempre disposto a nos ajudar, e por ter sido fonte de inspiração, conhecimento e profissionalismo.

Aos membros da banca, professores titulares, Prof. Dr. José Tadeu Nunes Tamanini, Profa. Dra. Marcela Grigol Bardin, Profa. Dra. Maria Celina Martins Fozzatti e Profa. Dra. Viviane Herrmann Rodrigues, e suplentes, Prof. Dr. Edilson Benedito de Castro, Profa. Dra. Ligia de Sousa e Prof. Dr. Luiz Gustavo Oliveira Brito, minha eterna gratidão pela contribuição com o crescimento dessa pesquisa, dosando críticas com comentários de incentivo. A vocês, todo meu respeito e admiração.

Ao Prof. Dr. Luiz Renato Paranhos e toda sua equipe de pesquisadores, pela produtiva parceria em estudos multicêntricos

desenvolvidos ao longo desse período, pelo apoio e incentivo nos momentos de incertezas.

À Profa. Dra. Cássia Raquel Teatin Juliato e toda a equipe do Departamento de Tocoginecologia do Programa de Pós-Graduação em Tocoginecologia – UNICAMP, pela parceria, receptividade e aprendizado, que foram tão importantes para o desenvolvimento dessa pesquisa.

À Profa. Dra. Andrea Marques e toda a equipe do Serviço de Fisioterapia do Centro Integral de Atenção à Saúde da Mulher – CAISM/UNICAMP, pelo acolhimento, apoio e parceria, essenciais nos momentos de dificuldades e incertezas.

Agradeço a todas as colegas do Grupo de UroFisioterapia do Programa de Pós-Graduação em Ciências da Cirurgia – UNICAMP, que compartilharam momentos de estudo, redação e correção de artigos e de tensão, como as longas discussões de análise estatística, no decorrer desta jornada. Aprendemos a trabalhar em grupo, a respeitar o próximo e, principalmente, que é muito mais fácil multiplicar quando sabemos dividir. Em especial à Natália Miguel Martinho Fogaça, agradeço pelos conselhos, apoio e confiança. Obrigada por ter sido minha companheira de viagem, coleta e análise de dados e por dividir comigo tanto momentos de alegria e descontração, como aqueles de dúvidas e angústia.

À Coordenação de Aperfeiçoamento de Pessoal de Nível Superior – CAPES – Finance Code 001, através do Programa de Pós-Graduação em Ciências da Cirurgia – UNICAMP, com suporte da Universidade Federal de Alfenas – UNIFAL e do Centro Universitário das Faculdades Associadas de Ensino – UNIFAE.

À funcionária e amiga Cláudia, que se fez presente nos momentos em que necessitei estar ausente, cuidando de mim e de minha família com muito amor.

À reitoria, corpo docente e funcionários do Centro Universitário das Faculdades Associadas de Ensino – UNIFAE, agradeço a amizade e

companheirismo. Com vocês tive a oportunidade de aprender o espírito de trabalho em equipe e amadureci muito como profissional.

Aos alunos dos cursos de Fisioterapia e Medicina da UNIFAE, todo meu afeto e sincera gratidão pelos ensinamentos nos desafios diários.

RESUMO

Introdução: A incontinência urinária (IU) é uma condição clínica que acomete milhares de pessoas no mundo, especialmente as mulheres. O seu tratamento é baseado no treinamento dos músculos do assoalho pélvico (TMAP), mas a adesão é uma barreira enfrentada pelos profissionais e pacientes. Baseado nisso, o uso da tecnologia pode contribuir para a adesão ao tratamento e melhorar a condição clínica. Entre as tecnologias disponíves, a gameterapia e o uso de terapia de lembrete por meio de aplicativos móveis (Apps) tem ganhado cada vez mais destaque na literatura científica. **Objetivos**: Avaliar os efeitos do uso de tecnologias (terapia de lembrete por meio de Apps e gameterapia) na redução dos sintomas urinários e no controle da IU em mulheres; verificar os efeitos da gameterapia nos parâmetros relacionados à função dos MAP. **Metodologia**: Foram realizadas duas revisões sistemáticas da literatura, desenvolvidas a partir das bases de dados (PubMed, Scopus, SciELO, LILACS, Web of Science, Embase, Cochrane, LIVIVO, OpenGrey, OpenThesis, OATD) Foram incluídos ensaios clínicos randomizados que avaliaram o controle da IU por App (na primeira revisão sistemática) e gameterapia (na segunda revisão sistemática), sem restrição de ano, idioma e status de publicação. O risco de viés dos estudos selecionados foi avaliado pela ferramenta "*The Joanna Briggs Institute Critical Appraisal tools for use in JBI Systematic Reviews Checklist for Randomized Controlled Trials*". No segundo momento, foram realizados dois ensaios clínicos randomizados com mulheres com IU predominantemente de esforço, divididas no grupo experimental - gameterapia e grupo controle. O primeiro ensaio clínico avaliou a viabilidade de associar a gameterapia ao TMAP e o segundo ensaio clínico investigou os efeitos do TMAP associado à gameterapia sobre os sintomas urinários e função dos MAP. A gravidade da investigação da IU foi realizada por meio dos questionários ICIQ UI-SF e ICIQ-OAB. A função dos músculos do assoalho pélvico foi avaliada através do exame de palpação digital (esquema

PERFECT), eletromiografia de superfície (sEMG) e ultrassonografia translabial 4D (4D TLUS). Ambos os grupos foram monitorados por cinco semanas consecutivas. Foram utilizados os testes estatísticos Kolmogorov-Smirnov, pareado-t, não-pareado-t e Mann-Whitney, com nível de significância de 5%. **Resultados**: Os sintomas urinários diminuíram significativamente, concomitante ao aumento de força e resistência dos MAP, após 5 semanas, em ambos os grupos. Adicionalmente, verificou-se aumento da capacidade de realização de contrações rápidas e contrações mantidas dos MAPs no grupo gameterapia, com p≤0,05 entre os grupos. Quanto à revisão sistemática, apenas 3 estudos preencheram os critérios de elegibilidade para cada uma das revisões sistemáticas. Todos os estudos mostraram redução dos sintomas urinários, melhora na adesão e na qualidade de vida. **Conclusões**: O uso das tecnologias por meio da gameterapia e terapia de lembrete por App parecem ser estratégias promissoras no controle da IU.

PALAVRAS-CHAVE: aplicativos móveis; gameterapia; músculos do assoalho pélvico; treinamento dos músculos do assoalho pélvico; incontinência urinária.

ABSTRACT

Introduction: Urinary incontinence (UI) is a clinical condition that affects thousands of people worldwide, especially women. Its treatment is based on pelvic floor muscle training (PFMT), but adherence is a challenge faced by professionals and patients. Based on that, the use of technology may contribute to treatment adherence and improvement of the clinical condition. Among the technologies available, gametherapy and the use of reminder therapy with mobile applications (Apps) have increasingly stood out in the scientific literature. **Objectives**: To assess the effects of the use of technologies (reminder therapy with Apps and gametherapy) in the reduction of urinary symptoms and the control of UI in women; also to verify the effects of gametherapy on the parameters related to PFM function. **Method**: Two systematic reviews of the literature were performed and developed from the databases (PubMed, Scopus, SciELO, LILACS, Web of Science, Embase, Cochrane, LIVIVO, OpenGrey, OpenThesis, OATD). We included randomized clinical trials that assessed the control of UI using Apps (in the first systematic review) and gametherapy (in the second systematic review), without restriction of year, language, and publication status. The risk of bias of the studies selected was assessed with the "Joanna Briggs Institute Critical Appraisal Tools for use in JBI Systematic Reviews Checklist for Randomized Controlled Trials". In a second moment, two randomized clinical trials were performed with women with prevalent stress UI, divided into experimental group (gametherapy) and control group. The first clinical trial assessed the feasibility of associating gametherapy with PFMT and the second clinical trial investigated the effects of PFMT associated with gametherapy on urinary symptoms and PFM function. The severity of UI investigation was performed with the ICIQ UI-SF and ICIQ-OAB questionnaires. The function of pelvic floor muscles was assessed with the digital palpation examination (PERFECT scheme), surface electromyography (sEMG), and 4D translabial ultrasound (4D TLUS). Both groups were monitored for five

consecutive weeks. The Kolmogorov-Smirnov, paired t, non-paired t, and Mann-Whitney statistical tests were used at a 5% significance level. **Results**: The urinary symptoms decreased significantly along with the increase in PFM strength and resistance, after five weeks, in both groups. Additionally, we verified an increase in the ability to perform fast and sustained contractions of PFM in the gametherapy group, with a p≤0,05 between the groups. As for the systematic review, only three studies fulfilled the eligibility criteria for each of the systematic reviews. All studies showed a reduction of urinary symptoms and improvement in adherence and quality of life. **Conclusions**: The use of technologies using gametherapy and reminder therapy with Apps may represent promising strategies in the control of UI.

KEYWORDS: mobile App; gametherapy; pelvic floor muscle; pelvic floor muscle training; urinary incontinence.

LISTA DE ILUSTRAÇÕES

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LISTA DE ABREVIATURAS E SIGLAS

ACSM	American College of Sports Medicine
App	Aplicativos Móveis
BMI	Body Mass Index
CAISM	Centro de Atenção Integral à Saúde da Mulher
CAPES	Coordenação de Aperfeiçoamento de Pessoal de Nível Superior
CG	Control Group
CI	Confiance Interval
CVA	Cerebral Vascular Accident
DeCS	Health Sciences Descriptors
DMP	Diferença Média Padronizada
EMTREE	Embase Subject Headings
EQ5D-VAS	EuroQoL 5D – Visual Analog Scale
G_Control	Control Group
G_Game	Gametherapy Group
GG	Gametherapy Group
GT	Gametherapy Group
ICC	Intraclass Correlation Coefficient
ICIQ UI-SF	International Consultation on Incontinence Questionnaire Urinary Incontinence - Short Form
ICIQ-LUTSQoL	International Consultation on Incontinence Questionnaire - Lower Urinary Tract Symptoms Quality of Life
ICIQ-OAB	International Consultation on Incontinence Questionnaire Urinary Incontinence - Overactive Bladder
ICIQ-VS	International Consultation on Incontinence Questionnaire - Vaginal Symptoms

ICIQ-VSQoL	International Consultation on Incontinence Questionnaire - Vaginal Symptoms - Quality of Life
ICS	International Continence Society
IQR	Interquartile Range
ITT	Intention to Treat
IU	Incontinência Urinária
IUE	Incontinência Urinária de Esforço
IUGA	International Urogynecological Association
IUM	Incontinência Urinária Mista
IUU	Incontinência Urinária de Urgência
JBI	Joanna Briggs Institute
LILACS	Latin-American and Caribbean Health Sciences Literature
LOCF	Last Observation Carried Forward
MAP	Músculos do Assoalho Pélvico
MeSH	Medical Subject Headings
MUI	Mixed Urinary Incontinence
N/A	Not Applicable
OMS	Organização Mundial da Saúde
PFM	Pelvic Floor Muscles
PFMT	Pelvic Floor Muscles Training
PGI-I	Patitent's Global Impression of Improvement
POP	Pelvic Organ Prolapse
POP-Q	Pelvic Organ Prolapse Quantification
PP	Per-Protocol

PRISMA	Preferred Reporting Items for Systematic Reviews and Meta-Analyses
QoL	Quality of Life
QUID	Questionnaire for Urinary Incontinence Diagnosis
RMS	Root Mean Square
SAD	Standardized Average Difference
SD	Standard Deviation
sEMG	Eletromiografia de Superfície
SMD	Standardized Mean Difference
SUI	Stress Urinary Incontinence
TCLE	Termo de Consentimento Livre e Esclarecido
TMAP	Treinamento dos Músculos do Assoalho Pélvico
UI	Urinary Incontinence
U	Unquoted
UDI-6	Urogenital Distress Inventory
UUI	Urgency Urinary Incontinence
WHO	World Health Organization
4DTLUS	Ultrassonografia Translabial Quadridimensional

SUMÁRIO

Prefácio

Este estudo teve início a partir de abril de 2015, após aprovação do Comitê de Ética em Pesquisa da Universidade Estadual de Campinas – UNICAMP (CAAE: 41304914.9.0000.5404), porém a admissão no Doutorado no Programa de Pós-Graduação em Ciências da Cirurgia da Faculdade de Ciências Médicas da UNICAMP, sob a orientação da Profa. Dra. Simone Botelho Pereira e coorientação do Prof. Dr. Cássio Luís Zanettini Riccetto, ocorreu em março de 2016. Estruturada de acordo com as normas estabelecidas pelo programa, esta tese foi elaborada no modelo alternativo, sendo os resultados apresentados na forma de artigos.

Neste período, além das atividades teórico-práticas relacionadas ao projeto do doutorado, foram desenvolvidas atividades acadêmico-científicas, as quais não estão descritas no corpo da tese e serão apresentadas brevemente. Entre essas, destacam-se a integração no Grupo de UroFisioterapia do Programa de Pós-Graduação em Ciências da Cirurgia – UNICAMP, através da qual foi possível a participação e apresentação de trabalhos em eventos científicos nacionais e internacionais, atuação acadêmica como Docente e Coordenadora do Curso de Fisioterapia, Coordenadora do Curso de Medicina e Pró-reitora de Extensão e Assuntos Comunitários no Centro Universitário das Faculdades Associadas de Ensino – UNIFAE, em São João da Boa Vista-SP.

A seguir estão apresentados algumas atividades desenvolvidas no decorrer deste estudo, com temática relacionada, que foram publicados e/ou apresentados em eventos científicos da área.

Artigos completos publicados em periódicos

1. Martinho, NM; Botelho, S; **Nagib, ABL**; Marques, J; Silva, VR; Jales, R; Marques, AA; Juliato, CRT; Palma, PCR; Riccetto C. The effects of pelvic floor and transverse abdominal muscles? maximal voluntary contractions on pelvic floor ultrasound biometric parameters in women with stress urinary incontinence: preliminary results. Pelviperineology. 2017; 36: 125-128.
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Brasileiro de Fisioterapia em Saúde da Mulher – ABRAFISM, realizado no período de 31 de agosto a 02 de setembro de 2016 em Recife/PE.

12. Martinho, N; Botelho, S; **Nagib, ABL**; Silva, V; Marques, A; Jales, R; Juliato, C; Riccetto, C. Influência da idade e IMC sobre a variação e espessura do músculo pubo-retal em mulheres incontinentes. Congresso Brasileiro de Fisioterapia em Saúde da Mulher, Pernambuco-Recife, 2016.
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23. Martinho, N; Botelho, S; **Nagib, ABL**; Jales, R; Juliato, C; Marques, A; Amorim, C; Tulha, A; Riccetto, C. Comparison of pelvic floor function and morphology between continent and incontinent women: an electromyography and 4D translabial ultrasound study. – Apresentado na modalidade Scientific Podium Short Oral no 49th International Continence Society Annual Meeting, realizado no período de 3 a 6 de setembro de 2019 em Gotemburgo/Suécia.
24. Martinho, N; Botelho, S; **Nagib, ABL**; Jales, R; Juliato, C; Marques, A; Piccini, A; Tulha, A; Riccetto, C. Is there difference in the pelvic floor and transverse abdominal muscles' co-contraction between continent and incontinent women? A 4D translabial ultrasound study. – Apresentado na modalidade Scientific Podium Short Oral no 49th International Continence Society Annual Meeting, realizado no período de 3 a 6 de setembro de 2019 em Gotemburgo/Suécia.
25. Martinho, N; Botelho, S; **Nagib, ABL**; Jales, RM; Juliato, C; Turel, F; Caagbay, D; Riccetto, CZ. 4D translabial ultrasound concordance with digital palpation and surface electromyography during dynamic pelvic floor muscles assessment: a cross sectional study. – Apresentado na modalidade ORAL no AUGS / IUGA Joint Scientific Meeting, realizado no período de 24 a 28 de setembro de 2019 em Nashville/TN, EUA.

26. Martinho, N; Botelho, S; **Nagib, ABL**; Marques, AA; Juliato, CR; Jales, RM; Amorim, C; Riccetto, CZ. Pelvic floor and transverse abdominal muscles' percentage of co-contraction in continent and incontinent women: an electromyography study. – Apresentado na modalidade E-pôster no AUGS / IUGA Joint Scientific Meeting, realizado no período de 24 a 28 de setembro de 2019 em Nashville/TN, EUA.

Orientações de Trabalhos de Conclusão de Curso de Graduação

1. Jéssica Zorgetto Dota. Treinamento dos músculos do assoalho pélvico por meio de realidade virtual em mulheres com IUE e IUM. 2015. Trabalho de Conclusão de Curso. (Graduação em Fisioterapia) - Centro Universitário das Faculdades Associadas de Ensino. Orientadora: Anita Bellotto Leme Nagib.
2. Thais Ferreira Alves. Análise da função sexual em mulheres portadoras de incontinência urinária em predominância de esforço por meio de terapia de exposição à realidade virtual. 2016. Trabalho de Conclusão de Curso. (Graduação em Fisioterapia) - Centro Universitário das Faculdades Associadas de Ensino. Orientadora: Anita Bellotto Leme Nagib.
3. Patrícia Fernandes. A eficácia do treinamento muscular do assoalho pélvico por meio de terapia de exposição à realidade virtual em mulheres com IUE. 2016. Trabalho de Conclusão de Curso. (Graduação em Fisioterapia) - Centro Universitário das Faculdades Associadas de Ensino. Orientadora: Anita Bellotto Leme Nagib.
4. Beatriz Melim. Treinamento por meio de gameterapia pode melhorar sintomas urinários e função dos músculos do assoalho pélvico na incontinência urinária de esforço? 2018. Trabalho de Conclusão de Curso. (Graduação em Fisioterapia) - Centro Universitário das Faculdades Associadas de Ensino. Orientadora: Anita Bellotto Leme Nagib.

1. INTRODUÇÃO

A continência urinária é um mecanismo dinâmico de interação anátomo-funcional que promove o aumento da pressão de fechamento uretral, tanto ao repouso quanto durante atividades que aumentem a pressão intra-abdominal, quando a pressão vesical excede a pressão uretral, impedindo que haja perda involuntária de urina. De acordo com Abrams e cols. (2017)[3], os fatores necessários para que isso aconteça incluem esfíncter estriado saudável e funcional, mucosa uretral bem vascularizada, esfíncter interno da uretra funcional e suporte da parede vaginal intacto.

Considerando os aspectos funcionais do mecanismo de continência urinária, Kari Bø e cols. (2018),[16] sugerem que o esfíncter uretral seja o principal responsável por manter a continência urinária, auxiliado por interações entre o músculo levantador do ânus e a fáscia endopélvica, que ajudam a manter o fechamento uretral e fornecem suporte às vísceras pélvicas. As deficiências geralmente se tornam evidentes em decorrência de fatores que possam promover um desequilíbrio na interação dessas estruturas.

Uma das condições clínicas que apresentam em sua fisiopatologia alguns desses desequilíbrios, a incontinência urinária (IU), é caracterizada pela perda involuntária de urina, e pode ser classificada em três subtipos principais (1) incontinência urinária de esforço (IUE); (2) incontinência urinária de urgência (IUU); e (3) incontinência urinária mista (IUM), conforme estabelecido pela *International Urogynecological Association* (IUGA)/ *International Continence Society* (ICS).[3,52] Apesar de haver um amplo consenso acerca das definições e sintomas da IU e seus subtipos, as condições sobre a etiologia, prevalência e incidência da IU ainda não estão bem estabelecidas.[3,16]

Estima-se que os distúrbios do assoalho pélvico aumentarão de 21,8 milhões para 43,8 milhões em 2050, representando o dobro do que se era verificado em 2010[122]. Em virtude da grande demanda e considerando a

necessidade de conscientização dos profissionais[14] e gestores de saúde acerca de como a IU pode afetar a qualidade de vida dos indivíduos, faz-se necessária a criação de estratégias de orientação básica que poderiam ser introduzidas em programas de atenção primária à saúde.

De fato, a IU parece representar um importante fator de saúde pública, especialmente para a população feminina, uma vez que a idade, o peso, a paridade e a via de parto estão, inequivocamente, associados à IU. Além disso, para todos esses fatores, a associação com a IUE parece ser mais relevante do que com os demais subtipos de IU.[16,52] Um estudo[14] conduzido no Brasil envolvendo 622 mulheres, com idade média de 64 anos, relatou uma prevalência de IU de 52,3%. Com o aumento da expectativa de vida das mulheres brasileiras, é esperado que haja também um aumento na incidência de todos os tipos de IU.[14,100]

Considerando o processo de investigação diagnóstica da função dos músculos do assoalho pélvico (MAP), são descritos palpação digital, eletromiografia, perineometria, e exames de imagem, como a ressonância magnética ou a ultrassonografia.[16,76] Para a indicação e uso desses recursos diagnósticos, devem ser considerados sua capacidade de resposta, confiabilidade e validade.

A palpação digital é um exame simples que permite a graduação da função muscular, como a capacidade de contrair e relaxar os MAP corretamente, possibilitando graduar a força, resistência, capacidade de realizar contrações repetidas, bem como a capacidade de realizar pré-contração.[16,70] A eletromiografia de superfície (sEMG), por sua vez, permite registrar os sinais bioelétricos gerados pelas fibras musculares, avaliando a função muscular durante a contração.[107,77] A ultrassonografia translabial quadridimensional (4D TLUS), permite avaliar os MAP durante atividades funcionais, sendo considerado uma ferramenta minimamente invasiva e confiável.[77,33]

Diante desse problema, que influencia a qualidade de vida de mulheres no mundo todo, as diretrizes da IUGA/ICS recomendam o treinamento dos músculos do assoalho pélvico (TMAP), supervisionado por fisioterapeuta, como tratamento conservador de primeira linha para a IUE (nível de evidência A).[16,12]

Essa indicação é baseada na existência da coativação dos músculos do assoalho pélvico e do abdome, especialmente o transverso do abdome.[36,62] Estudos[104,32,10] mostram que a uretra é comprimida após uma semana de treinamento de pré-contração em virtude da contração eficaz dos MAP antes e durante o esforço, tendo como consequência menor perda urinária. O protocolo do treinamento de pré-contração inclui a instrução dos pacientes para contrair os MAP repetidamente, de modo a inibir a contração do músculo detrusor, levando à redução da sensação de urgência para urinar.[32,10]

Assim, o principal objetivo do TMAP é melhorar o controle e coordenação dos MAP, promovendo melhora do suporte dos órgãos pélvicos e, consequentemente, do terço médio da uretra - região responsável pelo mecanismo de continência, associado ao melhor recrutamento das fibras rápidas durante atividades que aumentam a pressão intra-abdominal. Portanto, o treinamento dos MAP é uma modalidade terapêutica importante, sendo fundamental que o profissional treine as contrações abdominais e dos MAP com a paciente para que, durante as atividades funcionais, esses músculos atuem de forma coordenada.[36,84]

Apesar da grande importância dos TMAP na reabilitação de pacientes com IUE, a adesão ao tratamento é um dos principais desafios enfrentado, uma vez que o paciente precisa se comprometer em realizar os exercícios do planejamento terapêutico.[9,40] A adesão consiste no comportamento da paciente que desempenha as instruções fornecidas pelo profissional.[66] Trata-se de uma etapa de fundamental importância, tendo em vista que o efeito terapêutico é dependente da adesão ao regime de

exercícios propostos por um fisioterapeuta habilitado, especialmente a longo prazo.[118]

A adesão está relacionada com a motivação do paciente para realizar o TMAP, abordagem individualizada e informações precisas a respeito dos exercícios.[79] Assim, o TMAP deve considerar fatores relevantes da avaliação inicial, bem como o tempo e a frequência das sessões, de forma individualizada e adaptada, de acordo com as modalidades de tratamento mais adequadas para cada paciente. Desse modo, acredita-se que a frequência de contatos com o profissional, aliado ao *feedback*, promove maior adesão e motivação ao tratamento.[112,44]

Buscando preencher a lacuna existente da baixa adesão das pacientes ao TMAP, os ambientes virtuais começaram a ser explorados como forma de reabilitação, associada aos tratamentos convencionais. Uma dessas alternativas inclui a gameterapia, que é uma modalidade terapêutica baseada na interatividade da paciente por meio de um sistema computacional em três dimensões que ocorre em tempo real e permite um feedback sensorial, seja ele, visual, auditivo ou tátil.[107,9,48,43] Assim, a gameterapia é uma estratégia promissora[111], podendo ser aplicada em mulheres de diferentes idades,[43] permitindo a combinação de movimentos de dança e equilíbrio[20] e promovendo a reabilitação por meio da reeducação do assoalho pélvico.[78]

Os exercícios realizados durante a gameterapia mimetizam movimentos pélvicos funcionais, com coordenação adequada entre os músculos do assoalho pélvico e abdome, estimulando a incorporação do recrutamento muscular em atividades de vida diária. A coordenação adequada desempenha papel fundamental nesse processo, uma vez que os MAP são contraídos prioritariamente em relação aos músculos sinergistas.[107]

Com isso, é possível sugerir que a gameterapia contribui para o controle da IU melhorando a coativação dos MAP em resposta à contração do transverso abdominal e do oblíquo interno.[107] Além disso, a gameterapia

pode ser uma aliada para adesão ao tratamento, uma vez que a paciente pode interagir e acompanhar a sua evolução em tempo real (*biofeedback*), motivando-a a desempenhar as atividades propostas no planejamento terapêutico.[48] Entretanto, é preciso que novos estudos sejam realizados a fim de confirmar o efeito desta modalidade de tratamento sobre a resposta clínica e funcional dos MAP, utilizando-se de métodos de avaliação que permitam a análise quantitativa e qualitativa dos ganhos clínicos da sua aplicação.

Paralelamente, outras tecnologias com o foco de aumentar a adesão ao tratamento têm ganhado destaque para o gerenciamento de problemas de saúde. A terapia de lembrete é uma das estratégias promissoras, consistindo no lembrete diário, via aplicativo, para realizar os exercícios do TMAP. Isso é particularmente importante, tendo em vista o cenário atual do uso de smartphones.[20,6,45] A Organização Mundial da Saúde (OMS) estima que mais de 5,9 bilhões de pessoas terão acesso aos smartphones até 2025.[111] Normalmente as instruções são passadas aos pacientes durante a consulta, mas a falta de um lembrete profissional diário para o paciente realizar o treinamento fora do consultório pode levar a uma redução na adesão ao tratamento.[44] Baseado nisso, o uso de aplicativos pode ser uma ferramenta importante de comunicação entre pacientes e profissionais, além de fornecer as instruções necessárias sobre a execução dos exercícios. [20,6,45]

2. OBJETIVOS

2.1 Objetivo geral

Avaliar os efeitos do uso de tecnologias (terapia de lembrete por meio de Apps e gameterapia) na redução dos sintomas urinários e no controle da IU em mulheres; verificar os efeitos da gameterapia nos parâmetros relacionados à função dos MAP.

2.2 Objetivos específicos

- Investigar o impacto do uso do App no controle da IU por meio de TMAP, quando comparado ao tratamento postal (por e-mail ou correspondência);
- Investigar a influência da gameterapia no tratamento de pacientes com IU;
- Investigar a viabilidade do TMAP por meio da gameterapia sobre os sintomas da IU e função dos MAP em mulheres climatéricas com IUE ou IUM;
- Investigar o efeito do TMAP associado a gameterapia sobre a redução dos sintomas urinários e dos parâmetros relacionados à função dos MAP em mulheres com IUE.

3. METODOLOGIA

3.1 Organização da Tese

Esta tese foi estruturada no formato alternativo, tendo sido organizada com uma compilação dos manuscritos desenvolvidos no decorrer da evolução da pesquisa principal, e que, de alguma forma, delimitaram-se em uma linha de raciocínio clínico, em que cada um dos artigos contribui de forma significativa para responder aos objetivos e hipóteses do estudo inicial.

Entretanto, foram desenvolvidos quatro artigos científicos, sendo dois deles no formato de revisão sistemática, com o intuito de nos conduzirem para reflexões acerca das populações estudadas e resultados prévios existentes utilizando-se da tecnologia (aplicativos móveis e gameterapia) como recurso para o TMAP, e outros dois artigos realizados em formato de ensaio clínico aleatorizado controlado, com objetivos de investigação clínica dos efeitos da gameterapia associada ao treinamento dos músculos do assoalho pélvico de mulheres com incontinência urinária com predominância de esforço.

Nossos questionamentos científicos se desdobraram em manuscritos que, por sua vez, foram estruturados com seus próprios objetivos, estruturação metodológica, levantamento bibliográfico relacionado à problematização do tema, os quais fundamentaram aspectos específicos da introdução, discussão e considerações finais de cada um desses artigos.

3.2 Estruturação Metodológica dos Artigos

3.2.1 Artigo 1

Revisão sistemática conduzida em junho de 2019, seguindo as recomendações da declaração PRISMA[72] e as diretrizes da Cochrane,[26] com

registro realizado no banco de dados PROSPERO sob o número CRD 42020145709. Desenvolvida com o objetivo principal de avaliar o impacto do uso do aplicativo móvel (App) no controle da IU por meio de TMAP, quando comparado ao tratamento postal (por e-mail ou correspondência), e pela pergunta norteadora, com base na estratégia PICO: "Mulheres com Incontinência Urinária (*Population*) usando um aplicativo móvel (*Intervention*) tem melhores resultados com o controle da Incontinência Urinária (*Outcome*) quando comparadas com mulheres usando um método de tratamento por e-mail ou correio (*Comparative*)?". Foram incluídos ensaios clínicos aleatorizados que avaliaram o controle da IU pelo uso de Apps, sem restrição de ano, idioma e *status* de publicação (In Press). Os bancos de dados primários usados para as buscas dos estudos que respondessem à pergunta norteadora fofam: Embase, Literatura Latino-Americana e do Caribe em Ciências da Saúde (LILACS), PubMed (incluindo MedLine), SciELO, e Web of Science. Para as buscas da "literatura cinzenta" foram utilizados ainda bancos de dados como OpenThesis, OpenGrey e OATD. Os descritores foram pesquisados utilizando MeSH (*Medical Subject Headings*), DeCS (*Health Sciences Descriptors*), and Emtree (*Embase Subject Headings*), combinados aos operadores booleanos "AND" e "OR", com o intuito de aprimorar as estratégias da pesquisa. Os registros foram exportados para o software EndNote™ Basic/Online, sendo removidas as duplicatas. O estudo foi dividido em três estágios, sendo (1) dois revisores realizam a análise metódica dos títulos, após calibração do nível de concordância; (2) dois revisores realizam a leitura dos resumos, independentemente; e (3) dois revisores realizam a leitura dos textos completos, também de forma independente. Sempre que há a necessidade, um terceiro revisor é consultado para a decisão final. O risco de viés dos estudos selecionados foi avaliado pela ferramenta "*The Joanna Briggs Institute Critical Appraisal tools for use in JBI Systematic Reviews - Checklist for Quasi-Experimental Studies*" e "*The Joanna Briggs Institute Critical Appraisal*

tools for use in JBI Systematic Reviews – Checklist for Randomized Controlled Trials".

3.2.2 Artigo 2

Revisão sistemática com pesquisa bibliográfica foi feita em março de 2020, seguindo as recomendações da declaração PRISMA[72] e as diretrizes da Cochrane,[26] com registro realizado no banco de dados PROSPERO sob o número CRD 42020175766. Desenvolvida com o objetivo principal de realizar uma investigação na literatura científica acerca da influência (benefícios) da gameterapia no tratamento de pacientes com IU, e pela pergunta norteadora, com base na estratégia PICO: "Quais os benefícios da gameterapia (*Intervention*) no tratamento (*Outcome*) de mulheres com incontinência urinária (*Population*)?". Foram incluídos estudos clínicos prospectivos (ensaios clínicos randomizados e estudos quase-experimentais) que observaram os benefícios da gameterapia para o tratamento da IU em mulheres, sem restrição de idioma, ano e status de publicação. Foram usados como bancos de dados primários usados para as buscas dos estudos que respondessem à pergunta norteadora: Embase, Literatura Latino-Americana e do Caribe em Ciências da Saúde (LILACS), PubMed (incluindo MedLine), SciELO, e Web of Science. Para as buscas da "literatura cinzenta" foram utilizados ainda bancos de dados como OpenThesis, OpenGrey e OATD. Os descritores foram pesquisados utilizando MeSH (*Medical Subject Headings*), DeCS (*Health Sciences Descriptors*), and Emtree (*Embase Subject Headings*), combinados aos operadores booleanos "AND" e "OR", com o intuito de aprimorar as estratégias da pesquisa. Os registros foram exportados para o software EndNote™ Basic/Online, sendo removidas as duplicatas. O estudo foi dividido em três estágios, sendo (1) dois revisores realizam a análise metódica dos títulos, após calibração do nível de concordância; (2) dois revisores realizam a leitura dos resumos, independentemente; e (3) dois revisores

realizam a leitura dos textos completos, também de forma independente. Sempre que há a necessidade, um terceiro revisor é consultado para a decisão final. O risco de viés dos estudos selecionados foi avaliado pela ferramenta "*The Joanna Briggs Institute Critical Appraisal tools for use in JBI Systematic Reviews - Checklist for Quasi-Experimental Studies*" e "*The Joanna Briggs Institute Critical Appraisal tools for use in JBI Systematic Reviews – Checklist for Randomized Controlled Trials*".

3.2.3 Artigo 3

Desenvolvido com o objetivo principal de investigar a viabilidade do TMAP por meio da gameterapia sobre os sintomas da IU e função dos MAP em mulheres climatéricas com IUE ou IUM. Para esses fins, utilizamos um ensaio clínico aleatorizado controlado como estratégia de investigação. Este estudo foi aprovado pelo Comitê de Ética em Pesquisa da UNICAMP (CAAE: 41304914900005404) (ANEXO 1) e pela Comissão de Pesquisa do DTG/CAISM (Protocolo nº 054/2014) (ANEXO 2), e registrado no "ensaiosclinicos.gov.br" (U1111-1205-9058), conforme as recomendações do CONSORT.[105] O estudo foi conduzido pelo Grupo *UroFisioterapia* do Programa de Pós-Graduação em Ciências da Cirurgia e realizado no Serviço de Fisioterapia do CAISM - Hospital da Mulher Prof. Dr. José Aristodemo Pinotti (UNICAMP), Campinas/SP, onde foram recrutadas 50 mulheres com IU. As mulheres recrutadas foram avaliadas, por meio da Ficha de Avaliação (ANEXO 3), obedecendo aos critérios de inclusão e exclusão estabelecidos previamente, por meio dos questionários validados ICIQ UI-SF (*International Consultation on Incontinence Questionnaire Urinary Incontinence - Short Form*)[115] e ICIQ-OAB (*International Consultation on Incontinence Questionnaire Urinary Incontinence Overactive Bladder*),[92] para classificação de sintomas urinários e palpação digital (esquema PERFECT),[70] para avaliação da função dos MAP. Aquelas que preenchiam aos critérios de elegibilidade foram convidadas a participar do estudo, assinaram o Termo de

Consentimento Livre e Esclarecido (TCLE) aprovado pelo Comitê de Ética em Pesquisa da UNICAMP (ANEXO 4). Foram incluídas 40 mulheres com IUE/IUM que foram aleatoriamente alocadas em G_Controle (n=20) e G_Game (n=20). O G_Controle recebeu TMAP não supervisionado por meio de orientações e o G_Game recebeu o mesmo TMAP não supervisionado e, adicionalmente, participou de um programa de TMAP supervisionado por meio de gameterapia.

3.2.4 Artigo 4

Desenvolvido com o objetivo principal de investigar o efeito do TMAP associado a gameterapia sobre a redução dos sintomas urinários em mulheres com IUE, e sobre parâmetros relacionados à função dos MAP. Para esses fins, utilizamos um ensaio clínico aleatorizado controlado como estratégia de investigação. Este estudo foi aprovado pelo Comitê de Ética em Pesquisa da UNICAMP (CAAE: 41304914900005404) (ANEXO 1) e pela Comissão de Pesquisa do DTG/CAISM (Protocolo nº 054/2014) (ANEXO 2), e registrado no "ensaiosclinicos.gov.br" (U1111-1205-9058), conforme as recomendações do CONSORT[105]. O ensaio clínico aleatorizado controlado, foi conduzido entre agosto de 2015 e maio de 2018, pelo Grupo *UroFisioterapia* do Programa de Pós-Graduação em Ciências da Cirurgia, realizado no Serviço de Fisioterapia do CAISM - Hospital da Mulher Prof. Dr. José Aristodemo Pinotti (UNICAMP), Campinas/SP. Duzentas e dez mulheres foram previamente recrutadas para a realização de um estudo transversal conduzido por Martinho et al. (2020),[77] e aquelas elegíveis para esse estudo (n=100) foram aleatoriamente alocadas em G_Controle (n=8) e G_Game (n=10). Todas as mulheres recrutadas foram avaliadas, por meio da Ficha de Avaliação (ANEXO 3), por meio dos questionários validados ICIQ UI-SF[115] e ICIQ-OAB,[92] para classificação de sintomas urinários e por meio da palpação digital (esquema PERFECT),[70] sEMG e 4D TLUS,[77] para avaliação da função dos MAP. Aquelas que preenchiam aos

critérios de elegibilidade foram convidadas a participar do estudo, assinaram o Termo de Consentimento Livre e Esclarecido (TCLE) aprovado pelo Comitê de Ética em Pesquisa da UNICAMP (ANEXO 4). O G_Controle recebeu TMAP não supervisionado por meio de cartilha e o G_Game recebeu o mesmo TMAP não supervisionado e, adicionalmente, participou de um programa de TMAP supervisionado por meio de gameterapia.

4. RESULTADOS

A apresentação dos resultados será realizada no formato alternativo com quatro artigos científicos, um para cada estudo e objetivo específico previamente definidos:

ARTIGO 1

(Systematic Review): Nagib ABL, Riccetto C, Martinho NM, Camargos Pennisi PR, Blumenberg C, Paranhos LR, Botelho S. Use of mobile Apps for controlling of the urinary incontinence: A systematic review. Neurourology and Urodynamics. 2020; 1– 13. https://doi.org/10.1002/nau.24335 (Authorization from publisher provided: Anexo 5).

ARTIGO 2

(Systematic Review): Nagib ABL, Riccetto C, Martinho NM, Blumenberg C, Paranhos LR, Botelho S. Influence of gametherapy on patients with urinary incontinence: a systematic review. (Submitted)

ARTIGO 3

(Original Clinical Article): Nagib ABL, Riccetto C, Martinho NM, Marques A, Silva VR, Botelho S. Can supervised pelvic floor muscle training through gametherapy relieve urinary incontinence symptoms in climacteric women? A feasibility study. Rev. Bras. Ginecol. Obstet. (Submitted)

ARTIGO 4

(Original Clinical Article): Nagib ABL, Riccetto C, Martinho NM, Juliato CRT, Amorim C, Botelho S. Supervised Pelvic Floor Muscle Training Gametherapy vs. Unsupervised Pelvic Floor Muscle Training in women with stress urinary incontinence: a randomized controlled study. (Submitted)

Received: 15 October 2019 | Accepted: 25 February 2020
DOI: 10.1002/nau.24335

REVIEW ARTICLE

Neurourology Urodynamics ICS IUGA WILEY

Use of mobile apps for controlling of the urinary incontinence: A systematic review

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Funding information
Coordenação de Aperfeiçoamento de Pessoal de Nível Superior, Grant/Award Number: Finance Code 001

Abstract

Objective: The primary objective was to evaluate the impact of app use on urinary incontinence control through pelvic floor muscle training when compared to the postal treatment plan. The secondary objectives were to evaluate how app use may affect the quality of life (QoL) of users and treatment adherence.

Material and Methods: Eight databases (PubMed, SciELO, Embase, Web of Science, LILACS, Open Gray, Open Thesis, and OATD) were used as research sources. The protocol was registered in PROSPERO (CRD 42020145709). Randomized controlled trials assessing urinary incontinence (UI) control with app use, with no restriction of year, language, and status of publication were included. The JBI Systematic Reviews Checklist for Randomized Controlled Trials assessed the risk of bias of the studies selected. The mean scores of QoL between the pre- and postintervention periods were compared through standardized mean differences, which were weighted according to the number of months between the two periods.

Results: Only three studies met the eligibility criteria and were included. The methodological quality of the studies was from "low" to "moderate" risk of bias. The full sample included 203 patients with app-based treatment e 203 controls of postal treatment. All studies showed the reduction of urinary symptoms. In addition, two studies showed a reduction of QoL scores specific for the condition, while one study presented increased scores.

Conclusion: Reminder therapy seems to be a promising strategy for controlling UI.

KEYWORDS

mobile app, pelvic floor, pelvic floor muscle training, urinary incontinence

1 | INTRODUCTION

Urinary incontinence (UI) is a clinical condition defined as an involuntary loss of urine[1,2] and it affects around 400 million people worldwide,[3] with the highest prevalence in women, especially middle-aged ones. It is estimated that 50% of women will have UI at some point in their lives.[2,4] However, men can also develop UI, although this is still seen as a social taboo.[2,5] Current data estimate that demands for the care of pelvic floor disorders will increase by approximately 35% until 2030 in the United States.[6]

Quality of life (QoL) may be affected directly in people with UI,[2,7] regardless of its presentation,[3] considering the condition affects daily activities including work, sports, relationships, and even sleep.[2,8] This impact comes from the fear of UI to occur in public, causing anxiety and distress and reflecting on the mental health of women.[8,9] Many women do not seek care due to embarrassment, fear, or even ignorance of the treatment methods, because there is a belief that UI is a natural process associated with aging.[10]

Pelvic floor muscle training (PFMT) is the first choice of treatment for UI[2] and it should be based on the previous assessment of muscle deficiencies, so that patients resume slowly the control of the levator ani and urethral sphincter muscles, recovering the conditions of support of the pelvic organs and control of the continence mechanism.[2] Considering it is a treatment with no risks and low cost, it has been widely used, although it requires patient commitment. The supervised PFMT has shown satisfactory results in the remission of UI symptoms.[2,11] Therefore, physical therapy plays a fundamental role in the assessment process and the indication of the type of treatment for functional recovery of pelvic floor muscles (PFM), and it should be encouraged.[2]

The successful treatment requires patients to be motivated and instructed to perform the exercises properly.[12,13] Usually, patients receive the instructions during the consultation, but the lack of a professional reminder for patients to perform the training outside the office may lead to a reduction in treatment adherence.[13] Based on it, the use of mobile applications (apps) may be an important tool of communication between patients and professionals, besides providing the necessary instructions for the performance of exercises.[14] Reinforcing this hypothesis, a recent study[15] showed that reminder therapy is a valuable strategy and it may contribute to restore oral health. Other studies have also shown that reminder therapy is an effective strategy to increase follow-up rate[16] and help the rehabilitation process after a stroke.[17] Thus, app use is a low-cost measure that may increase treatment adherence, as it encourages active patient participation in exercise programs.[13] In addition, professionals can follow the evolution of patients during treatment, allowing performance analysis and promoting the necessary adaptations for a successful therapy.[13]

However, so far, few studies have evaluated whether app use can be used as a complementary tool in the treatment of UI. Thus, in view of the potential negative effect that UI may have on the QoL of individuals, this study aimed to conduct a systematic review of randomized controlled trials to assess the impact of app use on UI control through PFMT, when compared to the postal treatment plan (primary objective). It also aims to verify how app use can influence the QoL of users and treatment adherence (secondary objective). The hypothesis of the study was that app use could help control UI, thus promoting a positive impact on the QoL of patients.

2 | MATERIALS AND METHODS

2.1 | Protocol and registration

This systematic review was developed following the recommendations of the Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA Statement)[18] and the Cochrane guidelines.[19] The systematic review protocol was registered in the PROSPERO database under number CRD 42020145709.

2.2 | Study design and eligibility criteria

This is a systematic review that aimed to answer the following guiding question based on the PICO strategy: "Do women with urinary incontinence (Population) who use a mobile application (Intervention) have better results with UI control (Outcome) when compared with women using the postal treatment method (Comparative)?"

Randomized controlled trials assessing urinary incontinence control with the use of apps, with no restriction of year, language, and status of publication, were included (In Press).

Some studies were excluded due to the following reasons: (a) Not related to the subject; (b) Qualitative studies on UI control using apps; (c) Review studies, case reports, letters to the editor or editorials, conference abstracts, personal opinions, and books and/or book chapters; (d) Observational studies; and 5) Studies with pregnant women.

2.3 | Sources of information and search

Embase, Latin-American and Caribbean Health Sciences Literature (LILACS), PubMed (including MedLine), SciELO, and Web of Science were used as primary databases. The OpenThesis, OpenGrey, e OATD databases were used to capture the "gray literature". A manual search through a systematic analysis of the references of the eligible studies was also performed. All the stages were performed to reduce the risk of selection and publication biases.

MeSH (Medical Subject Headings), DeCS (Health Sciences Descriptors), and Emtree (Embase Subject Headings) were used to search the descriptors. The Boolean operators "AND" and "OR" were combined with the descriptors to enhance the search strategy (Appendix A). The bibliographic research was developed in June 2019. The records were exported to the EndNote™ Basic/Online software, desktop version (Thomson Reuters, New York) and the duplicates were removed.

2.4 | Study selection

The studies were selected at three distinct stages. In the first stage, as a calibration exercise, two reviewers discussed the eligibility criteria and applied them to a sample of 20% of studies recovered after the initial search, to determine interexaminer agreement. After achieving an appropriate level of agreement (Kappa ≥ 0.81), the reviewers (*ABLN and PRCP*) performed a methodical analysis of all study titles independently. The reviewers were not blind to the names of authors and journals. In this stage, titles that did not meet the eligibility criteria were removed.

In the second stage, the reviewers (*ABLN and PRCP*) read the abstracts independently for the initial application of the eligibility criteria. Studies containing titles that met the study objectives but did not have abstracts available were read in phase three.

In the third and last stage, the preliminary eligible studies had their full texts assessed to verify whether they met the eligibility criteria. When reviewers disagreed about a particular study, a third reviewer (*LRP*) was consulted to make a final decision. The studies excluded were registered in a separate database, listing the reasons for exclusion.

2.5 | Process of data collection and extraction

After the selection, the studies were analyzed and two reviewers (*ABLN and PRCP*) extracted information regarding study identification (author, year, and place of the study), sample characteristics (number of participants, age, and average), ethical criteria involved, name of app used, comparison group, information contained in the app, measurement time, and reminder frequency. To assess the impact of app use on UI control (primary objective), the following data were extracted: reduction of UI symptoms based on the International Consultation on Incontinence Modular Questionnaire Urinary Incontinence Short Form (ICIQ-UI SF), International Consultation on Incontinence Questionnaire—Vaginal Symptoms (ICIQ-VS), and the Questionnaire for Urinary Incontinence Diagnosis (QUID). To assess how app use can influence the QoL of users and treatment adherence (secondary objective), the following data were extracted: assessment of QoL specific to the condition based on the ICIQ-Lower Urinary Tract Symptoms QoL (ICIQ-LUTSQoL), International Consultation on Incontinence Questionnaire Vaginal Symptoms (ICIQ-VS), and the assessment of health-specific QoL. Accuracy was calculated using estimates of sensitivity and specificity provided in the studies.

To ensure consistency among the reviewers, a calibration exercise was performed (*ABLN and PRCP*), in which the information was collected jointly from an eligible study. Any disagreement between the reviewers was solved through discussions and when both reviewers disagreed, a third one (LRP) was consulted to make a final decision.

2.6 | Risk of individual bias of the studies

The "Joanna Briggs Institute Critical Appraisal tools for use in JBI Systematic Reviews Checklist for Randomized Controlled Trials"[20] assessed the risk of bias of the studies selected. Two authors *(ABLN and PRCP)* assessed independently each domain regarding the potential risk of bias, as recommended by PRISMA.[18]

Each study was categorized according to the percentage of positive answers to the questions corresponding to

the assessment tool. Therefore, the risk of bias was classified as High when the study reached up to 49% of "yes" score, Moderate when the study reached from 50% to 69% of "yes" score, and Low when the study reached more than 70% of "yes" score.[18]

2.7 | Summary measures and syntheses of results

The results referring to the reduction in UI symptoms according to the mean scores of the ICIQ-UI SF, ICIQ-VS, and QUID were described. The impact of UI on the QoL of the individuals was described from the mean scores of the ICIQ-LUTSQoL and ICIQ-VS-QoL.

The mean scores of symptoms and QoL were compared between studies by calculating the standardized mean difference (SMD) using the method of Yange and Dalton.[21] This difference was obtained by subtracting the mean postintervention score from the mean score in the initial period of the study, which was weighted according to the standard deviation of the difference between the groups. As the postintervention period ranged among the eligible studies, the SMD was weighted also according to the number of months between the pre- and postintervention periods.

3 | RESULTS

3.1 | Study selection

During the selection of the studies, 15 284 results were found distributed in the eight electronic databases. After the removal of duplicates, 11 108 studies were submitted for the analysis of titles and abstracts. After reading the titles, only 50 studies remained for the reading of abstracts. From these, 10 studies were eligible for the reading of the full text. The references from the 10 potentially eligible studies were carefully assessed and no additional studies were selected, resulting in 10 studies for the reading of the full text. Next, seven studies did not meet the inclusion criteria and were excluded. Appendix B shows the studies removed and the reasons for exclusion. Finally, three studies were selected for the qualitative analysis. Figure 1 reproduces the process of search, identification, inclusion, and exclusion of studies.

3.2 | Characteristics of eligible studies

The summary of the main features of the studies can be found in Table 1. The studies were published between 2013 and 2019 and conducted in Sweden[22,23] and Brazil.[13] The full sample included 203 patients with treatment via app and 203 controls of postal treatment. Age ranged from 18 to 72 years and all studies[13,22,23] informed the ethical criteria involved, including the use of a consent agreement. One study[22] did not mention the app used, while another[23] used the app Tät, and lastly, the app Diário Saúde[13] was used. All[13,22,23] studies reported that the apps provided information about UI and instructions about the pelvic floor exercise. The follow-up periods consisted in 3 months[13,23] and 4 months.[22] The reminders were sent three times[22,23] and twice[13] per day.

To assess the reduction of symptoms, all studies[13,22,23] used the ICIQ-UI SF, but one study[13] also used the ICIQ-VS and QUID. For assessing QoL specific to the condition, two studies[22,23] used the ICIQ- LUTSQoL. One study[13] used the ICIQ-VS applied to QoL. Aiming to assess the health-specific QoL, one study[13] also used the EuroQol 5D-Visual Analog Scale (EQ5D-VAS).

3.3 | Risk of individual bias of the studies

Appendix C shows the information related to the analysis of the risk of bias and individual quality of the studies included. Two studies[22,23] presented a moderate risk of bias and one study[13] presented a low risk of bias. Question 4 was considered "Not applicable" in all studies[13,22,23] because intervention group participants cannot be blind for app use. In addition, question 5 was considered "no" in all studies[13,22,23] because the researchers responsible for instructing the women knew to which group the participants belonged. The individuals responsible for analyzing the results knew from which group they were collecting the data, therefore, question 6 also was considered "no" for all studies.[13,22,23] Lastly, question 7 was considered "no" in two studies[22,23] because the group that used the app kept in touch with the urotherapists while the postal group completed the treatment on their own, which may characterize a difference in the care received.

3.4 | Specific results of the eligible studies

Two studies[23] assessed treatment adherence. Asklund et al[23] affirmed obtaining 100% adherence after 3 months of follow-up, while Araujo et al[13] verified that adherence reduced from 52.9 (mean) to 43.8 in the intervention group and from 43.7 to 17.7 in the control group after the

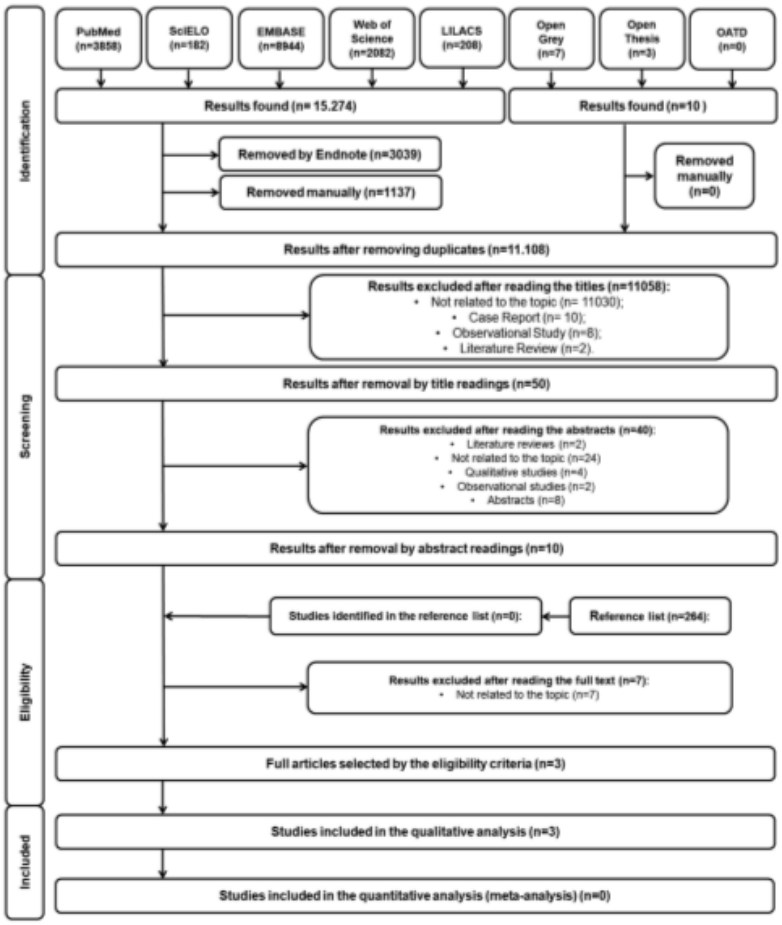

FIGURE 1 Flowchart of search, identification, inclusion, and exclusion processes of the studies, adapted from Preferred Reporting Items for Systematic Reviews and Meta-Analyses

3-month follow-up. One study[22] did not assess adherence as an outcome.

Table 2 provides a summary of results of the assessment of symptoms reduction based on the ICIQ-UI SF,[13,22,23] ICIQ-VS,[13] and QUID.[13] Sjöstrom et al[22] reported that the ICIQ-UI SF score reduced from 10.4 (average) to 6.4 in the intervention group and from 10.3 to 7.3 in the control group after 4 months of follow-up. Asklund et al[23] verified a reduction of the ICIQ-UI SF score from 11.1 to 7.0 in the intervention group and from 11.0 to 10.2 in the control group after 3 months of follow-up. Lastly, the study of Araujo et al[13] verified a reduction of the ICIQ-UI SF score from 16.3 to 9.1 in the intervention group and from 15.9 to 9.7 in the control group after 3 months of follow-up. In addition, Araujo et al[13] also assessed the vaginal symptoms through the ICIQ-UI SF, reporting a score reduction from 11.8 (mean) to 6.8 in the intervention group and from 13.7 to 6.0 in the control group after 3 months of follow-up.

Table 3 shows a summary of results of the assessment of QoL specific to the condition (UI) based on the ICIQ-LUTSQoL[22,23] and ICIQ-VS-QO.[13] Based on this, the study of Sjöstrom et al[22] verified a reduction in the ICIQ-LUTSQoL score from 33.6 (average) to 27.8 in the intervention group and from 33.6 to 28.8 in the control group after a follow-up of 4 months. Asklund et al[23] reported a reduction from 34.1 to 28.8 in the app group and from 34.8 to 34.1 in the control group. On the other hand, Araujo et al[13] revealed an increase of the ICIQ-VS-QO score from 5.0 to 5.6 in the intervention group and a reduction of the score from 5.9 to 1.3 in the control group. In addition, the study of Araujo et al[13] assessed the specific health-based

TABLE 1 Summary of the main features and results of the eligible studies

Reference	Country	Sample	Age (average)	App Name (country)	Comparative	App functions	Measurement time, mo	Reminder frequency	Outcome measurement
Sjöstrom et al[22]	Sweden	250 ♀ App: 124 Postal: 126	18-70 App (47,9) Control (49.4)	U	Postal treatment plan	Information about SUI; Instructions of PFMT; Statistics about your training; Urotherapist support;	4	3 reminders a day	ICIQ-UI SF ICIQ-LUTSQoL PGI-I EQ5D-VAS
Asklund et al[23]	Sweden	123 ♀ App: 62 Postal: 61	27-72 App (44,8) Control (44,7)	Tät (Sweden)	Postal treatment plan	Information about SUI; Instructions of PFMT; Statistics about your training; Reminder about PFMT.	3	3 reminders a day	ICIQ-UI SF ICIQ- LUTSQoL PGI-I
Araújo et al[13]	Brazil	33 ♀ App: 17 Postal: 16	App (47,2) Control (53,3)	Diário Saúde (Brazil)	Printed instructions	Instructions of PFMT; Visual alarm to remind to do the exercise twice a day.	3	2 reminders a day	ICIQ-VS QICIQ-UI SF QUID

Note: U, Unquoted *Mean, not informed in the study.

Abbreviations: ICIQ-UI SF, International Consultation on Incontinence Modular Questionnaire Urinary Incontinence Short Form; ICIQ- LUTSQoL, ICIQ Lower Urinary Tract Symptoms Quality of Life; ICIQ-VS, International Consultation on Incontinence Questionnaire—Vaginal Symptoms; PGI-I, Patient's Global Impression of Improvement; QUID, Questionnaire for Urinary Incontinence Diagnosis.

TABLE 2 Summary of the results for assessment of the reduction of the symptoms based on ICIQ-UI SF, ICIQ-VS,[13] and QUID[13]

		Assessment period									
		Initial		1 mo		2 mo		3 mo		4 mo	
References	Assessment method	Control	App	Control	App	Control	App	Control	App	Control	App
Sjöstrom et al[22]	ICIQ-UI SF	10.3 (3.5)	10.4 (3.1)	...	...	...	...	...	...	7.3 (3.9)	6.9 (3.1)
Asklund et al[23]	ICIQ-UI SF	11.0 (2.6)	11.1 (3.0)	...	...	...	...	10.2 (3.2)	7.0 (3.5)	...	...
Araujo et al[13]	ICIQ-UI SF	15.9 (4.7)	16.3 (4.0)	12.4 (6.7)	12.9 (4.6)	11.3 (5.0)	10.9 (6.9)	9.7 (6.6)	9.1 (6.6)	...	...
	ICIQ-VS	13.7 (8.4)	11.8 (8.8)	10.9 (8.1)	9.7 (8.5)	7.0 (3.9)	6.2 (7.9)	6.0 (4.9)	6.8 (8.2)	...	...
	QUID	15.6 (7.4)	14.4 (8.3)	9.2 (6.9)	10.4 (9.4)	4.5 (7.1)	8.7 (9.3)	3.9 (3.6)	7.5 (9.0)	...	...

Abbreviations: ICIQ-IU SF, International Consultation on Incontinence Modular Questionnaire Urinary Incontinence Short Form; ICIQ-VS, International Consultation on Incontinence Questionnaire—Vaginal Symptoms QUID = Questionnaire for Urinary Incontinence Diagnosis; SD, standard deviation.

TABLE 3 Summary of the results for assessment of the life quality specifications of the condition based on ICIQ- LUTSQoL and ICIQ-VS-QoL

		Assessment Period									
		Initial		1 mo		2 mo		3 mo		4 mo	
Reference	Assessment method	Control	App	Control	App	Control	App	Control	App	Control	App
Sjöstrom et al[22]	ICIQ-LUTSQoL	33.6 (8.2)	33.6 (6.8)	...	...	...	...	...	28.8 (7.3)	27.8 (6.0)	
Asklund et al[23]	ICIQ-LUTSQoL	34.8 (6.1)	34.1 (6.1)	...	...	...	...	34.1 (6.7)	28.8 (6.4)	...	...
Araujo et al[13]	ICIQ-VS-QoL	5.9 (4.1)	5.0 (4.6)	3.9 (4.2)	4.4 (4.3)	3.1 (3.7)	1.8 (3.2)	1.3 (2.9)	5.6 (4.3)	...	...

Abbreviations: ICIQ-LUTSQoL, International Consultation on Incontinence Modular Questionnaire–Lower Urinary Tract Symptoms Quality of Life; SD, standard deviation.

QoL on the EQ5D-VAS. These authors noted a score increase from 79.1 (mean) to 83.3 in the intervention group and from 79.2 to 81.8 in the control group.

3.5 | Synthesis of results

Table 4 presents the SMD in the ICIQ-UI SF and ICIQ-LUTSQoL scores of control and intervention groups in each of the eligible studies. The SMD is presented for each post-intervention period. It is noted that, regardless of the number of months in which the scores were reassessed, they were lower than the estimated preintervention scores. After considering the reassessment period, it is noted that the greatest reduction of the ICIQ-UI SF occurred 1 month after the beginning of the study of Araujo et al[13] (both for the control group; SMD = −0.60) and the intervention group; SMD = −0.79). This same study showed that the differences decreased as the reassessment period increased, reaching −0.36 and −0.44 in the control and intervention groups, respectively, after 3 months of study.

4 | DISCUSSION

PFMT is the first therapy of choice for the treatment of patients with urinary UI,[2] although the adherence to this modality is a barrier to therapeutic success. Based on this, the use of apps may be an important strategy.[14] However, few studies in the literature tested their efficiency in the treatment of patients with UI. This systematic review verified that the use of apps aided the reduction of urinary symptoms as well as the improvement of QoL of users, showing therapeutic potential in UI control.

The use of technology may be a valuable strategy for the self-management of health and it is the reason for research in different applications such as the residential monitoring of patients after outpatient surgery,[24] care for mental health,[25] and help in weight loss.[26] According to data from the WHO,[27] more than 5 billion people used a cell phone in the world in 2017, with an estimation that the number of users may reach 5.9 billion until 2025. At the same time, the number of apps developed specifically for health grows exponentially. Today, more than 100 000 apps in this category are available on Android and iOS platforms.[28] Thus, the use of apps has potential to expand the access to information and aid the management of patients,[22] especially for those who do not wish to seek conventional methods of health care through a series of face-to-face visits with a health professional.[29]

The control or reduction of urinary symptoms is one of the objectives during the treatment of UI. Therefore, PFMT is the gold standard to promote continence control by strengthening pelvic floor muscles.[30] A health professional should recommend PFMT, and the physiotherapist is the one qualified to investigate muscle deficiencies and propose a training protocol based on the conditions found in the functional assessment.[31] In this process, virtual tools such as game therapy and apps may stimulate the adherence of patients. However, it is necessary to ensure that the use of apps is comparable or superior to the postal treatment method.

The efficiency of PFMT may be assessed by investigating the reduction of urinary symptoms. The ICIQ-UI SF has been used extensively in the literature for this purpose, because it is a short questionnaire easy to understand and apply. All eligible studies[13,22,23] used this tool to analyze urinary symptoms. Based on that, it was possible to see a

TABLE 4 Standardized average difference in the scores of the ICIQ-UI SF and ICIQ-LUTSQoL comparing the initial values with the scores of the postintervention period

	ICIQ-UI SF			ICIQ-LUTSQoL		
	Period	SAD	SAD/mo	Period	SAD	SAD/Month
Sjostrom et al[22]						
Control	4	−0.81	−0.20	4	−0.62	−0.16
Intervention	4	−1.13	−0.28	4	−0.90	−0.23
Asklund et al[23]						
Control	3	−0.27	−0.09	3	−0.11	−0.04
Intervention	3	−1.26	−0.42	3	−0.85	−0.28
Araujo et al[13]						
Control	1	−0.60	−0.60			
Intervention	1	−0.79	−0.79			
Control	2	−0.95	−0.48			
Intervention	2	−0.96	−0.48			
Control	3	−1.08	−0.36			
Intervention	3	−1.32	−0.44			

Abbreviation: SAD, standardized average difference (escore in the period − escore pre-intervention).

significant reduction in the ICIQ-UI SF score when comparing the participants of the intervention group (app) with the control group. Besides the ICIQ-UI SF, Araújo et al[13] used the ICIQ-VS and QUID tools and noted a reduction in the scores. These results suggest that app use associated with reminder therapy can aid the reduction of symptoms in patients with UI.

Performing the exercises in the comfort of home can be attractive, reduce medical and travel expenses, and make logistics easier. Daily reminders via an app for performing the exercises is a way to encourage adherence discreetly and efficiently in case such protocol is appropriate to the functional condition of the patient, which requires indication and follow-up even at a distance from the physical therapist. Therefore, app use may be considered a noninvasive therapeutic tool for women who want to manage their routine more independently.[32] Corroborating such findings, one study[33] suggested that the use of an app to treat stress UI has a good cost-benefit ratio.

The compromise of QoL is one of the main complaints of patients with UI.[34] Such condition causes embarrassment and complicates interpersonal relationships as well as family relationships.[8] The UI is still considered a social taboo and the population does not acknowledge it as a severe health problem.[10] Reinforcing this statement, a study[35] performed with women who live in nursing homes showed that 66.3% of participants believe that UI is not a health problem, despite affecting their QoL. More alarmingly, another study[36] concluded that women take, on average, one decade to seek medical help and appropriate treatment for their condition.

The eligible studies for QoL assessment used the ICIQ-VS-QoL[13] and ICIQ-LUTSQoL,[22,23] verifying a reduction in the scores of patients in the intervention group (app), with recovery of QoL after months of follow-up. This could be explained by the reduction of urinary symptoms, with increased self-esteem and self-confidence to perform daily activities.

This study assessed the standardized mean difference in the ICIQ-UI SF and ICIQ-LUTSQoL scores, comparing the initial values with the scores of the postintervention period. It was found that the difference was higher in the intervention group (app) for the ICIQ-UI SF and ICIQ-LUTSQoL in all eligible studies.[13,22,23] Curiously, it is noted that in one study[13] the differences reduced as the reassessment period increased, reaching −0.36 and −0.44 in the control and intervention groups, respectively, after 3 months of study. This could be explained by the sample loss over time, which may affect directly the occurrence of such a phenomenon.

Thus, results show that therapy with apps is a strategy to be considered. The possibility of interactivity between health professionals and patients promoted by the apps added to daily reminders to perform the exercises may benefit patient adherence to treatment. However, this study is not exempt from limitations. Few studies met the eligibility criteria and the same research group conducted two[22,23] of the three studies included. The limited number of studies included made a statistical analysis of publication bias unfeasible. Nevertheless, some of the strengths of this review should be highlighted. This is the first systematic review on app use in UI control. In addition, an extensive search strategy was carefully prepared and applied to different databases to collect potentially eligible studies, with no restrictions of language, year, or status of a publication. Based on the present systematic review, further studies should be conducted until the findings allow structuring the scientific evidence.

5 | CONCLUSION

The use of apps seems to be a promising strategy for UI control, developing strategies of PFMT for reducing the symptoms, improving QoL, and enhancing the adherence of individuals.

ACKNOWLEDGMENTS

This study was financed in part by the Coordination for the Improvement of Higher. Education Personnel (CAPES)-Finance Code 001, through the Postgraduate Program in Surgical Science of the State University of Campinas (UNICAMP).

CONFLICT OF INTERESTS

The authors declare that there are no conflict of interests.

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How to cite this article: Leme Nagib AB, Riccetto C, Martinho NM, et al. Use of mobile apps for controlling of the urinary incontinence: A systematic review. *Neurourology and Urodynamics*. 2020;1–13. https://doi.org/10.1002/nau.24335

APPENDIX A: STRATEGIES FOR DATABASE SEARCH

Database	Search Strategy (June, 2019)	Results
PubMed http://www.ncbi.nlm.nih.gov/pubmed	("Urinary Incontinence"[All Fields] OR "Urinary Stress Incontinence"[All Fields] OR "Pelvic Floor"[All Fields] OR "Pelvic Floor Muscle"[All Fields] OR "Pelvic Floor Training"[All Fields]) AND ("Woman"[All Fields] OR "Women"[All Fields] OR "Girl"[All Fields] OR "Female"[All Fields]) AND ("Mobile"[All Fields] OR "Portable"[All Fields] OR "Eletronic"[All Fields] OR "eHealth"[All Fields] OR "mHealth"[All Fields] OR "App"[All Fields] OR "Software"[All Fields] OR "Reminder Therapy"[All Fields] OR "Programme"[All Fields] OR "Program"[All Fields] OR "System"[All Fields])	3.858
SciELO http://www.scielo.org/	("Urinary Incontinence") AND ("App" OR "Software" OR "Programme" OR "Program" OR "System")	120
	("Pelvic Floor Exercises") AND ("App" OR "Software" OR "Programme" OR "Program" OR "System")	0
	("Urinary Stress Incontinence") AND ("App" OR "Software" OR "Programme" OR "Program" OR "System")	56
	("Pelvic Floor Training") AND ("App" OR "Software" OR "Programme" OR "Program" OR "System")	6
LILACS http://lilacs.bvsalud.org/	("Urinary Incontinence") AND ("Mobile" OR "Portable" OR "Eletronic" OR "eHealth" OR "mHealth" OR "App" OR "Software" OR "Reminder Therapy" OR "Programme" OR	0

(Continues)

	"Program" OR "System")	
	tw:(("urinary incontinence") AND ("app" OR "software" OR "programme" OR "program" OR "system")) AND (instance: "regional") AND (db: ("LILACS"))	148
	("Urinary Stress Incontinence") AND ("Mobile" OR "Portable" OR "Eletronic" OR "eHealth" OR "mHealth" OR "App" OR "Software" OR "Reminder Therapy" OR "Programme" OR "Program" OR "System")	0
	tw:(("Pelvic Floor") AND ("app" OR "software" OR "programme" OR "program" OR "system")) AND (instance: "regional") AND (db: ("LILACS"))	60
Web of Science http://apps.webofknowledge.com/	(("Urinary Incontinence" OR "Urinary Stress Incontinence" OR "Pelvic Floor" OR "Pelvic Floor Muscle" OR "Pelvic Floor Training") AND ("Woman" OR "Women" OR "Girl" OR "Female") AND ("Mobile" OR "Portable" OR "Eletronic" OR "eHealth" OR "mHealth" OR "App" OR "Software" OR "Reminder Therapy" OR "programme" OR "program" OR "System"))	2.082
Embase http://www.embase.com	('urinary incontinence' OR 'urinary stress incontinence' OR 'pelvic floor' OR 'pelvic floor muscle' OR 'pelvic floor training') AND ('woman' OR 'women' OR 'girl' OR 'female') AND ('mobile' OR 'portable' OR 'eletronic' OR 'ehealth' OR 'mhealth' OR 'app' OR 'software' OR 'reminder therapy' OR 'programme' OR 'program' OR 'system')	8.944
OpenGrey http://www.opengrey.eu/	("Urinary Incontinence" OR "Urinary Stress Incontinence" OR "Pelvic Floor" OR "Pelvic Floor Muscle" OR "Pelvic Floor Training") AND ("Woman" OR "Women" OR "Girl" OR "Female") AND ("Mobile" OR "Portable" OR "Eletronic" OR "eHealth" OR "mHealth" OR "App" OR "Software" OR"Reminder Therapy" OR "Programme" OR "Program" OR "System")	7
OpenThesis http://www.openthesis.org/	("Urinary Incontinence") AND ("Mobile" OR "Portable" OR "Eletronic" OR "eHealth" OR "mHealth" OR "App" OR "Software" OR "Reminder Therapy" OR "programme" OR "program" OR "System")	3
OATD https://oatd.org/	("Urinary Incontinence" OR "Urinary Stress Incontinence") AND ("Woman" OR "Women" OR "Girl" OR "Female") AND ("Mobile" OR "Portable" OR "Eletronic" OR "eHealth" OR "mHealth" OR "App" OR "Software" OR "programme" OR "program" OR "System")	0
TOTAL		15.284

APPENDIX B: STUDIES EXCLUDED IN THE READING OF THE FULL TEXTS AND THE REASONS FOR EXCLUSION (n = 7)

	Reference	Reason for exclusion
1.	Wilson et al[37]	Not related to Apps.
2.	Ahlund et al[38]	Not related to Apps.
3.	Hirakawa et al[39]	Not related to Apps.
4.	Alves et al[40]	Not related to Apps.
5.	Andrade et al[41]	Not related to Apps.
6.	Starr et al[42]	Not a randomized clinical trial.
7.	Grimes et al[43]	Not focus in pelvic floor muscle training.

APPENDIX C: RISK OF BIAS ASSESSED BY THE JOANNA BRIGGS INSTITUTE CRITICAL APPRAISAL TOOLS FOR USE IN JBI SYSTEMATIC REVIEWS FOR RANDOMIZED CONTROLLED TRIALS.[20]

Reference	Q.1	Q.2	Q.3	Q.4	Q.5	Q.6	Q.7	Q.8	Q.9	Q.10	Q.11	Q.12	Q.13	% yes/risk
Sjöstrom et al[22]	√	...	√	NA	...	...	...	√	√	√	√	√	√	61.53% yes (moderate risk of bias)
Asklund et al[23]	√	√	√	NA	...	...	...	√	√	√	√	√	√	69.23% yes (moderate risk of bias)
Araujo et al[13]	√	√	√	NA	...	...	√	√	√	√	√	√	√	76.92% yes (low risk of bias)

Q.1) Was true randomization used for the assignment of participants to treatment groups? Q.2) Was allocation to treatment groups concealed? Q.3) Were treatment groups similar at the baseline? Q.4) Were participants blind to treatment assignment? Q.5) Were those delivering treatment blind to treatment assignment? Q.6) Were outcomes assessors blind to treatment assignment? Q.7) Were treatment groups treated identically other than the intervention of interest? Q.8) Was follow up complete and if not, were differences between groups in terms of their follow up adequately described and analyzed? Q.9) Were participants analyzed in the groups to which they were randomized? Q.10) Were outcomes measured in the same way for treatment groups? Q.11) Were outcomes measured in a reliable way? Q.12) Was an appropriate statistical analysis used? Q.13) Was the trial design appropriate, and any deviations from the standard RCT design (individual randomization, parallel groups) accounted for in the conduct and analysis of the trial? √, Yes; NA, not applicable.

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ARTIGO 2

Influence of gametherapy on patients with urinary incontinence: a systematic review

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Conflict of interest: none to be declared

ABSTRACT

Objective: To perform a systematic review of the literature on the influence (benefits) of gametherapy on patients with urinary incontinence (UI). Material and Methods: Eleven databases (PubMed, Scopus, SciELO, LILACS, Web of Science, Embase, Cochrane, LIVIVO, OpenGrey, OpenThesis, OATD) were used as research sources. The protocol was registered in PROSPERO (CRD 42020175766). We included clinical study that observed the benefits of gametherapy for the treatment of UI in women, without the restriction of language, year, and publication status. The risk of bias of the studies selected was assessed with the "Joanna Briggs Institute Critical Appraisal tools for use in JBI Systematic Reviews. Results: Only three studies fulfilled the eligibility criteria. The methodological quality of the studies presented a "low" risk of bias. The final sample included 80 patients. All studies presented a reduction in the one-hour pad test scores. Two studies presented a reduction in the ICIQ-SF scores. Only one study reported treatment adherence (92%) and one study showed improvement in the neuropsychological indexes. The reduction of urinary symptoms comparing the pre- and post-intervention periods was similar between the groups that associated gametherapy with the treatment and the group that used only conventional pelvic floor muscle training (PFMT). Conclusion: As a resource of PFMT, gametherapy seems to benefit UI, including the reduction of urinary symptoms, reduction in the one-hour pad test scores, and improvement in neuropsychological indexes. Moreover, statistically, the reduction of urinary symptoms was similar for gametherapy and conventional PFMT.

Keywords: virtual reality, pelvic floor, pelvic floor muscle training, urinary incontinence, gametherapy, rehabilitation.

1. INTRODUCTION

The pelvic floor muscles (PFM) work by supporting the pelvic structures to allow the coordination between contraction and relaxation.[1] Moreover, the PFMs are essential to ensure continence through their reflexive contraction associated simultaneously with the closing of the vagina and urethral and anal sphincters.[2] However, the deterioration of these structures may lead to pelvic floor disorders such as urinary incontinence (UI).[3] Some factors seem to affect the development of pelvic floor disorders, including age, pregnancy, number of deliveries, menopause, among others.[4]

Urinary incontinence is a clinical condition in which the carrier loses control of the bladder, resulting in unintentional urination.[5] It is more frequent in women, especially middle-aged ones. Despite relatively common, UI is still underreported in most cases[5] because it is considered an embarrassing and stigmatizing condition, leading patients not to report it to professionals out of shame[6]. Moreover, UI may affect significantly the quality of life of individuals.[5,6] Studies[7,8,9] show that women with UI present high rates of diagnosis of anxiety, depression, and social isolation, which may worsen the symptomatological condition of UI besides all the aggravations inherent to such conditions.

There are several types of treatment for UI, including medications, surgical interventions, lifestyle changes, and muscle strengthening, and this will be determined by the type of prevalent UI.[5] Pelvic floor muscle training (PFMT) is one of the therapies mostly accepted today for the treatment of UI.[10] The adherence to a regular exercise program is essential to reach the treatment goals.[11] However, this is considered a challenge because of the difficulty in keeping patients motivated.[12] Thinking of increasing treatment adherence, studies[12,13] have shown it is possible to combine exercises with playful and didactic activities, allowing the improvement of the condition pleasantly. Based on that, gametherapy (virtual reality) has stood out in the current scenario, allowing an interactive and beneficial experience.[12]

Gametherapy is a treatment modality that uses virtual reality as a way to perform the pelvic floor exercises.[14] In summary, the basic protocol includes exercises focused on the abdominopelvic cavity combined with a console and some games. Therefore, the patient plays seated on a device, such as the *Wii Balance Board*™, combining anteversion, retroversion, lateral inclination, and circumference exercises.[15] The main objective of this therapeutic approach, as in the conventional PFMT, is to allow the re-education of the abdominopelvic cavity.[15] However, gametherapy allows patient interaction in the game environment, which may work as a strategy to increase adherence and promote motivation to perform the exercises.[15]

Therefore, considering the need for developing therapies that value patient participation and promote treatment adherence, the present study aimed to perform a systematic review of the literature on the influence (benefits) of gametherapy on the treatment of patients with UI.

2. MATERIAL AND METHODS

2.1 Protocol and registration

This systematic review was performed according to the list of PRISMA (Preferred Reporting Items for Systematic Reviews and Meta-Analyses) recommendations[16] and the Cochrane guidelines.[17] The systematic review protocol was registered in the PROSPERO database under number CRD 42020175766.

2.2 Eligibility criteria and study design

It is a systematic review that aimed to answer the following guiding question: "What are the benefits of gametherapy (Intervention) in the treatment (Outcome) of women with urinary incontinence (Population)?".

We included clinical study that observed the benefits of gametherapy for the treatment of urinary incontinence in women, without the restriction of language, year, and publication status (Ahead of print).

The following were excluded: 1) Studies outside the objective; 2) Review articles, letters to the editor/editorials, personal opinions, books/book chapters, textbooks, reports, conference abstracts, and patents; 3) Case reports; 4) Studies including healthy patients.

2.3 Sources of information and search

The primary study sources used were the Embase, LILACS, PubMed/MedLine, SciELO, Scopus, Web of Science, LIVIVO, and Cochrane Library. The OpenThesis, OpenGrey, and OATD were used to partially capture the "gray literature". Additionally, a manual search was performed in the references of the eligible studies. All steps were performed to minimize a study selection bias.

The MeSH (Medical Subject Headings), DeCS (Health Sciences Descriptors), and Emtree (Embase Subject Headings) resources were used to select the search descriptors. The Boolean operators "AND" and "OR" were used to enhance the research strategy through several combinations according to each database. Appendix 1 shows the final search paths used for each database. The bibliographic research was performed in March 2020. The results obtained were exported to the EndNote Web™ software (Thomson Reuters, Toronto, Canada), in which duplicates were removed automatically.

2.4 Study selection

Before starting the selection of studies, a calibration exercise was performed, in which the reviewers discussed the eligibility criteria and applied them to a sample of 20% of the studies retrieved to determine the inter-examiner agreement. After achieving a proper level of agreement (Kappa ≥ 0.81) in the first selection phase, two eligibility reviewers (*ABLN and NMM*)

performed a methodical analysis of the titles of the studies, independently. The reviewers were not blind to the names of authors and journals. Titles outside the objective, book chapters, conference abstracts, case reports, and literature reviews were eliminated in this phase. In the second phase, the reviewers (*ABLN and NMM*) read the abstracts independently for the initial application of the exclusion criteria aforementioned. The results in which titles met the objectives of the study but did not have abstracts available were fully analyzed in phase three.

In the third phase, the preliminary eligible studies had their full texts obtained and evaluated to verify whether they fulfilled the eligibility criteria. When both reviewers disagreed, a third one (*LRP*) was consulted to make a final decision. The studies rejected in this phase were registered separately, explaining the reasons for exclusion.

2.5 Process of data collection and extraction

The following information was extracted from the eligible studies: identification of the study (author, year, country, type of study), sample characteristics (number of patients in each study, average age), treatment characteristics (type of game used, associated treatments, treatment duration, objectives assessed, and methods of result measurement), and main results. In case of incomplete or insufficient information, the corresponding author was contacted via e-mail.

To ensure the consistency between reviewers, training was performed with both reviewers, in which information was extracted jointly from an eligible study. The disagreements between reviewers were solved with discussions and a consensus. When this was not possible, a third reviewer (*LRP*) was consulted to make a final decision.

2.6 Risk of individual bias of the studies

The risk of bias and the individual quality of the studies selected were assessed with the "Joanna Briggs Institute Critical Appraisal tools for use in JBI Systematic Reviews - Checklist for Analytical Cross-Sectional studies"[18] and the "Joanna Briggs Institute Critical Appraisal tools for use in JBI Systematic Reviews - Checklist for Randomized Controlled Trials".[19] Two authors (*ABLN and NMM*) assessed independently each domain regarding their potential risk of bias, as recommended by the PRISMA statement.[16] Any disagreement between the reviewers was solved through discussions on the topics assessed and when both reviewers disagreed, a third one was consulted to make a final decision. The risk of bias was ranked as ***High*** when the study reached up to 49% of "yes" score, ***Moderate*** when the study reached from 50% to 69% of "yes" score, and ***Low*** when the study reached over 70% of "yes" score.

2.7 Summary of results

The results of the eligible studies were described from the means of the questionnaires used to assess the symptoms of urinary incontinence in the pre- and post-intervention periods with gametherapy in each of the groups: control and intervention.

The standardized mean difference (SMD) for each of the groups was calculated from the subtraction of the means of post- and pre-intervention periods. Thus, negative SMD values indicate that the mean of urinary symptoms was lower at the post-intervention than the one estimated at pre-intervention.

3. RESULTS

3.1 Study selection

During the first phase of study selection, 227 results were found distributed in eleven electronic databases, including the "gray literature". After removing the duplicates, 106 results remained for the analysis of titles and

abstracts. After applying the eligibility criteria on the reading of titles and abstracts, only eight results were eligible for the full-text analysis. The references of the eight potentially eligible studies were carefully assessed but no result was added. After reading the full texts, three studies were selected for the qualitative analysis. Figure 1 reproduces the process of search, identification, inclusion, and exclusion of articles. Appendix 2 shows the studies eliminated and the reasons for exclusion.

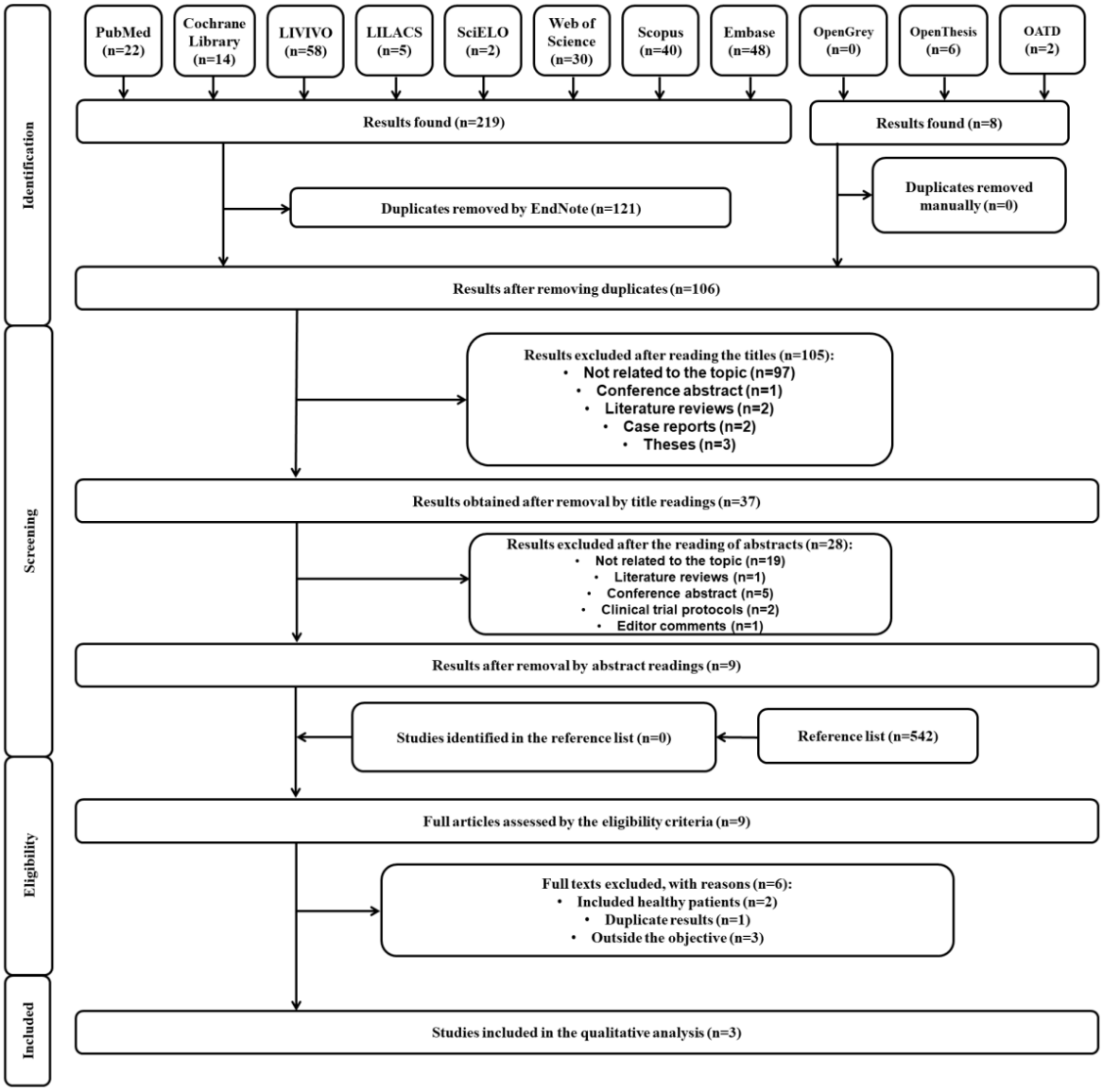

Figura 2 (Artigo 2): Figure 1 – Flowchart of the search, identification, inclusion and exclusion process of the papers, adapted from PRISMA.

3.2 Characteristics of eligible studies

The studies were published between 2014 and 2018 and they were performed in Canada[12,13] and Brazil.[20] Two studies had a quasi-experimental design[12,13] and one study was a randomized clinical trial.[20] The final sample included 80 women with UI and the average age of the participants involved varied between 52 and 65 years. The types of games used in the study were the *StepMania*[12,13] and the *Wii Fit Plus*™.[20] Two studies[12,13] performed gametherapy associated with pelvic muscle training exercises. The time of treatment varied between 8 and 12 months.

The eligible studies[12,13,20] assessed the effects of gametherapy in different aspects of UI, as follows: impact on executive functions, dual-task walking, symptoms of urinary incontinence, quality of life, treatment satisfaction, and the degree of urinary loss. Table 1 shows the characteristics of each eligible study.

Tabela 5 (Artigo 2): Table 1 – Summary of the main characteristics of the eligible studies.

Author, year, and country	Type of study	Sample (n)	Age (mean ± SD) in years	Type of game therapy	Associated therapy	Treatment duration	Control group	Outcomes measured	Data collection
Fraser et al., 2014[13] (Canada)	Quasi-experimental	24	Over 65 (70.4 ± 3.6)	Freeware dance game program (*StepMania*)	Pelvic Floor Training	12 weeks	N/A	Executive functions, amount of urine leaked, and dual-task walking.	Stroop task, Trail making test, modified pad test.
Elliott et al., 2015[12] (Canada)	Quasi-experimental	24	Over 65 (70.5 ± 3.6)	Freeware dance game program (*StepMania*)	Pelvic Floor Training	12 weeks	N/A	Feasibility, effectiveness of the intervention on MUI symptoms and QoL, and participant satisfaction with treatment.	Modified pad test, Urogenital Distress Inventory (UDI-6), the Incontinence. Impact Questionnaire (IIQ), and the ICIQ-SF.
Bezerra 2018[20] (Brazil)	Randomized clinical trial	32	45 to 70 (52)	*Wii Fit Plus*	N/A	8 weeks	Pelvic Floor Training	Pressure of the pelvic floor muscle, and degree of urinary loss.	Pad test, manometry, ICIQ-SF questionnaire, Patient Global. Impression of Improvement (PGI), and pelvic floor muscle strength test.

N/A – Not Applicable.

3.3 Risk of individual bias of the studies

All studies[12,13,20] presented a low risk of bias or high methodological quality. As for the cross-sectional studies[12,13] (Appendix 3), the only

methodological limitation was the lack of clarity regarding identification and the strategies to deal with confounding factors. Regarding the randomized clinical trial[20] (Appendix 4), the main methodological limitation was related to blinding.

3.4 Specific results of the eligible studies

Table 2 shows a summary of the main results of the eligible studies. The one-hour pad test was performed in all eligible studies.[12,13,20] All authors found a significant reduction of urinary loss after the treatment with gametherapy. Moreover, one study[20] did not observe a difference in the reduction of urinary loss with the one-hour pad test when comparing the treatment with gametherapy and PFMT.

Tabela 6 (Artigo 2): Table 2 - Main results of the eligible articles.

Author, year	Pad-test 1h (g)		ICIQ-SF		Main results
	Pre-treatment	Post-treatment	Pre-treatment	Post-treatment	
Fraser et al., 2014[13]	--	--	N/A	N/A	The authors observed improvement in neuropsychological indexes, improvement in dual-task performance, and significant reduction for the one-hour pad test after the treatment.
Elliott et al., 2015[12]	--	--	GT: 11.13 ± 3.35	GT: 5.00 ± 3.47	The authors observed that most of the participants presented high rates of weekly attendance to the treatment (91%). The participants presented significant reduction for the one-hour pad test after the intervention and better results in the 72-h urinary diary (mean voiding, leakage, and protections per day), in the UDI-6, IIQ, and ICIQ-SF scores. The majority of participants (91%) were satisfied with the treatment.
Bezerra, 2018[20]	GT: 2.32 ± 1.18 CG: 2.69 ± 1.94	GT: 0.51 ± 0.31 CG: 0.41 ± 0.20	GT: 15.62 ± 3.34 CG: 12.00 ± 3.98	GT: 8.12 ± 7.47 CG: 6.33 ± 5.00	The authors found a significant improvement in the manometry, one-hour pad test, and ICIQ-SF results after the therapeutic intervention in both groups assessed (GT and GC).

ICIQ UI-SF - International Consultation on Incontinence Questionnaire - Short Form; GT – Gametherapy group; CG – Control group; UDI-6 – Urogenital Distress Inventory; IIQ – Incontinence Impact Questionnaire

Another index assessed in two eligible studies[12,20] was responding to the International Consultation on Incontinence Questionnaire - Short Form (ICIQ UI-SF). Before the treatment, the patients presented mean indexes that varied between 11.13 and 15.62. After the treatment, the mean of responses varied between 5.00 and 8.12, showing a significant reduction of results. Moreover, one study[20] found that both gametherapy and pelvic floor muscle training are effective in reducing the indexes of response to the ICIQ UI-SF, without differences between them.

One study[13] also verified the significant improvement in neuropsychological indexes and the dual-task after the treatment, while another study[12] observed improvement in the quality of life and great treatment satisfaction. Lastly, Bezerra et al.[20] also assessed through manometry the pressure exercised by the pelvic floor before and after treatment. Said study concluded there was a significant improvement in the pressure of the pelvic floor muscle in the group treated with gametherapy and the group treated with pelvic floor strengthening, without difference between them.

Figure 2 shows the calculation of the SMD between the post- and pre-intervention periods for each of the groups included in the study. In the study by Bezerra et al.,[20] the SMD was comparable between the control and intervention groups for both the pad test and the ICIQ UI-SF. In turn, the study by Elliott et al.[12] did not include a control group, but still, the SMD of the intervention group was comparable to the groups of Bezerra et al.[20] Thus, the reduction of urinary symptoms between the pre- and post-treatment periods with gametherapy were comparable to the traditional treatment.

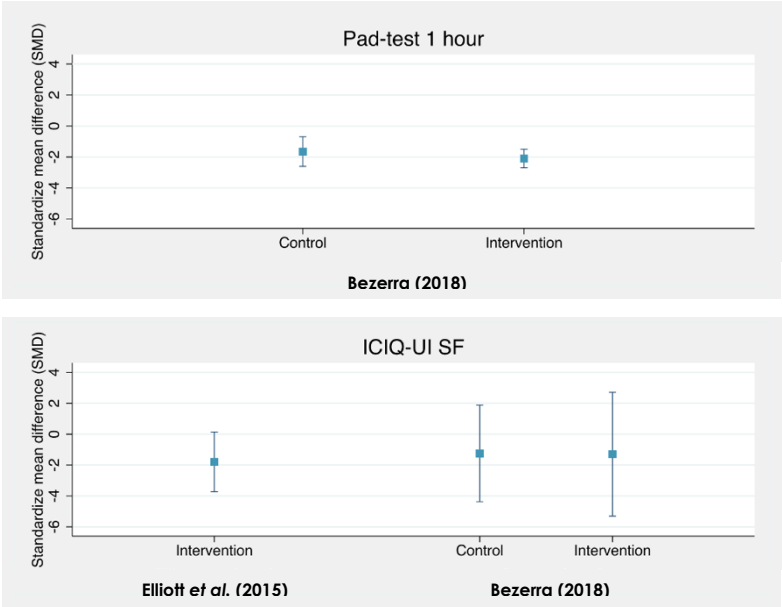

Figura 3 (Artigo 2): Figure 2 - Standardized mean difference between post- and pre-intervention periods stratified by the test applied and according to allocation group.

4. DISCUSSION

The treatment adherence of the PFMs in patients with UI is one of the most challenging conditions for the therapeutic success.[12] Gametherapy, based on virtual reality, appears as an interesting alternative, combining interaction and immersion and providing patients with a different way of performing the exercises. In the present systematic review, we observed that patients with UI presented a high rate of adherence (performance of exercises) and improvement in the reduction of urinary symptoms. Based on that, we strongly suggest this approach as an additional tool for the treatment of UI.

Gametherapy has been used in several areas such as in the rehabilitation of Parkinson's disease,[21] treatment of phobias,[22] and the rehabilitation of patients with brain stroke.[23] However, few studies[12,13,20] were developed to assess the impact on patients with UI. The great advantage of this approach lies in the possibility of increasing treatment adherence, considering it combines game movements, which ensures visual and auditory feedback.[24] This is particularly important in patients with UI because the adherence to a regular exercise program is directly responsible for failure.[25]

The one-hour pad test is a method of quantifying urinary loss, which may classify UI in mild, moderate, and severe.[26] For its application, a tampon is used and patients are asked to perform some physical efforts typical of their routine, allowing the analysis from daily activities.[26] In the present systematic review, all studies[12,13,20] used the one-hour pad test to assess urinary loss before and after gametherapy. This may be explained for being a method of easy application, low cost, and non-invasive, and it may be easily applied in clinical studies.[26] Moreover, it is a test with high sensitivity and specificity when compared to the urodynamic examination.[27]

However, only one study[20] made the pad test results available before and after gametherapy and they were satisfactory, considering the experimental group presented a reduction in the test scores after the

treatment with gametherapy. Although they did not present numerical results, Elliott et al.[12] reported that the participants presented a significant reduction in the scores after intervention in the one-hour pad test. Similarly, Steenstrup et al.[28] verified improvement in the posture of patients who used gametherapy, improving the automatic activation of the PFMs, potentially resulting in the improvement of continence. One study[23] also showed that gametherapy might replace the conventional treatment for the rehabilitation of the upper limbs after a cerebral vascular accident (CVA). This is particularly relevant because patients with CVA present severe motor impairments, further reinforcing the potential effect of gametherapy in rehabilitation programs.

The ICIQ UI-SF was also used as a tool to assess urinary symptoms. It is a short and simple questionnaire that may be applied easily in the clinical routine. In the present systematic review, two studies[12,20] used the ICIQ UI-SF and both showed a reduction in the scores of urinary symptoms. The greatest difference was observed in the experimental group (gametherapy). This may be explained by the coactivation of the PFMs during gametherapy. A recent study[29] observed an increase in the electrical activity of the PFMs after gametherapy and suggested that contracting the transverse muscle of the abdomen during the performance of the virtual game favors the coactivation of PFMs. Thus, these results suggest that gametherapy affects directly the reduction of urinary symptoms.

Adherence to a regular exercise program is one of the main challenges found in the treatment of UI.[25] Studies[11,30] show that low treatment adherence is directly responsible for therapeutic failure, and it is therefore considered an important determinant factor in the short and long terms of the effectiveness of rehabilitation. In the present systematic review, only one study[12] reported the adherence of participants and the results were promising, obtaining 92% of adherence during the regular exercise program combined with gametherapy. Similarly, Meldrum et al.,[31] studying a population of patients with unilateral peripheral vestibular loss through gametherapy observed high

adherence to the exercise (± 77%). Reinforcing this hypothesis, Perez-Marcos et al.,[32] assessing the rehabilitation of patients with CVA through gametherapy reported high levels of adherence and motivation from patients. Said authors[32] suggest that adherence affects directly the results of the intervention.

The positive results may be attributed to the easy application of gametherapy, increasing the likelihood of patient acceptance.[33] Corroborating such findings, a study[33] verified and increase in the contraction force of PFMs associated with the reduction of urinary symptoms, as well as the prolapses of the anterior wall, resulting in a better quality of PFM functionality. Thus, the coordinated action of PFMs and abdominal muscles should be the goal of the rehabilitation process.[34] Moreover, gametherapy provides auditory and visual biofeedback, leading patients to learn, which gradually changes muscle recruitment, promoting improvement in the coordination between the muscles that rule urinary continence.[35]

Thus, the results of the present systematic review suggest that gametherapy is an important strategy for the treatment of patients with UI. Furthermore, some limitations should be highlighted. Few studies fulfilled the eligibility criteria, which prevented the performance of a meta-analysis. However, this study presents strengths that deserve to be highlighted. It is the first systematic review of the influence of gametherapy on patients with UI. Therefore, we used an extensive and judicious search strategy to capture potentially eligible studies, without restrictions of language, year, or publication status. Thus, we strongly suggest the performance of further studies until the findings allow constructing scientific evidence.

5. CONCLUSION

As a resource of PFMT, gametherapy promoted benefits to patients with UI, including the reduction of urinary symptoms, reduction in the one-hour pad test scores, and improvement in neuropsychological indexes. Moreover,

the reduction of urinary symptoms was similar between gametherapy and the conventional treatment of the pelvic muscle, and it was not a determinant tool for the treatment prognosis.

Acknowledgments

We thank the financial support of the Coordination for the Improvement of Higher Education Personnel (CAPES) - Finance Code 001, through the Postgraduate Program in Surgical Sciences of the State University of Campinas (UNICAMP), with support of the Federal University of Alfenas - UNIFAL-MG, the Research Support Foundation of the state of Minas Gerais - FAPEMIG (PPM-00471-18) and the University Center of Associated Colleges (UNIFAE), São João da Boa Vista/SP, Brazil.

Author Disclosure Statement

There are no competing financial interests.

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UNICAMP

ARTIGO 3

Can supervised pelvic floor muscle training through gametherapy relieve urinary incontinence symptoms in climacteric women? A feasibility study

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Conflict of interest: none to be declared

ABSTRACT

Objectives: To investigate the feasibility of pelvic floor muscle training (PFMT) through gametherapy for urinary incontinence (UI) symptoms and PFM function in climacteric women with stress or mixed UI. **Methods:** This randomized clinical trial included 36 women with stress UI divided into a group gametherapy – G_Game (n=20) and a control group – G_Control (n=16). Both groups received unsupervised PFMT and the G_Game also received supervised PFMT through gametherapy. The severity of UI was investigated through the ICIQ-UI-SF. The PFM function was assessed through a digital palpation examination (PERFECT Scheme). Both groups were monitored for five consecutive weeks. Intention-to-Treat analysis, Fisher's exact, Kruskal-Wallis, Wilcoxon sign paired, and Mann-Whitney U test were used. **Results:** In the intragroup analysis, a decrease in the ICIQ-UI-SF score was observed in both groups (14.0 to 10.0, $p<0.001$, $r=0.3$; 13.5 to 0,0, $p<0.001$, $r=0.3$), associated with increased endurance (2.5 to 3.5, $p=0.016$, $r=0.2$; 2.5 to 4.0, $p<0.001$, $r=0.3$), in G_Control and G_Game, respectively. Moreover, there was a concomitant increase in PFM power (2.0 to 3.0, $p<0.001$, $r=0.4$), repetition (3.0 to 5.0, $p<0.001$; $r=0.3$) and fast (10.0 to 10.0, $p=0.008$; $r=0.2$) in G_Game. In the intergroup analysis, a reduction in urinary symptoms was observed ($p <0.001$; $r = 0.8$), as well as the PFM power ($p = 0.028$, $r = 0.3$) in the G_Game. **Conclusion:** All women presented relief in urinary symptoms and increased in PFM endurance, but only those who using supervised PFMT through gametherapy improved PFM power, repetition and fast, showing the feasibility this protocol.

Keywords: pelvic floor dysfunctions, urinary incontinence, pelvic floor muscle, gametherapy, climacteric, rehabilitation.

1. INTRODUCTION

According to the International Continence Society (ICS),[1] urinary incontinence (UI) is defined as the involuntary loss of urine, and its importance lies rather in its impact on the quality of life in physical, psychological, and sexual aspects than in its related morbimortality. Stress urinary incontinence (SUI) is defined as the involuntary loss of urine on effort or physical exertion, while urgency urinary incontinence (UUI) is characterized by the involuntary loss of urine accompanied or immediately preceded by urgency, followed or not by other urinary symptoms such as frequency and nocturia. Mixed urinary incontinence (MUI) corresponds to the association of both types.

The prevalence of UI reported among women ranges from 5% to 70%, with most studies reporting a prevalence of any UI in the range of 25-45%. In postmenopausal women, more than 40% of the population is affected. The prevalence of UI is strongly related to the age of women. Therefore, due to the increase in mean life expectancy, the overall relevance of UI in women is expected to increase in the future. The urinary symptoms are classic and they have been investigated by the application of validated questionnaires without the need for more accurate examinations.[2]

According to Dumoulin, Cacciari and Mercier (2019),[3] in the climacteric period the modifications in the composition of pelvic floor muscles (PFM) appear to affect their properties and their ability to function adequately, leading to UI.

Thus, the assessment of PFM has been recommended by the ICS[1] as part of the clinical routine for investigating the PFM function associated with the urogynecological signs and symptoms, considering essential to evaluate the effect of the treatments performed. Digital palpation is one of the most practical and widely used methods due to its simplicity and low cost.[4,5]

The conservative treatment of UI is recommended by the ICS as a first-line treatment and it has been performed through pelvic floor muscle

training (PFMT), with satisfactory levels of scientific evidence.[1,6] Recently, due to complications from midurethral mesh slings, less invasive alternatives have been considered for patients, who should be involved in the decision-making.[7,8]

According to Dumoulin et al.,[9] supervised PFMT is more effective than unsupervised PFMT. Supervised PFMT is considered the golden standard for the treatment of SUI and MUI, showing a high level of scientific evidence.[1] However, patient adherence to the training protocols represents the greatest threat to therapy success.

Gametherapy seems to be an interesting method to stimulate adherence to the exercises due to the possibility of performing a training protocol that encourages and motivates the participants.[10]

Elliott *et al*.[11] showed feasibility of PFMT through virtual environment, for PFMT for MUI, using a computer with a dance game program (StepMania). Botelho et al.,[12] Martinho et al.[9] and Silva et al.[13] developed a protocol capable of stimulating PFM contractions during the execution of pelvic movements, induced by gametherapy.

This study aimed to investigate the feasibility of supervised PFMT gametherapy for relieving UI symptoms and PFM function in climacteric women with SUI or MUI when compared to an unsupervised protocol. We hypothesize that gametherapy may be an interesting, effective, and encouraging tool to be added to a conventional PFMT program, aiming at favoring adherence.

2. METHODS

2.1 Study design and setting

The *UroFisioterapia* group of the Postgraduate Program in Surgical Sciences, Surgery Department, Division of Urology, State University of Campinas performed a randomized clinical trial in the Clinic of Physiotherapy of the Center for Integral Attention to Women's Health (CAISM) of the State University

of Campinas (UNICAMP) – Campinas – SP/Brazil.

The study was approved by the Research Ethics Committee of UNICAMP (Institutional Review Board approval CAAE: 41304914900005404; Approval number 1.012.691) and registered at "ensaiosclinicos.gov.br" (U1111-1205-9058), following the CONSORT recommendations.[14] The participants of the study were instructed and informed about the procedures of the trial and the ones who agreed, formalized their acceptance by signing an informed consent form.

2.2 Participants

Inclusion criteria were climacteric women (starting at 45 years old, a time when ovarian failure leads to decreased plasma steroid levels)[15] with dominant stress UI, assessed both by the International Consultation on Incontinence Questionnaire - Short Form (ICIQ UI-SF)[16] and the International Consultation on Incontinence Questionnaire Overactive Bladder (ICIQ OAB).[17]

Exclusion criteria were women with cognitive, neurological, and/or physical disorders that could hinder their participation in the assessment; current urinary tract infection (identified during the initial evaluation); a history of instrumental delivery, stress UI and/or surgical pelvic organ prolapse (POP), and oncology treatment and/or previous PFMT; inability to contract PFM (grade zero or 1, according to the Modified Oxford Grading Scale)[4] and/or POP greater than II, according to the pelvic organ prolapse quantification (POPq)[18] observed during the initial assessment; and inability to complete the initial assessment process.

2.3 Interventions

Participants were randomized into two groups:

Control Group (G_Control): The control group received only recommendations about unsupervised PFMT, carried out by the main researcher, as follows: 1. PFM anatomy and function; 2. PFM control and coordination - performed during the assessment using digital palpation; 3. Delivery of a booklet about PFM control during daily activities. The instructions included the performance of PFM contraction exercises, at home (weeks 1 to 5), in different postures (laid down in supine position with bent knees, seated, and squatting): A. Three sets with 10 maximum PFM contractions, ensuring 1 minute of rest between sets; B. Three sets of 10 moderate PFM contractions for up to 8 seconds. Then, relax gently. Keep 16 seconds of rest between sets; and C. Three sets of 10 quick contractions, followed by relaxation of the PFM, with 20 seconds of rest between sets. Moreover, the Knack Maneuver[19,20] was recommended, contracting the PFM before an activity involving physical effort (coughing, sneezing, carrying weight, and exercising) and when you are in a hurry to urinate (strong need to pee).

Gametherapy Group (G_Game): The intervention group received the same set of recommendations given to the control group and they performed PFMT through gametherapy supervised by a physiotherapist (ABLN), twice a week for 30 minutes, for five consecutive weeks, resulting in 10 sessions. The exercises were based on a specific gametherapy protocol developed by the research group[10,12,13], using Wii™ console with the Wii Fit Plus™ CD (games: Lotus Focus™, Penguin Slide™, Table Tilt™, and Balance Bubble™) and the Wii Balance Board™ platform. According to Martinho et al.,[10] the game is controlled using pelvic exercises, with control and stabilization of the trunk. The volunteer remained seated on the Wii Balance Board™ platform, which was placed on a bench for the adequate maintenance and alignment at a 90° flexion of knee joints and hip. Then, the performance of retroversion, anteversion, and pelvic inclination was requested according to the avatar corresponding to the game played. For this study, we added specific PFM contractions through verbal commands from the physiotherapist (Figure 1).

Figura 4 (Artigo 3): Figure 1. PELVIC FLOOR MUSCLE TRAINING PROTOCOL GAMETHERAPY

2.4 Outcomes

2.4.1 Primary outcome measure

Feasibility was defined as the rate of participant adherence and completion of the protocol of both groups. To calculate adherence to the protocol, the participants had to perform the 10 PFMT sessions. Adherence to PFMT at home was calculated considering the frequency of exercises performed at home for five consecutive weeks. The rate of completion of the PFMT protocol through gametherapy was calculated as the proportion of participants who completed the final assessment.

The relief of urinary symptoms after the treatment was the main clinical result. It was investigated by the validated questionnaire that investigate the severity of UI, using the Portuguese version of the ICIQ UI-SF,[16] which allows a quick investigation of the impact of UI on the quality of life and

the measurement of urinary loss and interference with daily life, quantifying it from 0 to 21 (high scores mean more severe symptoms).

2.4.2 Secondary outcome measure

The secondary outcome was measured based on the functional parameters of PFM. It was assessed with the "Power" of the PERFECT scheme, proposed by Laycock e Jerwood[4], and graduated according to the Modified Oxford Grading Scale, which allows the graduation of muscular strength, with a score ranging from 0 to 5, in which zero means absence of muscle contraction noticeable to the examiner's fingers and five indicates strong contraction.[4]

A physical therapist and researcher specialized in women's health carried out the PFM physical examination.

Additionally, the overactive bladder symptoms were investigated by the Portuguese version of ICIQ–OAB,[17] validate questionnaire which allows exploring the presence of frequency, nocturia, urgency and urgency urinary incontinence, quantifying it from 0 to 16 (high scores mean more severe symptoms), in mixed UI women.

2.5 Randomization

Women included in the study were randomly divided into two groups through a simple randomization process (computerized random numbers): control and experimental groups. Every participant was aware of the possibility of being allocated to either one of the groups.

2.6 Statistical analysis

The analysis were conducted using the Intention-to-Treat (ITT) analysis methods, the variables presenting missing data were imputed with the Last Observation Carried Forward (LOCF) method.

The categorical variables were presented through absolute and relative frequencies and they were compared with Fisher's exact test. All

continuous variables were described and compared using medians and non-parametric methods, respectively, considering they presented asymmetrical distribution. The medians of control and intervention groups (comparison between groups) were compared with the Kruskal-Wallis rank test. The different moments of the study (pre- and post-intervention) were compared with the paired Wilcoxon sign rank test. The effect sizes intra- and inter-group were also calculated from the paired Wilcoxon sign rank test and Mann-Whitney U statistics, respectively. The analyses were performed using the Stata 15.1 software at a 5% significance level ($p<0.05$). As suggested by Cohen,[21] the norms for interpreting the effect-size values were divided into "small" (0.1-0.3), "medium" (0.4-0.5), and "large" (> 0.5) effect, and we standardized the r to identify them.

3. RESULTS

Initially, 50 women were recruited, evaluated, and distributed for treatment, according to Figure 2. From these women, 40 were randomly divided for treatment between the groups. Adherence to the PFMT protocol was completed by 16/20 (80%) participants in G_Control and 20/20 (100%) participants in G_Game, showing the highest adherence for G_Game. The completion rate of the PFMT protocol showed the same proportion as the adherence rate.

CONSORT 2010 Flow Diagram

Enrollment

Assessed for eligibility (n=50)

Excluded (n=10)
Not meeting inclusion criteria (n=8)
Declined to participate (n=2)

Randomized (n=40)

Allocation

Allocated to intervention - CONTROL GROUP (n=20)
- Received allocated intervention (n=20)
- Excluded (n=0)

Allocated to intervention - GAMETHERAPY GROUP (n=20)
- Received allocated intervention (n=20)
- Excluded (n=0)

Follow-Up

After 5 training weeks (n=16)
Discontinued intervention (due to personal issues or transport difficulties) (n=4)

After 5 training weeks (n=20)
Discontinued intervention (due to personal issues or transport difficulties) (n=0)

Analysis

Per-Protocol Analysis (n=16)
- Analyzed by digital palpation (n=16) - Excluded (n=4)
- Analyzed by ICIQ UI-SF (n=16) - Excluded (n=4)

Intention-to-Treat Analysis (n=20)
- Analyzed by digital palpation (n=20) - Excluded (n=0)
- Analyzed by ICIQ UI-SF (n=20) - Excluded (n=0)

Per-Protocol Analysis (n=20)
- Analyzed by digital palpation (n=20) - Excluded (n=0)
- Analyzed by ICIQ UI-SF (n=20) - Excluded (n=0)

Intention-to-Treat Analysis (n=20)
- Analyzed by digital palpation (n=20) - Excluded (n=0)
- Analyzed by ICIQ UI-SF (n=20) - Excluded (n=0)

Figura 5 (Artigo 3): Figure 2. CONSORT flow diagram

Table 1 presents the clinical and demographic characteristics of the participants.

Tabela 7 (Artigo 3): Table 1 – Demographic and clinical characteristics of participants

	G_Control (n=20)		G Game (n=20)		p-value[1]
	N (%)	95% CI	N (%)	95% CI	
DEMOGRAPHIC DATA					
Skin color					
White	16 (80.0)	56.4; 92.5	18 (90.0)	66.5; 97.6	0.661
Other	4 (20.0)	7.5; 43.6	2 (10.0)	2.4; 33.5	
Marital status					
Single	1 (5.0)	0.7; 29.5	2 (10.0)	2.4; 33.5	1.000
Married/Cohabitating	14 (70.0)	46.5; 86.2	13 (65.0)	41.8; 82.8	
Divorced/Widower	5 (25.0)	10.5; 48.7	5 (25.0)	10.5; 48.7	
Level of education					
Illiterate	0 (0.0)	0.0; 0.0	0 (0.0)	0.0; 0.0	0.052
Elementary school	12 (60.0)	37.3; 79.1	6 (30.0)	13.7; 53.6	
High school	2 (10.0)	2.4; 33.4	10 (50.0)	28.7; 71.3	
Higher education	6 (30.0)	13.8; 53.5	4 (20.0)	7.4; 43.7	
Physical activity					
Does not practice	11 (55.0)	33.0; 75.2	9 (45.0)	24.7; 67.1	0.752
Up to twice a week	9 (45.0)	24.7; 67.1	11 (55.0)	32.9; 75.3	
HORMONAL DATA					
Menopause					
No	8 (40.0)	20.9; 62.7	4 (20.0)	7.4; 43.7	0.301
Yes	12 (60.0)	37.3; 79.1	16 (80.0)	56.3; 92.6	
Hormonal replacement					
No	16 (80.0)	56.4; 92.5	16 (80.0)	56.3; 92.6	1.000
Yes	4 (20.0)	7.5; 43.6	4 (20.0)	7.4; 43.7	
OBSTETRIC DATA					
Pregnancies					
0	1 (5.0)	0.7; 29.5	3 (15.0)	4.7; 38.6	0.094
1	2 (10.0)	2.4; 33.4	3 (15.0)	4.7; 38.6	
2	3 (15.0)	4.7; 38.6	8 (40.0)	20.9; 62.7	
3	14 (70.0)	46.5; 86.2	6 (30.0)	13.7; 53.6	
Number of vaginal deliveries					
0	11 (55.0)	33.0; 75.2	8 (40.0)	20.9; 62.7	0.546
1	1 (5.0)	0.7; 29.5	3 (15.0)	4.7; 38.6	
2-3	8 (40.0)	20.9; 62.7	9 (45.0)	24.7; 67.1	
Number of cesarean deliveries					
0	9 (45.0)	24.7; 67.1	10 (50.0)	28.7; 71.3	0.054
1	2 (10.0)	2.4; 33.4	7 (35.0)	17.2; 58.2	
2-3	9 (45.0)	24.7; 67.1	3 (15.0)	4.7; 38.6	
PERSONAL DATA	**Median**	**IQR**	**Median**	**IQR**	**p-value[2]**
Age (years)	49.5	41.0; 61.0	57.0	51.5; 61.0	0.116
BMI (kg/m2)	25.4	21.7; 30.5	24.6	22.0; 29.2	0.818

The table presents demographic and clinical data expressed in percentage (%) followed by the confidence interval (CI), using [1]Fisher's exact test and considering a 95% confidence interval (CI). It also presents personal data expressed in median and interquartile range (IQR), using [2]Kruskal-Wallis rank test and considering p-value<0.05.

Table 2 shows the urinary symptoms assessed by ICIQ UI-SF and ICIQ–OAB questionnaires, comparing both times (intra group analysis) and groups (inter group analysis).

Tabela 8 (Artigo 3): Table 2 – Comparison of urinary symptoms in both groups, pre-and post-intervention, using the ICIQ UI-SF and ICIQ-OAB questionnaires

		Intra-group analysis								Inter-group estimates	
		G_Control (n=20)				G_Game (n=20)					
		Median	IQR	P value[1]	Effect size[3]	Median	IQR	P value[1]	Effect size[3]	P value[2]	Effect size[4]
Intention-to-Treat	**ICIQ UI-SF**										
	Pre-intervention	14.0	12.0 – 15.0	**< 0.001**	0.317	13.5	12.0 – 17.5	**< 0.001**	0.393	0.560	0.446
	Post-intervention	10.0	6.0 – 12.5			0.0	0.0 – 4.5			**< 0.001**	0.863
	ICIQ-OAB										
	Pre-intervention	4.5	2.0 - 8.0	0.058	0.194	3.0	1.0 - 5.5	**0.002**	0.290	0.317	0.593
	Post-intervention	3.0	1.5 - 5.5			2.0	1.0 - 3.0			0.074	0.665

Legend: The table presents comparisons between pre- and post-intervention periods, comparing the times ([1]Wilcoxon rank test) and groups ([2]Kruskal-Wallis rank test). The data is presented with medians and interquartile range (IQR), according to intention-to-treat analysis. Effect sizes were calculated both for intra- ([3]Paired signed-rank Wilcoxon test) and inter-group comparisons ([4]Mann-Whitney U statistic).
ICIQ UI-SF: International Consultation on Incontinence Questionnaire Urinary Incontinence - Short Form
ICIQ-OAB: International Consultation on Incontinence Questionnaire Urinary Incontinence - Overactive Bladder

Additionally, Table 3 presents PFM strength measured by digital palpation, comparing both times (intra group analysis) and groups (inter group analysis).

Tabela 9 (Artigo 3): Table 3 – Investigation of PFM function in both pre- and post-intervention groups, through digital palpation.

		Intra-group analysis								Inter-group analysis	
		G_Control (n=20)				G_Game (n=20)					
		Median	IQR	P value[1]	Effect size[3]	Median	IQR	P value[1]	Effect size[3]	P value[2]	Effect size[4]
Intention-to-Treat	**Power**										
	Pre-intervention	2.0	2.0 - 3.0	0.250	0.173	2.0	2.0 - 2.0	**< 0.001**	0.407	0.256	0.605
	Post-intervention	2.5	2.0 - 3.0			3.0	3.0 - 3.0			**0.027**	0.295
	Endurance										
	Pre-intervention	2.5	2.0 - 4.0	**0.016**	0.256	2.5	2.0 - 3.0	**< 0.001**	0.383	0.598	0.549
	Post-intervention	3.5	2.5 - 4.0			4.0	3.5 - 6.0			**0.033**	0.302
	Repetition										
	Pre-intervention	3.5	2.5 - 5.0	0.114	0.163	3.0	3.0 - 4.0	**< 0.001**	0.376	0.579	0.551
	Post-intervention	4.0	3.0 - 6.0			5.0	4.0 - 6.5			0.055	0.323
	Fast										
	Pre-intervention	10.0	7.0 - 10.0	0.922	0.031	10.0	5.0 - 10.0	**0.008**	0.280	0.607	0.547
	Post-intervention	10.0	7.0 - 10.0			10.0	10.0 - 10.0			0.250	0.394

Legend: The table presents comparisons between pre- and post-intervention periods, comparing the times ([1]Wilcoxon rank test) and groups ([2]Kruskal-Wallis rank test). The data is presented with medians and interquartile range (IQR), according to intention-to-treat analysis. Effect sizes were calculated both for intra- ([3]Paired signed-rank Wilcoxon test) and inter-group comparisons ([4]Mann-Whitney U statistic).

Feasibility was adopted as a generic term including the constructs of retention and adherence. This study was completed by 16/20 (80%) participants in the control group and 20/20 (100%) participants in the experimental group.

4. DISCUSSION

According to the results obtained in this study, all participants observed relief of urinary symptoms and increased of PFM endurance. However, the increase in PFM power, repetition and fast was verified only in the supervised PFMT through gametherapy. As described by Braekken *et al.*,[22] the improvement in PFM contractility after PFMT increases muscle volume, contributing to their support, resistance, and coordination, and improves PFM functionality, which is an important aspect to show the effectiveness of PFMT, as indicated by Bø *et al.*[23] Based on this premise, we assume that the gametherapy protocol provided not only the relief of incontinence symptoms but also a significant increase in PFM function.

However, we believe that a PFMT program performed routinely, especially the one "learned" after a "complete" pelvic floor evaluation, could promote an increase in PFM activity, contributing to greater pelvic floor support and closure of the urethral sphincter, also improving the control of urinary symptoms, especially when combined with the pre-contraction test (The Knack).[20]

The execution of PFM pre-contraction during everyday activities that involve increasing the intra-abdominal pressure may have a fundamental role in preventing future dysfunctions, which leads to an improvement in the quality of life. However, despite providing knowledge about such muscles and the possibility of their recruitment during functional activities, such exercise does not guarantee a significant effect on the maximum contraction capacity of the PFM.[24] Henderson *et al.*,[25] evaluated 779 women through the Brinks Scale

and showed that most women with or without mild PFM disorders are capable of correctly contracting those muscles after simple verbal orientation. We believe that, in the present study, both the reduction of urinary symptoms and the increase in PFM strength were due to the recommendations received during the physiotherapy assessment and to the booklet of domestic recommendations that both groups received.

Hung *et al.*[26] affirms that learning from training can modify muscular recruitment, with consequent improvement in the coordination between PFM and abdominal muscles, considering the pelvic floor works coordinately with the stabilizing abdominal muscles, promoting closure of the urethral sphincter after receiving effort commands from the upper part of the body.[27]

Gametherapy has been used as a rehabilitation technique in multiple health care fields.[28] Studies by Elliott *et al.* (2015),[11] Botelho *et al.* (2015),[12] Martinho *et al.* (2016),[10] and Silva *et al.* (2016),[13] have shown that this tool can be complementary to PFMT, which could stimulate the adherence of patients because of the sensorial feedback, easy handling, and low cost. Between the studies performed, positive results were observed in both asymptomatic young women and incontinent women.

Elliott *et al.*[11] investigated the viability of using PFM strengthening exercises associated with virtual reality in elderly women with urinary incontinence. The authors concluded that the association of the exercises was effective to improve symptoms and the quality of life.

The gametherapy protocol used in the present study corroborates the study by Silva *et al.*[13] performed with continent nulliparous young women. The authors verified an increase in muscle strength identified by vaginal palpation and improvement in the coactivation of pelvic floor muscles in response to abdominal contraction. According to the authors, one of the challenges of the preventive practice in this area refers to the introduction of proposals that emphasize the importance of the awareness of abdominopelvic muscles as a type of prevention against pelvic floor overload during daily activities.

Additionally, Martinho *et al.*[10] observed an increased PFM strength and ability to maintain contraction in the reduction of urinary symptoms, which reflected in the improvement of PFM functionality and quality of life in postmenopausal women. The authors observed good acceptance, easy applicability, and treatment continuity.

The current protocol was based on the one performed by Martinho *et al.*[10] and Silva *et al.*,[13] which consisted of the addition of PFM contraction at the time of exercise practice using virtual games with the training focused on PFM contraction, attending to the specificity principle as recommended by the Physical Activity Guidelines Advisory Committee.[29] Still according to the Committee,[29] as the participant familiarizes with the game (training adaptation), gametherapy provides higher interactivity through the increase in the level of execution, attending to the overload principle. This principle is defined as the physical stress applied to the body when physical activity is more intensive than usual, reflecting on the adaptation of body structures and functions as a response to stimuli.

The maintenance of the treatment's effect is secondary to the continuity of the training proposed, which requires attention to the frequency, intensity, and duration of exercises. These parameters are easily programmed in gametherapy, with precision in reproducing the techniques proposed.

Adherence to training is still the greatest challenge to overcome, considering the dropout rate could harm the results obtained during the treatment. Porta Roda *et al.*,[30] identified that low adhesion may occur even in an efficient exercise program. Considering that PFMT requires adherence, the supervision by a trained professional tends to increase motivation and consequently the adherence to the treatment program, besides providing better control in the execution of the techniques proposed.

The association of supervision by a professional physiotherapist with the exercise program may have contributed positively to the findings of our study.[31] Moreover, higher assiduity was observed in the experimental group, which

infers that gametherapy may be more attractive and increase the adherence of women.

Another relevant aspect of adherence refers to motivation, which is an essential condition for the assiduity of participants in the exercise program. Araujo, Marques and Juliato (2019)[32] used a digital app as a guide for PFMT and compared it to the control group, which received only written PFMT instructions. The authors observed that app use increased PFMT adherence in women with urinary incontinence.

Such findings suggest that training programs using innovative instruments combined with motivation and adequate understanding of the exercises may stimulate PFM and increase the chance of adherence to treatment.[13,33]

This study suggests that exercises performed with gametherapy could increase PFM strength and reduce urinary symptoms in women with a prevalence of stress urinary incontinence. However, new studies with a higher number of participants could establish a better understanding of these benefits.

As a limiting factor, we consider the small number of subjects in our sample. Furthermore, the individualized patient-therapist contact in the experimental group does not draw away the possibility of a greater endeavor in performing the exercises, as shown in previous supervised studies. The reduced period of training could have affected the findings, considering that some authors[31] recommend the performance of PFMT for a minimum of six weeks for adaptation. The performance of further studies is recommended to elucidate the effects of different kinds of treatment on the anatomic and functional conditions of this population.

We observed that all women presented relief in urinary symptoms and increased of the PFM endurance. However, those who performed the supervised training program using gametherapy also improved other domains of the PERFECT scheme (power, repetition and fast), which shows the feasibility to add gametherapy as a tool for PFMT.

5. CONCLUSION

The feasibility of the supervised PFMT through gametherapy was identified observing adherence of participants, relief of urinary symptoms and improvement in PFM function.

Acknowledgments

We thank the financial support of the Coordination for the Improvement of Higher Education Personnel (CAPES) - Finance Code 001, through the Postgraduate Program in Surgical Sciences of the State University of Campinas (UNICAMP), with support of the Federal University of Alfenas - UNIFAL-MG, the Research Support Foundation of the state of Minas Gerais - FAPEMIG (PPM-00471-18) and the University Center of Associated Colleges (UNIFAE), São João da Boa Vista/SP, Brazil.

Author Disclosure Statement

There are no competing financial interests.

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ARTIGO 4

Supervised Pelvic Floor Muscle Training Gametherapy vs. Unsupervised Pelvic Floor Muscle Training in women with stress urinary incontinence: a randomized controlled study

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Conflict of interest: none to be declared

ABSTRACT

Objectives: To compare the Supervised Pelvic Floor Muscle Training (PFMT) protocol gametherapy with Unsupervised PFMT on urinary incontinence (UI) symptoms and PFM function in women with predominant stress UI. **Methods:** Randomized controlled clinical trial: Group Control (G_Control=50) and Group Gametherapy (G_Game=50). Both groups performed unsupervised PFMT. Additionally, the women in G_Game performed supervised PFMT through gametherapy. Before and after the interventions, the ICIQ-UI-SF, ICIQ-OAB, digital palpation (PERFECT scheme, which includes the assessment of power, endurance, repetition, and fast PFM contraction), surface electromyography (sEMG), and 4D translabial ultrasound (4D TLUS) were performed. The analysis was performed using the Intention-to-Treat analysis. Fisher's exact, Kruskal-Wallis, Wilcoxon sign paired, and Mann-Whitney U test were used. **Results:** Intra-group analysis: reduced ICIQ-UI-SF score (14.0 to 10.5, $p<0.001$, $r=0.6$; 14.5 to 4.5, $p<0.001$, $r=0.8$) with increased power (2.0 to 3.0, $p<0.001$, $r=0.3$; 2.0 to 3.0, $p<0.001$, $r=0.5$) and endurance (3.0 to 4.0, $p<0.001$, $r=0.4$; 3.0 to 5.0, $p<0.001$, $r=0.5$) in G_Control and G_Game, respectively. The G_Game also showed an increase in repetition (4.0 to 5.0, $p<0.001$; $r=0.4$) and fast (10.0 to 10.0, $p<0.001$; $r=0.3$). In the inter-group analysis, the reduction of urinary symptoms was observed by ICIQ-UI-SF ($p<0.001$; $r=0.7$), as well as endurance ($p=0.024$, $r=0.3$) and repetition ($p=0.007$, $r=0.3$) in G_Game. There was no statistical significance in sEMG and 4D TLUS. **Conclusion:** The supervised PFMT protocol gametherapy showed to be a promising tool, able of reducing UI symptoms and improving the function of PFM in women with predominant SUI when compared to the unsupervised PFMT protocol.

Keywords: digital palpation, electromyography, gametherapy, pelvic floor, physiotherapy, translabial ultrasound.

1. INTRODUCTION

Urinary incontinence (UI) defined as "any involuntary urine loss" is classified in three main types: stress urinary incontinence (SUI), urge urinary incontinence (UUI), and mixed urinary incontinence (MUI). The SUI is the most common type and it affects especially women[1,2]. According to Legendre et al. (2020),[3] who followed-up 2640 women in a longitudinal study for eight years, the global incidence of UI is 21.9%, with 14.9% for SUI, 3.2% for UUI, and 3.1% for MUI.[3] With exponential growth, the estimate for 2050 is that more than 28 million women will develop UI in the USA.[4]

The SUI from multiple failures in continence mechanisms occurs during situations of physical effort such as coughing or sneezing and it affects especially young and middle-aged women, originating from anatomical defects in the structures that support the bladder and urethra[2]. However, UUI is more common in older women, as it is the result of increased bladder pressure from the contraction of the detrusor muscle[2]. In most cases of SUI, vaginal birth is considered the initiating factor - although women without obstetric history may also develop it - and the aggravating factors are overweight, previous muscular conditions, overload activities, and aging.[2,5]

The International Urogynecological Association (IUGA) and the International Continence Society (ICS) recommend pelvic floor muscle training (PFMT) as the first line of treatment for UI.[1,2] Therefore, the correct and effective contraction of pelvic floor muscles (PFM) is required, which according to Kegel (1952), should be performed to squeeze and elevate, cranially.[5] According to De Lancey et al. (1988)[6] and Miller et al. (2008),[7] the voluntary and effective contraction of PFM before and during effort (The Knack Maneuver) is sufficient to compress and close the urethra, which may reduce significantly the urinary loss during the stress test after one week of pre-contraction training.

Additionally, other studies suggest that a PFM ultrasound may be used to teach PFM contraction, and it may be performed for pre-contraction

training or contractions that are effective enough to elevate the bladder neck and prevent urinary loss.[8,9]

Studies show that, depending on the specificity of the program, PFMT may promote morphological adaptations in the muscle fiber, with consequent hypertrophy, the transverse elevation of PFM, increment in the support system, and changes in the mechanical properties of the muscle, affecting the number of active motor neurons.[5]

Thus, PFMT for women with SUI aims to improve the control and coordination of PFM, incrementing the support mechanism of the pelvic organs and consequently the middle third of the urethra, which is a region responsible for the continence mechanism, associated with better recruitment of fast fibers during activities that increase intra-abdominal pressure.[2,5]

Therefore, functional activities should be encouraged so that patients resume muscle control gradually, which tends to improve PFM functionality.[10] However, the great challenge of the conservative treatment based on PFMT programs is treatment adherence, considering the adherence by women is required for exercise maintenance.[5,11] Studies show that, under the supervision of a physiotherapist, PFMT has a higher potential for therapeutic success, showing higher effectiveness than the unsupervised PFMT.[5,12]

The feasibility of using virtual reality rehabilitation as a PFMT method was first described by Elliot et al. (2015)[11] as a ludic, accessible, and effective tool to treat women of different ages.[11] In parallel, a gametherapy protocol aiming to stimulate PFM contractions during pelvic movements, induced by virtual games, was developed by Botelho et al. (2015)[13] and tested by Martinho et al. (2016)[14] and Silva et al. (2016)[15] using exercises that attempted to promote functional pelvic movements to stimulate the recruitment of PFM in daily activities.

Thus, gametherapy seems to represent a promising tool, especially for being a motivating therapy. However, although some studies use gametherapy in different populations,[11,14,15] the effect of this therapy on the

clinical and functional PFM response needs to be confirmed before used in the clinical practice.

Therefore, we aimed to investigate the effect of PFMT through with gametherapy on the reduction of urinary symptoms in women with SUI and the parameters related to PFM function. We hypothesized that the reduction in urinary symptoms and the improvement of PFM function is greater in the supervised PFMT protocol gametherapy, in women with predominant SUI, when compared to those only performed the unsupervised PFMT protocol.

2. MATERIALS AND METHODS

2.1 Design, setting, and participants

The randomized controlled clinical trial was performed between August 2015 and May 2018 by the Postgraduate Program in Surgical Sciences at the Physiotherapy Service of CAISM – *Centro de Atenção Integral à Saúde da Mulher* (UNICAMP), Campinas/SP, Brazil. Two-hundred and ten women were previously recruited for a cross-sectional study conducted by Martinho et al. (2020),[16] and those included in the present study (n=100) were recruited from a urogynecological outpatient clinic and the community, and they were randomly attributed to either the control or intervention group.

2.2 Eligibility criteria

The inclusion criteria for this study were women aged between 35 and 70 years with prevalent urinary symptoms of stress urinary incontinence, according to the International Consultation on Incontinence Questionnaire - Short Form (ICIQ UI-SF)[17] and the International Consultation on Incontinence Questionnaire - Overactive Bladder (ICIQ–OAB)[18], considering the positive response of urinary loss during stress situations and those with urinary loss both in stress and urge situation, as long as stress prevailed.

A study conducted by Martinho et al.[16] excluded women with current urinary tract infection, cognitive, physical, or neurological disorders that could hinder their participation in the evaluation, previous oncology treatment such as brachytherapy or neovagina, both SUI or/and pelvic organ prolapse surgical history, pelvic organ prolapse exceeding the vaginal opening, PFM contraction grade either zero or one according to the Modified Oxford Grading Scale,[19] women who were unable to complete the assessment process, and those with missing ultrasound or PFM sEMG data. Additionally, we excluded other 110 women, as follows: women with a history of instrumental delivery (n=24), more than three pregnancies (n=5), POP greater than II (according to the POPq)[1] (n=5), a complaint of PFM pain and spasm (n=6) observed during the initial assessment, women who had performed supervised PFMT (n=18), women who did not accept to participate in the research (n=2), and those who did not accept to participate in the training due to mobility difficulties (n=50).

The women admitted to treatment who could not complete the final assessment process but performed at least 80% of the treatment proposed were included and analyzed by intention to treat.

2.3 Ethical criteria

This study was approved by the Ethics in Research Committee of the State University of Campinas – UNICAMP (CAAE: 41304914900005404) and registered at "ensaiosclinicos.gov.br" (U1111-1205-9058), following the CONSORT recommendations. All participants gave their informed and written consent according to the Helsinki declaration, before the initial assessment.

2.4 Interventions

Participants were randomized into two groups:

Control Group: This group only received recommendations about PFM function based on anatomy, coordination, and PFM control, as well as a booklet of

recommendations (Figure 1a) to perform PFM contractions during daily activities (Unsupervised PFMT protocol). A researcher specialist in physiotherapy (ABLN) performed all recommendations during the initial assessment (digital palpation). After five weeks, a researcher specialist in physiotherapy (NMM) other than the one who performed the first assessment, evaluated the participants.

Intervention Group (Gametherapy Group): The intervention group received the same booklet of recommendations (Figure 1a) given to the control group. Additionally, this group performed PFMT using gametherapy, supervised by a researcher specialist in physiotherapy (ABLN) during 10 sessions applied twice a week for 30 minutes and five consecutive weeks (Supervised PFMT protocol Gametherapy). Later, a researcher specialist in physiotherapy (NMM) other than the one who performed the first assessment, evaluated the group. The research group developed specific protocol[13,14,15] through gametherapy, with the Wii*TM* console, using the game Wii Fit Plus*TM*, which selected the sub-games (1) Lotus Focus*TM*, (2) Penguin Slide*TM*, (3) Table Tilt*TM*, and (4) Balance Bubble*TM*[19,20] (Figure 1b).

The participants trained to perform the virtual games, executing the correct pelvic movements, keeping a calm breath, and promoting isometric PFM contraction. During gametherapy, verbal commands were given for the maximum voluntary contractions of PFM, and throughout the session, participants were reminded to contract the lower abdominal muscles gently, stabilizing the pelvis, maintaining an upright posture and correct breathing, with the following command: "Tighten the abdominal muscles by pulling the navel inwards, keep the posture upright, contract the PFM, inhale through the nose and exhale through the mouth".

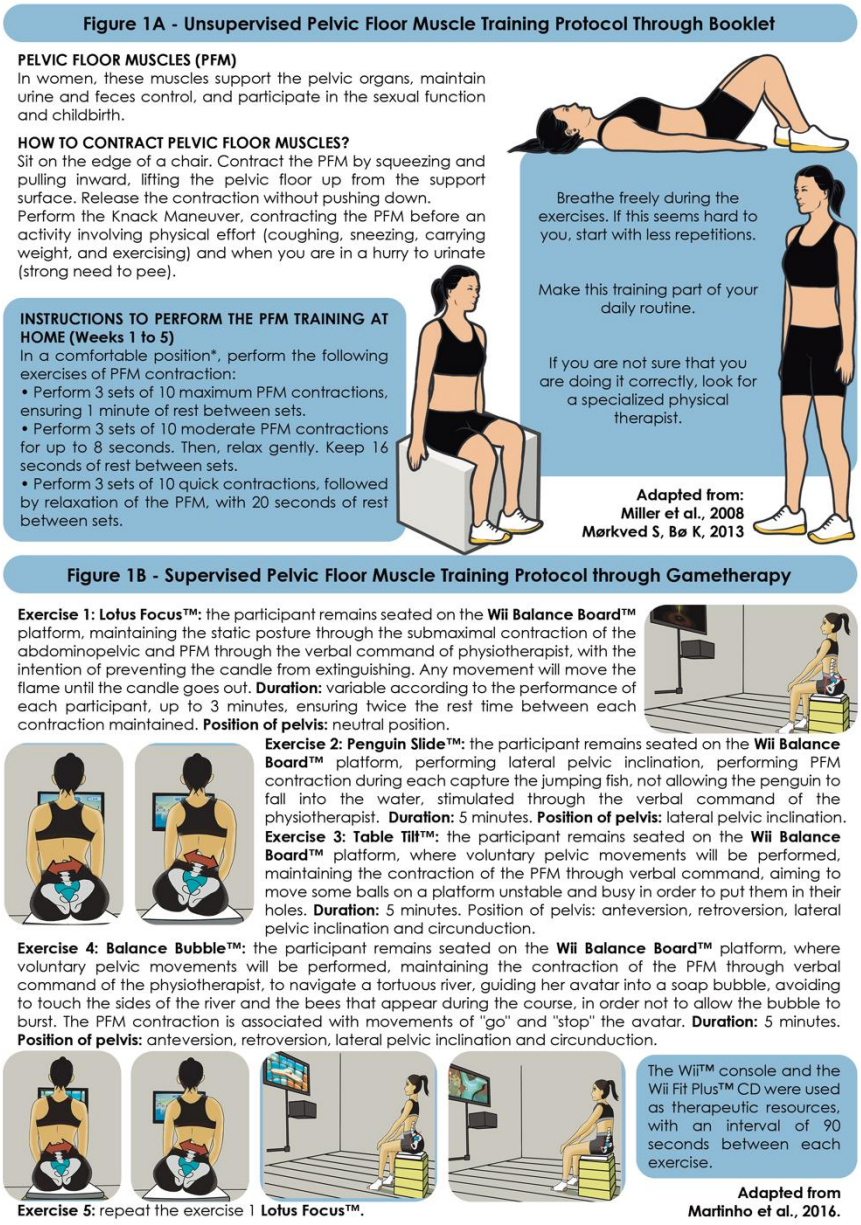

Figura 6 (Artigo 4): Figure 1 – Pelvic Floor Muscle Training Protocol. Figure 1a – Unsupervised Pelvic Floor Muscle Training Protocol through Booklet. Figure 1b – Supervised Pelvic Floor Muscle Training Protocol through Gametherapy.

This study added the recommendation of PFM contractions during the performance of pelvic exercises in the virtual games, with instructions of contracting the PFM at the beginning of the pelvic movement and maintaining it for the most possible time (up to 10 seconds), followed by PFM relaxation for 30 seconds and resuming the contraction in the same parameters during the

entire performance of exercises 2, 3, and 4 (PFMT with supervised gametherapy).

2.5 Outcome measures

2.5.1 Main outcome measures

Urinary symptoms

Stress urinary incontinence (complaint of involuntary urine loss due to physical effort)[1,2] or Mixed urinary incontinence (complaint of involuntary urine loss associated with urge and stress),[1,2] investigated with the ICIQ UI-SF,[17] which allows qualifying and quantifying urinary loss, reproducing its severity, and investigating its impact on the quality of life, and with the ICIQ-OAB,[18] which investigates the presence of overactive bladder symptoms (urge, frequency, nocturia, and urge incontinence) and its impact on the quality of life.

2.5.2 Secondary outcome measures

The secondary results were measured according to the functional parameters of the PFM assessed with digital palpation (power, endurance, repetitions, and fast PFM contractions according to the PERFECT scheme)[19]. Power is measured on a modified Oxford scale; Resistance is expressed as the period of up to 10 seconds, in which a maximum voluntary contraction can be maintained before the force is reduced by 35% or more; Repetition is the number of repetitions (up to 10) of the specific maximum voluntary contractions, allowing four seconds of rest between each contraction; and Fast is the number of repetitions of maximum voluntary contractions of one second (up to 10), measured after a brief rest (at least one minute).[19] The PFM surface electromyography (PFM sEMG) and 4D translabial ultrasound (4D TLUS) (bladder neck elevation and hiatal area reduction) were also used, as described by Martinho et al. (2020).[16]

Aiming to compare the groups, the following demographic, clinical, and personal characteristics were considered: reported skin color, marital status, level of education, the practice of physical activities, hormonal data (menopause, hormonal replacement therapy), obstetric data (pregnancies, type of delivery, number of episiotomies), age, and body mass index (BMI).

2.6 Sample

The sample was calculated by comparing both groups, considering the power of 80% and a significance level of 5% for the following outcomes: severity of urinary incontinence based on the ICIQ-UI-SF[17] (n=45 per group), PFM function based on *power* (n=45 per group) and *endurance* (n=54 per group) using the *PERFECT scheme,*[19] and hiatal area measured by ultrasound (n=54 per group).

2.7 Randomization

The women included in the study were randomly divided into two groups through a simple randomization process (computerized random numbers): control and experimental groups. The allocation of subjects was hidden by sequentially numbered, opaque, and sealed envelopes. After the assessment, the researcher opened the envelope attributed it to each participant, following the treatment process. Every participant was aware of the possibility of being allocated to either one of the groups.

A physical therapist researcher specialized in women's health, blind to the participant's personal, clinical, and obstetric data, carried out the physical PFM examination.

2.8 Statistical analysis

The analyses were conducted using the Per-Protocol (PP) and Intention-to-Treat (ITT) analysis methods. The variables presenting missing data were imputed with the Last Observation Carried Forward (LOCF) method.

The categorical variables were presented through absolute and relative frequencies and they were compared with Fisher's exact test. All continuous variables were described and compared using medians and non-parametric methods, respectively, considering they presented asymmetrical distribution. The medians of control and intervention groups (comparison between groups) were compared with the Kruskal-Wallis rank test. The different moments of the study (pre- and post-intervention) were compared with the paired Wilcoxon sign rank test. The effect sizes intra- and inter-group were also calculated from the paired Wilcoxon sign rank test and Mann-Whitney U statistics, respectively. The analyses were performed using the Stata 15.1 software at a 5% significance level ($p<0.05$). As suggested by Cohen[20], the norms for interpreting the effect-size values were divided into "small" (0.1-0.3), "medium" (0.4-0.5), and "large" (> 0.5) effect, and we standardized the r to identify them.

3. RESULTS

From the 100 eligible women, 33 in G_Control and 43 in G_Game completed the study, as represented in Figure 2.

CONSORT 2010 Flow Diagram

Enrollment

Assessed for eligibility (n= 210)

Excluded (n= 110)
Not meeting inclusion criteria (n= 34)
Declined to participate (n= 52)
Other reasons (n= 24)

Randomized (n= 100)

Allocation

Allocated to intervention - CONTROL GROUP (n= 50)
- Received allocated intervention (n= 50)
- Excluded (n= 0)

Allocated to intervention - GAMETHERAPY GROUP (n= 50)
- Received allocated intervention (n= 50)
- Excluded (n= 0)

Follow-Up

After 5 training weeks (n= 33)
Discontinued intervention (due to personal issues or transport difficulties) (n= 17)

After 5 training weeks (n= 43)
Discontinued intervention (due to personal issues or transport difficulties) (n= 7)

Analysis

Intention-to-Treat Analysis (n= 50)
- Analyzed by digital palpation (n=50) - Excluded (n=0)
- Analyzed by 4D TLUS (n=50) - Excluded (n=0)
- Analyzed by sEMG (n=50) - Excluded (n=0)

Per-Protocol Analysis (n= 50)
- Analyzed by digital palpation (n=33) - Excluded (n= 17) not completed the training protocol
- Analyzed by 4D TLUS (n=33) - Excluded (n= 17) not completed the training protocol
- Analyzed by sEMG (n=33) - Excluded (n= 17) not completed the training protocol

Intention-to-Treat Analysis (n= 50)
- Analyzed by digital palpation (n=50) - Excluded (n=0)
- Analyzed by 4D TLUS (n=50) - Excluded (n=0)
- Analyzed by sEMG (n=50) - Excluded (n=0)

Per-Protocol Analysis (n=50)
- Analyzed by digital palpation (n=43) - Excluded (n=7) not completed the training protocol
- Analyzed by 4D TLUS (n=43) - Excluded (n=7) not completed the training protocol
- Analyzed by sEMG (n=43) - Excluded (n=7) not completed the training protocol

Figura 7 (Artigo 4): Figure 2 - CONSORT flow diagram

Table 1 presents the characteristics of the study participants. The groups were considered homogeneous for demographic, personal, and clinical variables.

Tabela 10 (Artigo 4): Table 1. Clinical characteristics of the population studied

	G_Control (n=50)		G Game (n=50)		p-value[1]
	N (%)	95% CI	N (%)	95% CI	
DEMOGRAPHIC DATA					
Skin color					
White	39 (78.0)	64.3; 87.5	44 (88.0)	75.6; 94.6	0.287
Other	11 (22.0)	12.5; 35.7	6 (12.0)	5.4; 24.4	
Marital status					
Single	6 (12.0)	5.4; 24.4	11 (22.0)	12.5; 35.7	0.255
Married/Cohabitating	37 (74.0)	60.0; 84.4	29 (58.0)	43.9; 70.9	
Divorced/Widower	7 (14.0)	6.8; 26.8	10 (20.0)	11.0; 33.5	
Level of education					
Illiterate	1 (2.0)	0.3; 13.2	0 (0.0)	0.0; 0.0	0.382
Elementary school	14 (28.0)	17.2; 42.1	16 (32.0)	20.5; 46.2	
High school	10 (20.0)	11.0; 33.5	15 (30.0)	18.9; 44.2	
Higher education	25 (50.0)	36.3; 63.7	19 (38.0)	25.6; 52.2	
Physical activity					
Does not practice	21 (42.0)	29.1; 56.1	24 (48.0)	34.5; 61.8	0.581
Up to twice a week	11 (22.0)	12.5; 35.7	13 (26.0)	15.6; 40.0	
HORMONAL DATA					
Menopause					
No	21 (42.0)	29.1; 56.1	18 (36.0)	23.9; 50.2	0.838
Yes	29 (58.0)	43.9; 70.9	32 (64.0)	49.8; 76.1	
Hormonal replacement					
No	45 (90.0)	77.9; 95.8	41 (82.0)	68.7; 90.4	0.441
Yes	5 (10.0)	4.2; 22.1	9 (18.0)	9.6; 31.3	
OBSTETRIC DATA					
Pregnancies					
0	5 (10.0)	4.2; 22.1	6 (12.0)	5.4; 24.4	0.516
1	5 (10.0)	4.2; 22.1	8 (16.0)	8.1; 29.1	
2	17 (34.0)	22.2; 48.2	20 (40.0)	27.3; 54.2	
3	23 (46.0)	32.7; 59.9	16 (32.0)	20.5; 46.2	
Number of vaginal deliveries					
0	27 (54.0)	40.1; 67.3	28 (56.0)	42.0; 69.1	1.000
1	6 (12.0)	5.4; 24.4	6 (12.0)	5.4; 24.4	
2-3	17 (34.0)	22.2; 48.2	16 (32.0)	20.5; 46.2	
Number of cesarean deliveries					
0	22 (44.0)	30.9; 58.0	20 (40.0)	27.3; 54.2	0.057
1	9 (18.0)	9.6; 31.3	19 (38.0)	25.6; 52.2	
2-3	19 (38.0)	25.6; 52.2	11 (22.0)	12.5; 35.7	
Number of abortions					
0	36 (72.0)	57.9; 82.8	38 (76.0)	62.1; 85.9	0.820
1-2	14 (28.0)	17.2; 42.1	12 (24.0)	14.1; 37.9	
PERSONAL DATA	**Median**	**IQR**	**Median**	**IQR**	**p-value[2]**
Age (years)	48.5	41.0; 56.0	53.0	47.0; 59.0	0.051
BMI (kg/m2)	26.6	21.8; 29.0	25.8	23.3; 30.2	0.560

The table presents demographic and clinical data expressed in percentage (%) followed by the confidence interval (CI), using [1]Fisher's exact test and considering a 95% confidence interval (CI). It also presents personal data expressed in median and interquartile range (IQR), using [2]Kruskal-Wallis rank test and considering p-value<0.05.

Tables 2 and 3 present the intra- and inter-group analysis data, considering the ITT analyses. Appendix 1 and 2 present the intra- and inter-group analysis data, considering the PP analysis.

Primary outcome measurement

Comparing pre- and post-intervention periods, the intra-group analysis showed a reduction of urinary symptoms, especially in UI severity of both groups (large effect), as presented in Table 2, which also shows a significant difference between the groups (large effect) in the inter-group analysis after five weeks of PFMT, in which G_Game showed a greater reduction in UI impact.

Tabela 11 (Artigo 4): Table 2. Comparison of urinary symptoms in both groups, pre-and post-intervention, using the ICIQ UI-SF and ICIQ-OAB questionnaires, by Intention-to-Treat analysis.

		Intra-group analysis								Inter-group analysis	
		G_Control (n=50)				G_Game (n=50)					
		Median	**IQR**	**P value[1]**	**Effect size[3]**	**Median**	**IQR**	**P value[1]**	**Effect size[3]**	**P value[2]**	**Effect size[4]**
Intention-to-Treat	**ICIQ UI-SF**										
	Pre-intervention	14.0	13.0 - 16.0			14.5	12.0 - 18.0			0.934	0.495
	Post-intervention	10.5	6.0 - 14.0	**< 0.001**	0.600	4.5	0.0 - 9.0	**< 0.001**	0.860	**< 0.001**	0.728
	ICIQ-OAB										
	Pre-intervention	4.5	2.0 - 8.0			4.5	3.0 - 7.0			0.989	0.499
	Post-intervention	3.0	1.0 - 6.0	0.011	0.360	2.0	1.0 - 4.0	**< 0.001**	0.640	0.145	0.584

Legend: The table presents comparisons between pre- and post-intervention periods, comparing the times ([1]Wilcoxon rank test) and groups ([2]Kruskal-Wallis rank test). The data is presented with medians and interquartile range (IQR), according to intention-to-treat analysis. Effect sizes were calculated both for intra- ([3]Paired signed-rank Wilcoxon test) and inter-group comparisons ([4]Mann-Whitney U statistic).
ICIQ UI-SF: International Consultation on Incontinence Questionnaire Urinary Incontinence - Short Form
ICIQ-OAB: International Consultation on Incontinence Questionnaire Urinary Incontinence - Overactive Bladder

Secondary outcome measurement

Table 3 shows, in the intra-group analysis pre- and post-intervention, increased power (G_Control: medium effect and G_Game: large effect) and endurance (G_Control: medium effect and G_Game: large effect), and increased repetition (medium effect) and fast PFM contraction (medium effect) in G_Game. The group comparisons in the inter-group analysis after five weeks of PFMT showed a difference between the groups regarding endurance (medium effect) and repetition (medium effect), showing that G_Game

obtained a significantly greater improvement and there was no significant difference in power and fast PFM contractions.

Tabela 12 (Artigo 4): Table 3. Investigation of PFM function in both pre- and post-intervention groups, through digital palpation, transperineal ultrasound (4D TLUS), and sEMG, by Intention-to-Treat analysis.

		Intra-group analysis								Inter-group analysis	
		G_Control (n=50)				G_Game (n=50)					
		Median	IQR	P value[1]	Effect size[3]	Median	IQR	P value[1]	Effect size[3]	P value[2]	Effect size[4]
Intention-to-Treat	**Palpation**										
	Power										
	Pre-intervention	2.0	2.0 - 3.0	**< 0.001**	0.374	2.0	2.0 - 3.0	**< 0.001**	0.536	0.848	0.511
	Post-intervention	3.0	2.0 - 3.0			3.0	3.0 - 3.0			0.051	0.383
	Endurance										
	Pre-intervention	3.0	2.0 - 4.0	**< 0.001**	0.419	3.0	2.0 - 4.0	**< 0.001**	0.525	0.963	0.497
	Post-intervention	4.0	3.0 - 5.0			5.0	3.0 - 6.0			**0.024**	0.368
	Repetition										
	Pre-intervention	4.0	3.0 - 5.0	0.493	0.069	4.0	3.0 - 5.0	**< 0.001**	0.413	0.489	0.460
	Post-intervention	4.0	3.0 - 6.0			5.0	4.0 - 7.0			**0.007**	0.340
	Fast										
	Pre-intervention	10.0	8.0 - 10.0	0.583	0.055	10.0	7.0 - 10.0	**< 0.001**	0.328	0.734	0.483
	Post-intervention	10.0	8.0 - 10.0			10.0	10.0 - 10.0			0.090	0.401
	4D TLUS										
	Bladder neck elevation										
	Pre-intervention	0.5	0.4 - 0.7	0.175	0.136	0.6	0.4 - 0.8	0.784	0.027	0.164	0.419
	Post-intervention	0.5	0.0 - 0.7			0.5	0.2 - 0.9			0.160	0.419
	Hiatal area reduction										
	Pre-intervention	18.0	8.7 - 25.8	0.247	0.156	19.0	12.3 - 26.2	0.679	0.041	0.475	0.458
	Post-intervention	16.3	8.7 - 22.4			21.2	9.7 - 31.0			0.071	0.395
	sEMG										
	Normalized RMS										
	Pre-intervention	90.9	85.5 - 94.1	0.277	0.109	92.2	87.9 - 95.1	0.081	0.175	0.247	0.432
	Post-intervention	92.1	86.6 - 94.3			93.6	89.6 - 96.1			0.098	0.403

Legend: The table presents comparisons between pre- and post-intervention periods, comparing the times ([1]Wilcoxon rank test) and groups ([2]Kruskal-Wallis rank test). The data is presented with medians and interquartile range (IQR), according to intention-to-treat analysis. Effect sizes were calculated both for intra- ([3]Paired signed-rank Wilcoxon test) and inter-group comparisons ([4]Mann-Whitney U statistic).

Table 3 also shows, in the intra-group analysis, no significant differences between the pre- and post-intervention periods for the sEMG and 4D TLUS data analyzed. In the inter-group analysis, the results were similar and there were no significant differences between the pre- and post-intervention periods for the sEMG and 4D TLUS data analyzed, except for the reduction of

hiatal area at post-intervention, which presented a significant difference between the groups.

4. DISCUSSION

Both PFMT protocols improved significantly the severity of urinary incontinence symptoms and the function of pelvic floor muscles when assessed clinically.

These findings confirm our hypothesis that supervised PFMT protocol gametherapy could be more effective in reducing urinary symptoms and improving PFM function in women with predominant SUI when compared to those who performed only unsupervised PFMT protocol, which reinforces the results found in previous studies.[11,14,15] However, it is up to us, the researchers, to discuss and understand the true role of adding gametherapy to PFMT.

In this study, we compared two PFMT protocols in women with prevalent SUI. The severity of UI symptoms was measured with the total score of the ICIQ UI-SF and the symptoms of an overactive bladder were measured with the total score of the ICIQ-OAB. The results show that after five weeks of PFMT, the women were clinically better concerning the symptoms of urinary loss, and, for having prevalent SUI, the symptoms of an overactive bladder were less affected in a predictable way.

Aiming to verify whether gametherapy could present an effect on the parameters of muscular function, we used three different assessment instruments. Digital palpation, a clinical method considered reliable because it was performed by one single researcher who was experienced, trained, and skilled, using the PERFECT scheme[19] as a parameter, which differentiates the parameters of power, endurance, repetition, and fast. This was followed by sEMG to verify the electrical activity of the pelvic muscles, although we currently believe the method has major limitations to refer to clinically significant responses. Finally, to add an anatomic and functional parameter in

increasing use in the physiotherapeutic field, the 4D TLUS was performed to measure the bladder neck elevation and the hiatal area reduction.[16]

Thus, the group that received treatment with gametherapy presented improvement in the different parameters of muscular function (power, endurance, repetition, and fast), which suggests that gametherapy may represent a strategy of association with conventional PFMT protocols to reduce urinary symptoms and improve PFM function in women with SUI.

The guidelines of the clinical practice at the ICS and IUGA recommend PFMT as the first line of conservative treatment for SUI and MUI (Evidence level: 1),[1,2,5] showing that the results of the supervised training tend to be superior to the training with little or no supervision (Degree of recommendation: A).[1,10]

Moreover, to be effective, any PFMT program needs to promote gain of strength, resistance, power, relaxation, or a combination of these parameters, which requires dedication, awareness by the women in training, and an adequate selection of the type of exercise and the training program used.[5,13] However, other factors seem to affect the effectiveness of PFMT, including rates of adherence, lack of motivation, and supervised or unsupervised follow-up of the training program. [7,11,12]

Thus, the adherence to the practice of physical exercises of isolated contraction of the PFM has been a great challenge faced by patients and professionals for the maintenance of results.[11,12] The rates of adherence to conservative treatment tend to decrease its effects in the long term. Therefore, efforts have been made so the training protocols are more interactive and dynamic, preventing a tedious routine that favors treatment dropout.[21]

With this purpose, researchers[11,13] have investigated the feasibility of using virtual reality in women with UI. Elliot et al.[11] observed a reduction in frequency and volume of urinary loss, which also reflected in the improvement of quality of life and urinary complaints, with good acceptance among the participants. Martinho et al. (2016)[14] performed a randomized controlled trial

with 60 women in post-menopause, comparing groups of women who performed PFMT with virtual reality and with a gym ball. They concluded that both were effective to improve PFM strength but the muscle resistance was higher in the virtual reality group. The study performed by Silva et al. (2016)[15] applying a PFMT protocol with gametherapy in young, continent, and nulliparous women concluded that gametherapy training allowed a better coactivation of PFM in response to the contraction of the abdominal transverse muscle.

In our study, the supervised PFMT protocol using gametherapy, adapted from Martinho et al. (2016)[14] and Silva et al. (2016)[15] followed the principles of exercise physiology for muscle training recommended by the American College of Sports Medicine (ACSM),[22] which include specificity, overload, and reversibility. Considering these recommendations, we added maximum voluntary contractions of PFM during the performance of pelvic exercises in the virtual games to provide more specificity to the protocol and improve muscular function. This potentially favored the increase in power, endurance, fast, and repetition in G_Game, while G_Control presented only an increase in power and endurance. However, the group comparison showed a significant increase in repetition and endurance only in G_Game.

The unsupervised PFMT protocol using the booklet was based on the PFMT program proposed by Mørkved and Bø[23] and on the recommendation of "The Knack Maneuver" proposed by Miller et al.[7] to prescribe PFMT associated with pre-contraction during effort situations, which could be sufficient to reduce the severity of urinary symptoms.

Our study showed not only the reduction of urinary loss symptoms but also the concomitant increase in the ability of PFM contraction in both groups, suggesting that the instructions given to the participants were sufficient to promote a perceptible clinical improvement. However, most participants of our study had a high level of education (as presented in Table 1, higher

education), which may have favored the understanding of the treatment proposed.

Two of the parameters studied (sEMG and 4D TLUS) showed no statistical significance in our findings, although we may currently believe that the highest clinical significance is truly in the symptomatic complaint of patients and the perception of muscular function identified by the hands of the physiotherapist.

Today, the applicability of sEMG for the specific assessment of PFM function is debatable and it was not found in the present study. The study by Dornowski et al.,[24] including 64 women with and without urinary symptoms and followed-up for six weeks of PFMT, increased electromyographic values of the PFM. Although the treatment time did not differ much from our protocol, the five-week follow-up may not have been sufficient to promote changes in the electromyographic findings of the PFM.

According to Junginger et al. (2010),[25] the functional contraction of PFM is sufficient to elevate the bladder neck and prevent urinary loss during activities of increased intra-abdominal pressure. Based on this premise, our study investigated the positioning of the bladder neck and the area of the genital hiatus before and after interventions, calculating bladder neck elevation and hiatal area reduction, as proposed by Martinho et al. (2020).[16] However, there were no differences in the pre- and post-intervention findings in both groups, which suggests that the training proposed was not sufficient to promote functional changes visible to the 4D TLUS examination. The limitation of training time could have promoted such effect, although Junginger et al.[25] have reported that the bladder neck elevation would represent a temporary, that is, functional response.

From the results obtained, it is suggested that gametherapy might be a supporting resource to PFMT, adding benefits to the clinical practice. However, we found some limitations in its application. In our study, we used clear tools to determine the adherence to the protocols, the population

included women with mild to moderate SUI from a waiting list for physiotherapeutic treatment and perhaps the results are not similar in women with more severe SUI. The protocol or even its duration was insufficient to promote functional adaptations that could be detected using sEMG and 4D TLUS of the PFM, which justifies the performance of further investigations until its indication is applied in the clinical practice.

5. CONCLUSION

The supervised PFMT protocol gametherapy showed to be a promising tool, able of reducing UI symptoms and improving the function of PFM in women with predominant SUI when compared to the unsupervised PFMT protocol.

Acknowledgments

We would like to thank the financial support of the Coordination for the Improvement of Higher Education Personnel (CAPES) - Finance Code 001, through the Post-graduation Program in Surgical Sciences of the State University of Campinas (UNICAMP), with support from the Federal University of Alfenas - UNIFAL-MG, the Research Support Foundation of the state of Minas Gerais - FAPEMIG (PPM-00471-18) and the University Center of Associated Colleges (UNIFAE), São João da Boa Vista/SP, Brazil.

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5. DISCUSSÃO GERAL

Reconhecida como uma das maiores preocupações no campo de saúde pública, a redução na qualidade de vida é uma condição estigmatizante,[102] podendo resultar em comportamentos limitadores, reduzindo assim a autoestima das mulheres com IU.[23] Estudos[19,81] têm relatado a ocorrência de depressão e isolamento social em pacientes incontinentes, tornando tal condição um problema de saúde de alta relevância, que deve ser amplamente discutido, em equipes multiprofissionais, de modo a reestabelecer as condições físicas e emocionais dessas mulheres. Além disso, a hipoatividade sexual é mais um dos desafios enfrentados pelas pacientes com IU, muitas vezes relacionada à ansiedade e medo de que ocorra uma perda involuntária durante a relação.[23]

Conforme estabelecido e amplamente recomendado pela IUGA/ICS, o TMAP supervisionado é o tratamento conservador de primeira linha para a IU, especialmente na IUE e IUM, com elevado nível de evidência.[16,12] Essas mesmas diretrizes propõem ainda que a melhora relatada pelas pacientes, em termos de sintomas urinários e impacto na qualidade de vida, deve ser considerada como medida primária de resultado em futuras investigações.

Apesar disso, a baixa adesão aos programas de TMAP é uma dificuldade frequentemente enfrentada por profissionais no mundo todo, que reflete num importante desafio para a melhora das pacientes[118]. Neste contexto, pesquisadores do mundo todo têm buscado novos recursos terapêuticos que possam impactar positivamente na redução das queixas urinárias relatadas pelas pacientes, na função dos MAP e na melhora da qualidade de vida dessas mulheres.

Dentre esses recursos, têm sido discutida a aplicabilidade da tecnologia em mulheres com disfunções do assoalho pélvico que apresentam sintomas de IUE e IUM. Considerando essa possibilidade, encontram-se

disponíveis estudos de viabilidade e resultados encontrados em programas de TMAP por meio de realidade virtual (gameterapia) e terapia de lembrete (App).

Considerando que o número de Apps desenvolvidos especificamente para a saúde vem crescendo exponencialmente, – mais de 100.000 Apps nesta categoria estão disponíveis nas plataformas *Android* e *IOS*[120] – realizamos uma revisão sistemática para avaliar os possíveis impactos da terapia de lembrete (App) no controle da IU, por meio de TMAP.

Foram realizadas buscas em oito bases de dados, tendo sido incluídos apenas três estudos elegíveis,[6,111,11] observando redução dos sintomas urinários em todos eles, e redução nos escores de qualidade de vida específicos para a IU em dois deles, enquanto um apresentou aumento nos escores.

Baseado nisso, após criteriosa análise dos estudos inclusos, pudemos observar redução significativa no escore do ICIQ UI-SF, ICIQ-VS e QUID quando se comparou os participantes do grupo intervenção (App) ao grupo controle. Um ensaio clínico randomizado[111] realizado na Austrália, verificou redução dos sintomas urinários pelo escore do questionário ICIQ UI-SF de 8,6 – 12,0 para 3,0 – 4,5 em pacientes submetidas a exercícios dos MAP convencionais, sem uso de Apps. De maneira semelhante, isso pode ser observado no grupo intervenção (App) do nosso trabalho, no qual a diferença média padronizada do período pós-intervenção atingiu 1.32 quando comparado ao período pré-intervenção. Isso poderia ser explicado pela facilidade de realizar os exercícios em casa, sem a necessidade de deslocamento até o consultório.[106] Contudo, é importante ressaltar que a terapia de lembrete não substitui o acompanhamento profissional, sendo função do fisioterapeuta promover o monitoramento dos pacientes mesmo que à distância.

Pudemos perceber ainda que o grupo de intervenção (App) obteve redução nos escores dos questionários ICIQ-VS-QoL e ICIQ-LUTSQoL, sendo possível inferir que, com a adesão ao tratamento e a melhora dos sintomas,

as pacientes se sentem mais confiantes para realizar suas atividades rotineiras, recuperando a autoestima e, consequentemente, a qualidade de vida.

Apesar dos possíveis benefícios, ainda há poucos estudos sobre o efeito da gameterapia no controle da IU. Com o objetivo de investigar a influência do TMAP por meio de gameterapia no tratamento conservador da IU, e considerando a complementação de nosso entendimento a respeito da eficácia dos recursos tecnológicos na redução dos sintomas urinários, função dos MAP e melhora da qualidade de vida de pacientes com IU, realizamos ainda uma revisão sistemática da literatura. Similarmente à primeira revisão sistemática desenvolvida para investigação da terapia de lembrete na IU, foram realizadas buscas em onze bases de dados, tendo sido elegíveis apenas três estudos.[40,43,15]

Mesmo com poucas evidências científicas, essa revisão sistemática sugeriu que o uso da gameterapia associada aos protocolos de TMAP têm apresentado resultados promissores. Os estudos incluídos relataram redução significativa dos sintomas urinários avaliados por meio do questionário ICIQ UI-SF e pelos escores de pad-teste de uma hora, além de melhora na adesão das participantes (apesar de apenas um estudo ter relatado análise das taxas de adesão).[40,43,15] Possivelmente, a facilidade na utilização e a interação gerada entre os jogos virtuais e as participantes, represente um aspecto positivo na aceitação ao recurso terapêutico, o que pode ter refletido na melhora da adesão ao programa de treinamento.

Estudos prévios realizados com mulheres assintomáticas para IU, corroboram com esses resultados, tendo sido verificados também melhora da função e coativação dos MAPs, sugerindo que esses resultados possam ser similares em mulheres com queixas urinárias.[107,78]

Não foi possível a realização de metanálise em nenhuma das revisões sistemáticas, uma vez que poucos estudos preencheram os critérios de elegibilidade, mesmo tendo sido utilizadas estratégias de pesquisa

criteriosas e abrangente, sem restrições de idioma, ano ou status de publicação.

Alguns desses resultados foram confirmados nos estudos clínicos desenvolvidos nessa pesquisa. No primeiro ensaio clínico aleatorizado, com o objetivo de investigar a viabilidade do TMAP por meio da gameterapia sobre os sintomas de IU, avaliados por meio do questionário ICIQ UI-SF, e a função dos MAP, avaliada por meio de palpação digital - todas os participantes experimentaram alívio dos sintomas urinários. No entanto, a melhora na função dos MAP, mais especificamente, na força muscular, foi observada apenas no grupo gameterapia. Com alto índice de concordância na literatura científica, a melhora na função dos MAP após programas de treinamento muscular, é proveniente do incremento na força, resistência e coordenação desse grupo muscular, contribuindo para a melhora na função de suporte exercida pelos MAPs e fechamento do esfíncter uretral, com consequente reflexo no controle dos sintomas urinários.[3,16,52,36,32] A melhora na funcionalidade dos MAP pode ser explicada pelas adaptações neurais e morfológicas que ocorrem durante um período de realização dos exercícios.[91] Além disso, a contração dos MAP realizada de forma correta, no sentido de "apertar" e "elevar", tende a promover aumento da pressão uretral, favorecendo a contenção urinária.[89]

Sugerimos ainda que a redução dos sintomas urinários observada por ambos os grupos, possivelmente apresente forte relação com as recomendações recebidas durante a avaliação fisioterapêutica, bem como com a cartilha de exercícios domiciliares que ambos os grupos receberam.

Após constatada a viabilidade da associação da gameterapia ao protocolo de TMAP, realizamos um ensaio clínico aleatorizado com 100 mulheres alocadas em grupo controle (n=50) e grupo gameterapia (n=50), utilizando três diferentes instrumentos de avaliação: palpação digital, utilizando como parâmetro o esquema PERFECT[70] (*power, endurance, repetition* e *fast*), seguido de sEMG e 4D TLUS.[77]

Após cinco semanas de intervenção, ambos os grupos apresentaram redução da severidade dos sintomas urinários, verificado pelos escores de ICIQ UI-SF. De modo similar ao estudo de viabilidade, adicionalmente, o TMAP por meio da gameterapia, apresentou melhora em todos os parâmetros da função muscular (power, endurance, repetition e fast), sugerindo que a gameterapia possa ser um recurso efetivo na associação aos protocolos de TMAP convencionais, em mulheres com IUE. A possibilidade de combinar as estratégias da gameterapia, permitindo a interatividade por meio de movimentos lúdicos, bem como a facilidade de realizar os exercícios dos MAP em casa, são atrativos que merecem atenção.

Neste contexto, o uso das tecnologias, a exemplo da realidade virtual e do uso de Apps, têm se mostrado perfeitamente aplicável no gerenciamento da IU, tendo em vista que o programa de exercícios pode ser realizado no conforto de sua residência de maneira lúdica e acessível,[40] com potenciais efeitos na melhora da função dos MAP e na redução dos sintomas urinários.

Assim, nossos resultados sugerem que a gameterapia e o uso de Apps por meio de terapia de lembrete podem impactar positivamente os resultados obtidos com o tratamento conservador de IU. Contudo, o acompanhamento profissional ainda é imprescindível, cabendo ao fisioterapeuta o monitoramento, mesmo que à distância, dos pacientes.

6. CONCLUSÃO

1. O uso de Apps tem mostrado impacto positivo no controle da IU, promovendo estratégias de TMAP com consequente redução dos sintomas, melhora da qualidade de vida e da adesão das participantes;

2. A gameterapia como estratégia de TMAP oferece benefícios as mulheres com IU, incluindo redução de sintomas urinários, redução dos escores de Pad Test de uma hora, com melhoria dos aspectos neuropsicológicos. Seus resultados tendem a ser similares ao TMAP convencional;

3. A viabilidade da utilização da gameterapia, em mulheres climatéricas com IUE ou IUM, foi identificada observando adesão dos participantes, alívio dos sintomas urinários e melhora da função do PFM;

4. Assim, o protocolo de TMAP supervisionado por meio de gameterapia mostrou-se ser uma ferramenta promissora, capaz de reduzir os sintomas de IU e melhorar a função dos MAP, em mulheres com IUE predominante, quando comparado ao TMAP não supervisionado.

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8. APÊNDICES

Apêndice 1 (Artigo1): Appendix 1 - Strategies for database search.

Database	Search Strategy (June, 2019)	Results
PubMed http://www.ncbi.nlm.nih.gov/pubmed	("Urinary Incontinence"[All Fields] OR "Urinary Stress Incontinence"[All Fields] OR "Pelvic Floor"[All Fields] OR "Pelvic Floor Muscle"[All Fields] OR "Pelvic Floor Training"[All Fields]) AND ("Woman"[All Fields] OR "Women"[All Fields] OR "Girl"[All Fields] OR "Female"[All Fields]) AND ("Mobile"[All Fields] OR "Portable"[All Fields] OR "Eletronic"[All Fields] OR "eHealth"[All Fields] OR "mHealth"[All Fields] OR "app"[All Fields] OR "Software"[All Fields] OR "Reminder Therapy"[All Fields] OR "Programme"[All Fields] OR "Program"[All Fields] OR "System"[All Fields])	3.858
SciELO http://www.scielo.org/	("Urinary Incontinence") AND ("app" OR "Software" OR "Programme" OR "Program" OR "System")	120
	("Pelvic Floor Exercises") AND ("app" OR "Software" OR "Programme" OR "Program" OR "System")	0
	("Urinary Stress Incontinence") AND ("app" OR "Software" OR "Programme" OR "Program" OR "System")	56
	("Pelvic Floor Training") AND ("app" OR "Software" OR "Programme" OR "Program" OR "System")	6
LILACS http://lilacs.bvsalud.org/	("Urinary Incontinence") AND ("Mobile" OR "Portable" OR "Eletronic" OR "eHealth" OR "mHealth" OR "app" OR "Software" OR "Reminder Therapy" OR "Programme" OR "Program" OR "System")	0
	tw:(("urinary incontinence") AND ("app" OR "software" OR "programme" OR "program" OR "system")) AND (instance: "regional") AND (db: ("LILACS"))	148
	("Urinary Stress Incontinence") AND ("Mobile" OR "Portable" OR "Eletronic" OR "eHealth" OR "mHealth" OR "app" OR "Software" OR "Reminder Therapy" OR "Programme" OR "Program" OR "System")	0
	tw:(("Pelvic Floor") AND ("app" OR "software" OR "programme" OR "program" OR "system")) AND (instance: "regional") AND (db: ("LILACS"))	60
Web of Science http://apps.webofknowledge.com/	(("Urinary Incontinence" OR "Urinary Stress Incontinence" OR "Pelvic Floor" OR "Pelvic Floor Muscle" OR "Pelvic Floor Training") AND ("Woman" OR "Women" OR "Girl" OR "Female") AND ("Mobile" OR "Portable" OR "Eletronic" OR "eHealth" OR "mHealth" OR "app" OR "Software" OR "Reminder Therapy" OR "programme" OR "program" OR "System"))	2.082
Embase http://www.embase.com	('urinary incontinence' OR 'urinary stress incontinence' OR 'pelvic floor' OR 'pelvic floor muscle' OR 'pelvic floor training') AND ('woman' OR 'women' OR 'girl' OR 'female') AND ('mobile' OR 'portable' OR 'eletronic' OR 'ehealth' OR 'mhealth' OR 'app' OR 'software' OR 'reminder therapy' OR 'programme' OR 'program' OR 'system')	8.944
OpenGrey http://www.opengrey.eu/	("Urinary Incontinence" OR "Urinary Stress Incontinence" OR "Pelvic Floor" OR "Pelvic Floor Muscle" OR "Pelvic Floor Training") AND ("Woman" OR "Women" OR "Girl" OR "Female") AND ("Mobile" OR "Portable" OR "Eletronic" OR "eHealth" OR "mHealth" OR "app" OR "Software" OR "Reminder Therapy" OR "Programme" OR "Program" OR "System")	7
OpenThesis http://www.openthesis.org/	("Urinary Incontinence") AND ("Mobile" OR "Portable" OR "Eletronic" OR "eHealth" OR "mHealth" OR "app" OR "Software" OR "Reminder Therapy" OR "programme" OR "program" OR "System")	3
OATD https://oatd.org/	("Urinary Incontinence" OR "Urinary Stress Incontinence") AND ("Woman" OR "Women" OR "Girl" OR "Female") AND ("Mobile" OR "Portable" OR "Eletronic" OR "eHealth" OR "mHealth" OR "app" OR "Software" OR "programme" OR "program" OR "System")	0
TOTAL		15.284

Apêndice 2 (Artigo 1): Appendix 2 – Studies excluded in the reading of the full texts and the reasons for exclusion (n=7).

	Study excluded	Reason for exclusion
1.	Wilson et al., 1998	Not related to apps.
2.	Ahlund et al., 2013	Not related to apps.
3.	Hirakawa et al., 2013	Not related to apps.
4.	Alves et al., 2015	Not related to apps.
5.	Andrade et al., 2015	Not related to apps.
6.	Starr et al., 2016	Not a randomized clinical trial.
7.	Grimes et al., 2019	Not focus in pelvic floor muscle training.

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Apêndice 3 (Artigo 1): Appendix 3 - Risk of bias assessed by the Joanna Briggs Institute Critical Appraisal Tools for use in JBI Systematic Reviews for Randomized Controlled Trials[20].

Authors	Q.1	Q.2	Q.3	Q.4	Q.5	Q.6	Q.7	Q.8	Q.9	Q.10	Q.11	Q.12	Q.13	% yes/ risk
Sjöstrom, et al., 2013[22]	√	--	√	NA	--	--	--	√	√	√	√	√	√	61,53% yes (moderate risk of bias)
Asklund, et al., 2016[23]	√	√	√	NA	--	--	--	√	√	√	√	√	√	69,23% yes (moderate risk of bias)
Araujo, et al., 2019[13]	√	√	√	NA	--	--	√	√	√	√	√	√	√	76,92% yes (low risk of bias)

Q.1) Was true randomization used for assignment of participants to treatment groups? Q.2) Was allocation to treatment groups concealed? Q.3) Were treatment groups similar at the baseline? Q.4) Were participants blind to treatment assignment? Q.5) Were those delivering treatment blind to treatment assignment? Q.6) Were outcomes assessors blind to treatment assignment? Q.7) Were treatment groups treated identically other than the intervention of interest? Q.8) Was follow up complete and if not, were differences between groups in terms of their follow up adequately described and analysed? Q.9) Were participants analysed in the groups to which they were randomized? Q.10) Were outcomes measured in the same way for treatment groups? Q.11) Were outcomes measured in a reliable way? Q.12) Was appropriate statistical analysis used? Q.13) Was the trial design appropriate, and any deviations from the standard RCT design (individual randomization, parallel groups) accounted for in the conduct and analysis of the trial? √ - Yes; -- - No; U – Unclear; NA - Not Applicable.

Apêndice 4 (Artigo 2): Appendix 1 - Strategies for database search.

Database	Search strategy (March, 2020)	Results
PubMed http://www.ncbi.nlm.nih.gov/pubmed	("Urinary Incontinence"[All Fields] OR "Urinary Stress Incontinence"[All Fields] OR "Pelvic Floor"[All Fields] OR "Pelvic Floor Muscle"[All Fields] OR "Pelvic Floor Training"[All Fields] OR "Pelvic muscle"[All fields]) AND ("Virtual reality"[All fields] OR "gametherapy"[All Fields] OR "Virtual Reality exposure"[All Fields] OR "videogame"[All Fields] OR "Virtual Reality Exposure Therapy"[All Fields] OR "Virtual Reality Therapy"[All Fields] OR "Virtual Reality Immersion Therapy"[All Fields] OR "Video Games"[All Fields])	22
Scopus www.scopus.com	("Urinary Incontinence" OR "Urinary Stress Incontinence" OR "Pelvic Floor" OR "Pelvic Floor Muscle" OR "Pelvic Floor Training" OR "Pelvic muscle") AND ("Virtual reality" OR "gametherapy" OR "Virtual Reality exposure" OR "videogame" OR "Virtual Reality Exposure Therapy")	40
SciELO http://www.scielo.org/	"pelvic muscle" AND "Virtual reality"	1
	"Urinary incontinence" AND "Virtual reality"	0
	"Pelvic muscle" AND "videogame"	0
	"Pelvic Floor Training" AND "Virtual reality"	1
LILACS http://lilacs.bvsalud.org/	tw:("pelvic muscle" AND "Virtual reality") AND (instance:"regional") AND (db:("LILACS"))	2
	tw:("Urinary incontinence" AND "Virtual reality") AND (instance:"regional") AND (db:("LILACS"))	1
	tw:("Pelvic muscle" AND "videogame") AND (instance:"regional") AND (db:("LILACS"))	0
	tw:("Pelvic floor" AND "virtual reality") AND (instance:"regional") AND (db:("LILACS"))	2
Web of Science http://apps.webofknowledge.com/	(("Urinary Incontinence" OR "Urinary Stress Incontinence" OR "Pelvic Floor" OR "Pelvic Floor Muscle" OR "Pelvic Floor Training") AND ("Virtual reality" OR "gametherapy" OR "Virtual Reality exposure" OR "videogame" OR "Virtual Reality Exposure Therapy"))	30
Embase http://www.embase.com	('urinary incontinence'/exp OR 'urinary incontinence' OR 'urinary stress incontinence'/exp OR 'urinary stress incontinence' OR 'pelvic floor'/exp OR 'pelvic floor' OR 'pelvic floor muscle'/exp OR 'pelvic floor muscle' OR 'pelvic floor training'/exp OR 'pelvic floor training') AND ('virtual reality'/exp OR 'virtual reality' OR 'gametherapy' OR 'virtual reality exposure' OR 'videogame'/exp OR 'videogame' OR 'virtual reality exposure therapy'/exp OR 'virtual reality exposure therapy')	48
Cochrane Library https://www.cochranelibrary.com/	("Urinary Incontinence" OR "Urinary Stress Incontinence" OR "Pelvic Floor" OR "Pelvic Floor Muscle" OR "Pelvic Floor Training") AND ("Virtual reality" OR "gametherapy" OR "Virtual Reality exposure" OR "videogame" OR "Virtual Reality Exposure Therapy")	14
LIVIVO https://www.livivo.de/	(Urinary Incontinence OR Urinary Stress Incontinence OR Pelvic Floor OR Pelvic Floor Muscle OR Pelvic Floor Training) AND (Virtual reality OR gametherapy OR Virtual Reality exposure OR videogame OR Virtual Reality Exposure Therapy)	58
OpenGrey http://www.opengrey.eu/	("Urinary Incontinence" OR "Urinary Stress Incontinence" OR "Pelvic Floor" OR "Pelvic Floor Muscle" OR "Pelvic Floor Training") AND ("Virtual reality")	0
OpenThesis http://www.openthesis.org/	("Urinary Incontinence" OR "Urinary Stress Incontinence" OR "Pelvic Floor" OR "Pelvic Floor Muscle" OR "Pelvic Floor Training") AND ("Virtual reality")	6
OATD https://oatd.org/	("Urinary Incontinence" OR "Urinary Stress Incontinence" OR "Pelvic Floor" OR "Pelvic Floor Muscle" OR "Pelvic Floor Training") AND ("Virtual reality")	2
TOTAL		227

Apêndice 5 (Artigo 2): Appendix 2 – Studies excluded in the full-text analysis and the reasons for exclusion.

Author, year	Reason for exclusion
Steenstrup *et al*., 2014[28]	Outside the objective
Botelho *et al*., 2015[15]	Included healthy patients
Silva, 2015[36]	Thesis with results from a published study
Martinho *et al*., 2016[33]	Included healthy patients
Silva *et al*., 2016[29]	Included healthy patients
Villot *et al.*, 2016[37]	Outside the objective

Apêndice 6 (Artigo 2): Appendix 3 - Risk of bias assessed by the Joanna Briggs Institute Critical Appraisal tools for use in JBI systematic reviews - checklist for analytical cross-sectional studies.

Author, year	Q.1	Q.2	Q.3	Q.4	Q.5	Q.6	Q.7	Q.8	% of yes/risk
Elliott *et al.*, 2015[12]	√	√	√	√	U	U	√	√	75% yes/low risk
Fraser *et al.*, 2014[13]	√	√	√	√	U	U	√	√	75% yes/low risk

Q.1: Were the inclusion criteria in the sample clearly defined?; Q.2: Were the study subjects and the setting described in detail?; Q.3: Was the exposure measured in a valid and reliable way?; Q.4: Were objective and standard criteria used for measuring the condition?; Q.5: Were confounding factors identified?; Q.6: Were strategies to deal with confounding factors stated?; Q.7: Were the outcomes measured in a valid and reliable way?; Q.8: Was there an appropriate statistical analysis?; √: yes; --: No.

Apêndice 7 (Artigo 2): Appendix 4 - Risk of bias assessed by the Joanna Briggs Institute Critical Appraisal tools for use in JBI systematic reviews - checklist for randomized clinical trials

Author, year	Q.1	Q.2	Q.3	Q.4	Q.5	Q.6	Q.7	Q.8	Q.9	Q.10	Q.11	Q.12	Q.13	% of yes/risk
Bezerra, 2018[20]	√	√	√	--	--	U	√	√	√	√	√	√	√	77% yes/low risk

Q.1: Was true randomization used for assigning participants to treatment groups?; Q.2: Was allocation to treatment groups concealed?; Q.3: Were treatment groups similar at the baseline?; Q.4: Were participants blind to treatment assignment?; Q.5: Were those delivering treatment blind to treatment assignment?; Q.6: Were outcome assessors blind to treatment assignment?; Q.7: Were treatment groups treated identically other than the intervention of interest?; Q.: Was follow-up complete and, if not, were differences between groups in terms of their follow-up adequately described and analyzed?; Q.9: Were participants analyzed in the groups to which they were randomized?; Q.10: Were outcomes measured in the same way for treatment groups?; Q.11: Were outcomes measured in a reliable way?; Q.12: Was there an appropriate statistical analysis?; Q.13: Was the trial design appropriate and were any deviations from the standard RCT design (individual randomization, parallel groups) accounted for in the conduct and analysis of the trial?; √: yes; --: No; U: Unclear.

Apêndice 8 (Artigo 4): Appendix 1 – Comparison of urinary symptoms in both groups, pre- and post-intervention, using the ICIQ UI-SF and ICIQ-OAB questionnaires, by Per-Protocol analysis.

Appendix 1. Comparison of urinary symptoms in both groups, pre-and post-intervention, using the ICIQ UI-SF and ICIQ-OAB questionnaires, by Per-Protocol analysis.

		Intra-group analysis								Inter-group estimates	
		G_Control (n=33)				G_Game (n=43)					
		Median	IQR	P value[1]	Effect size[3]	Median	IQR	P value[1]	Effect size[3]	P value[2]	Effect size[4]
Per-Protocol	**ICIQ UI-SF**										
	Pre-intervention	14.0	13.0 - 16.0	**< 0.001**	0.507	14.5	12.0 - 18.0	**< 0.001**	0.603	0.934	0.495
	Post-intervention	8.0	5.0 - 11.0			0.0	0.0 - 7.0			**< 0.001**	0.729
	ICIQ-OAB										
	Pre-intervention	4.5	2.0 - 8.0	0.006	0.255	4.5	3.0 - 7.0	**< 0.001**	0.492	0.989	0.499
	Post-intervention	3.0	0.0 - 4.0			2.0	1.0 - 3.0			0.483	0.547

Legend: The table presents comparisons between pre- and post-intervention periods, comparing the times ([1]Wilcoxon rank test) and groups ([2]Kruskal-Wallis rank test). The data is presented with medians and interquartile range (IQR) and according to per-protocol and intention-to-treat analyses. Effect sizes were calculated both for intra- ([3]Paired signed-rank Wilcoxon test) and inter-group comparisons ([4]Mann-Whitney U statistic).
ICIQ UI-SF: International Consultation on Incontinence Questionnaire Urinary Incontinence - Short Form
ICIQ-OAB: International Consultation on Incontinence Questionnaire Urinary Incontinence - Overactive Bladder

Apêndice 9 (Artigo 4): Appendix 2 – Investigation of PFM function in both pre- and post-intervention groups, through digital palpation, transperineal ultrasound (4D TLUS), and sEMG, by Per-Protocol analysis.

Appendix 2. Investigation of PFM function in both pre- and post-intervention groups, through digital palpation, transperineal ultrasound (4D TLUS), and sEMG, by Per-Protocol analysis.

		Intra-group analysis								Inter-group analysis	
		G_Control (n=33)				G_Game (n=43)					
		Median	IQR	P value[1]	Effect size[3]	Median	IQR	P value[1]	Effect size[3]	P value[2]	Effect size[4]
Per-Protocol	**Power**										
	Pre-intervention	2.0	2.0 - 3.0	**< 0.001**	0.374	2.0	2.0 - 3.0	**< 0.001**	0.534	0.848	0.511
	Post-intervention	3.0	2.0 - 3.0			3.0	3.0 - 3.0			0.055	0.371
	Endurance										
	Pre-intervention	3.0	2.0 - 4.0	**< 0.001**	0.410	3.0	2.0 - 4.0	**< 0.001**	0.517	0.963	0.497
	Post-intervention	4.0	3.0 - 5.0			5.0	4.0 - 6.0			0.079	0.382
	Repetition										
	Pre-intervention	4.0	3.0 - 5.0	0.383	0.087	4.0	3.0 - 5.0	**< 0.001**	0.414	0.489	0.460
	Post-intervention	4.0	3.0 - 6.0			5.0	4.0 - 8.0			**0.026**	0.350
	Fast										
	Pre-intervention	10.0	8.0 - 10.0	0.595	0.053	10.0	7.0 - 10.0	**< 0.001**	0.328	0.734	0.483
	Post-intervention	10.0	9.0 - 10.0			10.0	10.0 - 10.0			0.153	0.404
	4D TLUS										
	Bladder neck elevation										
	Pre-intervention	0.5	0.4 - 0.7	0.175	0.136	0.6	0.4 - 0.8	0.784	0.027	0.164	0.419
	Post-intervention	0.5	0.0 - 0.7			0.5	0.2 - 0.9			0.160	0.419
	Hiatal area reduction										
	Pre-intervention	18.0	8.7 - 25.8	0.239	0.118	19.0	12.3 - 26.2	0.627	0.049	0.475	0.458
	Post-intervention	16.3	7.7 - 21.3			22.0	7.3 - 31.2			**0.045**	0.363
	sEMG										
	Normalized RMS										
	Pre-intervention	90.9	85.5 - 94.1	0.295	0.105	92.2	87.9 - 95.1	0.139	0.148	0.247	0.432
	Post-intervention	92.4	87.4 - 94.4			94.3	90.7 - 96.1			0.066	0.373

Legend: The table presents comparisons between pre- and post-intervention periods, comparing the times ([1]Wilcoxon rank test) and groups ([2]Kruskal-Wallis rank test). The data is presented with medians and interquartile range (IQR) and according to per-protocol and intention-to-treat analyses. Effect sizes were calculated both for intra- ([3]Paired signed-rank Wilcoxon test) and inter-group comparisons ([4]Mann-Whitney U statistic).

9. ANEXOS

Anexo 1: Parecer do Consubstanciado CEP

COMITÊ DE ÉTICA EM PESQUISA DA UNICAMP - CAMPUS CAMPINAS

PARECER CONSUBSTANCIADO DO CEP

DADOS DO PROJETO DE PESQUISA

Título da Pesquisa: Treinamento dos músculos do assoalho pélvico feminino nos sintomas miccionais de IUE e IUMista

Pesquisador: Anita Bellotto Leme Nagib

Área Temática:

Versão: 2

CAAE: 41304914.9.0000.5404

Instituição Proponente: Hospital da Mulher Prof. Dr. José Aristodemo Pinotti - CAISM

Patrocinador Principal: Financiamento Próprio

DADOS DO PARECER

Número do Parecer: 1.012.691

Data da Relatoria: 07/04/2015

Apresentação do Projeto:

Esta proposta visa investigar o efeito do treinamento dos músculos do assoalho pélvico (TMAP) por meio de terapia de exposição à realidade virtual (TMAP_RV) sobre os sinais e intomas das disfunções uroginecológicas. Métodos: Serão recrutadas 56 mulheres portadoras de sintomas uroginecológicos, selecionadas do Ambulatório de Uroginecologia do CAISM/UNICAMP, após investigação da presença de sintomas urinários por meio do International Consultation on Incontinence Questionnaire – Urinary Incontinence Short Form (ICIQ-UI SF) e International Consultation on Incontinence Questionnaire – Overactive Bladder (ICIQ-OAB); sintomas vaginais por meio do International Consultation on Incontinence Questionnaire - Vaginal Symptoms (ICIQ VS) e investigação do impacto dos sintomas sobre a função sexual por meio do Índice de Função Sexual Feminino (IFSF). Todas as mulheres serão avaliadas por meio de exame físico (palpação digital e avaliação da presença de prolapsos), exame eletromiográfico dos músculos do assoalho pélvico e transverso do abdômen/obliquo interno, além de ultrassonografia tridimensional endovaginal (US_3D) para investigação funcional uroginecológica. Após o processo de avaliação, as mulheres receberão orientações de TMAP durante suas atividades de vida diária (TMAP_AVDs), e serão monitoradas por meio de diário de exercícios, por cinco semanas consecutivas, quando serão reavaliadas e convidadas a participar do TMAP_RV. Este será realizado individualmente,

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COMITÊ DE ÉTICA EM PESQUISA DA UNICAMP - CAMPUS CAMPINAS

Continuação do Parecer: 1.012.691

supervisionado por fisioterapeuta, com duração de 30 minutos, duas vezes por semana, totalizando 10 sessões terapêuticas. Após seu encerramento, as participantes serão reavaliadas para investigação do efeito dos treinamentos propostos. Análise Estatística: Os dados serão analisados estatisticamente através do teste t pareado, se os dados tiverem normalidade ou, teste de Wilcoxon, se os dados não tiverem normalidade. Resultados Esperados: Ambos os TMAP sejam eficazes para diminuir os sintomas urinários, entretanto, que o TMAP_RV somado ao TMAP_AVDs possa apresentar melhora não somente dos sintomas urinários, quanto aumento da atividade elétrica dos músculos do assoalho pélvico.

Objetivo da Pesquisa:

Objetivo Primário:

Investigar o efeito da terapia de exposição à realidade virtual sobre a função dos músculos do assoalho pélvico feminino quando associado ao treinamento por meio de orientações de AVDs.

Objetivo Secundário:

• Avaliar a função dos MAP, pré e pós intervenção.

• Avaliar a atividade elétrica dos MAP e dos músculos Transverso do Abdome / Obliquo Interno (Tra/OI), pré e pós intervenção.

• Avaliar a biometria do assoalho pélvico (medidas de espessura do músculo elevador do ânus e tamanho do hiato genital), pré e pós intervenção.

• Comparar as alterações anatômicas na musculatura do assoalho pélvico, pré e pós intervenção.

• Diagnosticar a presença de descenso da junção uretro vesical (JUV), pré e pós intervenção.

• Avaliar a presença de prolapsos urogenitais, pré e pós intervenção.

•Quantificar a urina perdida, pré e pós intervenção.

• Avaliar a presença de sintomas uroginecológicos por meio de questionários validados e específicos, pré e pós intervenção.

• Avaliar a postura pélvica, pré e pós intervenção.

Avaliação dos Riscos e Benefícios:

Riscos:

O risco é mínimo, incluindo desconforto para introduzir a sonda vaginal e alergia ao gel lubrificante íntimo, minimizado utilizando gel antialérgico.

Benefícios:

Como benefícios específicos às participantes do estudo, elas receberão avaliação e

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acompanhamento gratuitamente, instruções fisioterapêuticas preventivas sobre possíveis cuidados com o assoalho pélvico e a postura pélvica e desenvolverão semanalmente atividades de treinamento, com o objetivo de melhorar a postura pélvica e o equilíbrio do recinto abdomino-pélvico.Além dos benefícios gerados às participantes, espera-se desenvolver como fruto do presente estudo, literatura suficiente para o norteamento de processos de reabilitação virtual nesses distúrbios e introduzir um novo instrumento para ser utilizado na prática clínica em uroginecologia.

Comentários e Considerações sobre a Pesquisa:

Este protocolo se refere ao Projeto de Pesquisa intitulado "Treinamento dos músculos do assoalho pélvico feminino por meio de terapia de exposição à realidade virtual nos sintomas miccionais de IUE e IUM", cuja Pesquisadora responsável é a Mestre Anita Bellotto Leme Nagib com a orientação da pesquisadora Profa. Dra. Simone Botelho Pereira e co-orientação do Prof. Dr. Cássio Luís Zanettini Riccetto. A pesquisa embasará a Tese de Doutorado da pesquisadora. A Instituição Proponente é a Faculdade de Ciências Medicas - UNICAMP. Segundo as Informações Básicas do Projeto, a pesquisa tem orçamento estimado em R$ 4.873,00 (Quatro mil e oitocentos e setenta e três reais) e o cronograma apresentado contempla início do estudo para março de 2015, com término em novembro de 2016. Serão abordados ao todo 56 pessoas, sendo 28 TMAP por meio de orientações de AVDs(TMAP_AVDs) e 28 TMAP por meio de terapia de exposição à realidade. Este projeto contempla aplicação de washout: O TMAP_AVDs será iniciado imediatamente após a AV_1, pelo período de cinco semanas consecutivas, sendo realizado durante rotina domiciliar e monitorado por meio de diário de exercícios. Este programa será considerado como controle.

Considerações sobre os Termos de apresentação obrigatória:

A pesquisadora anexou os seguintes termos de apresentação obrigatório:

1. A folha de rosto confere com o título do projeto de pesquisa e apresenta a assinatura do pesquisador responsável e do responsável pela instituição, mas a mesma contempla data de assinatura de 16/10/2014;
2. O cronograma está adequado conforme compromisso assumido pela pesquisadora com a resolução 466/12 do CNS/MS. A data do recrutamento para coleta de dados terá início em 01/08/2015;
3. Orçamento no valor de RR 4.873,00;
4. Termo de Consentimento Livre e Esclarecido (TCLE);
5. Projeto de Pesquisa, com finalidade de doutorado, anexado à Plataforma Brasil;

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Continuação do Parecer: 1.012.691

6. Aprovação da COMISSÃO DE PESQUISA DO CAISM, sob número 054/2014;
7. Apêndice 2- Avaliação Uroginecológica;
8. Apêndice 3- Diário Miccional

Recomendações:

Conclusões ou Pendências e Lista de Inadequações:
Lista de pendências e inadequações emitidas no parecer CEP Nº984.166 em 24/02/2015:

1- A folha de rosto deve ser assinada pelo diretor CAISM, pois a seleção das voluntárias será realizada no Ambulatório de Urologia Feminina - Ambulatório de Uroginecologia do Centro de Atenção à Saúde Integral da Mulher – CAISM/UNICAMP.
Resposta: Foi anexada a folha de rosto assinada pela Diretora da CAISM
Análise:Pendência atendida

2- Segundo as Informações básicas do projeto o n é de 56 participantes e o tamanho amostral descrito no projeto detalhado é de 55 (item 5.2). Solicitamos uniformidade no valor do tamanho amostral descrito nas Informações básicas do projeto e no projeto detalhado.
Resposta: A correção foi realizada "Tamanho da Amostra no Brasil: 56"
Análise:Pendência atendida

Situação do Parecer:
Aprovado

Necessita Apreciação da CONEP:
Não

Considerações Finais a critério do CEP:
- O sujeito de pesquisa deve receber uma cópia do Termo de Consentimento Livre e Esclarecido, na íntegra, por ele assinado.

- O sujeito da pesquisa tem a liberdade de recusar-se a participar ou de retirar seu consentimento em qualquer fase da pesquisa, sem penalização alguma e sem prejuízo ao seu cuidado.

- O pesquisador deve desenvolver a pesquisa conforme delineada no protocolo aprovado. Se o pesquisador considerar a descontinuação do estudo, esta deve ser justificada e somente ser realizada após análise das razões da descontinuidade pelo CEP que o aprovou. O pesquisador deve

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aguardar o parecer do CEP quanto à descontinuação, exceto quando perceber risco ou dano não previsto ao sujeito participante ou quando constatar a superioridade de uma estratégia diagnóstica ou terapêutica oferecida a um dos grupos da pesquisa, isto é, somente em caso de necessidade de ação imediata com intuito de proteger os participantes.

- O CEP deve ser informado de todos os efeitos adversos ou fatos relevantes que alterem o curso normal do estudo. É papel do pesquisador assegurar medidas imediatas adequadas frente a evento adverso grave ocorrido (mesmo que tenha sido em outro centro) e enviar notificação ao CEP e à Agência Nacional de Vigilância Sanitária – ANVISA – junto com seu posicionamento.

- Eventuais modificações ou emendas ao protocolo devem ser apresentadas ao CEP de forma clara e sucinta, identificando a parte do protocolo a ser modificada e suas justificativas. Em caso de projetos do Grupo I ou II apresentados anteriormente à ANVISA, o pesquisador ou patrocinador deve enviá-las também à mesma, junto com o parecer aprovatório do CEP, para serem juntadas ao protocolo inicial.

- Relatórios parciais e final devem ser apresentados ao CEP, inicialmente seis meses após a data deste parecer de aprovação e ao término do estudo.

CAMPINAS, 07 de Abril de 2015

Assinado por:
Renata Maria dos Santos Celeghini
(Coordenador)

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Anexo 2: Parecer do Comissão de Pesquisa DTG/CAISM

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Comissão de Pesquisa do DTG / CAISM

Campinas, 02 de dezembro de 2014.

Protocolo nº: 054/2014

O protocolo de pesquisa *"Treinamento dos músculos do assoalho pélvico feminino por meio de terapia de exposição á realidade virtual nos sintomas miccionais de IUE e IUM "*, da pesquisadora Anita Belloto Leme Nagib, foi aprovado pela Comissão de Pesquisa do DTG/CAISM em 02/12/2014.

Atenciosamente,

PROF. DR. JOSÉ GUILHERME CECATTI
Presidente da Comissão de Pesquisa do DTG/CAISM

Rua Alexander Flemming, n.º101 – Cidade Universitária Zeferino Vaz – Campinas-SP
Fone: (19) 3521-9400
comissaopesquisa@caism.unicamp.br

Anexo 3: Ficha de Avaliação Uroginecológica

ANEXO 3 - AVALIAÇÃO UROGINECOLÓGICA

FISIOTERAPIA – UROLOGIA FEMININA

DATA: __ __ / __ __ / __ __ HC __ __ __ __ __ __ __

Nome: _____

Endereço:_____ nº __ __ __ __ __

Bairro:_____Cidade:_____ Estado: _____

Telefone fixo: (___) _____ - _____ Telefone Celular: (___) _____ - _____ E-mail:_____@_____

Sexo: Masculino Feminino **Cor da pele**: Branca Preta Outra **Estado Civil:** Solteiro Casado Divorciado Viúvo Outro

Data Nascimento: __ __ / __ __ / __ __ **Idade**: __ __ anos **Escolaridade (completo/incompleto):** não alfabetizado 1º grau 2º grau 3º grau

Profissão: _____ **Renda familiar:** 1-2 SM 3-4 SM +4 SM (salário mínimo) **Peso:** __ __, __ kg **Altura:** __, __ __m

ANAMNESE:

QP:_____

HMA:_____

_____

HP:_____

Doenças associadas: **N[1]** **S:** cardiovascular[1] (HAS) respiratória[2] (tosse crônica) neurológica[3] (miopatia) endócrina[4] (diabetes) digestiva[5] urológica[6] ginecológica[7] psiquiátrica[7] ortopédica[8] reumato[9]

Medicamentos:_____

ANTECEDENTES:

OBSTETRICOS: Gestações:__ __ Partos vaginais: __ __ Cesáreas: __ __ Abortos: __ __ Partos domiciliares: N[1] S[2] Fórceps: N[1] S[2]

Episiotomia: __ __ >peso RN: __ __ Kg. >aumento de peso gestacional: __ __ Kg. Data do último parto: __ __ / __ __ / __ __

CIRURGICOS: Nº cirurgias previas para IUE:__ __ Histerectomia: N[1] S[2] Outras cirurgias prévias: _____

HORMONAIS: Menopausa: N[1] S: <1 ano[2] 1-5 anos[3] 5-10 anos[4] >10 anos[5] Data da ultima menstruação: __ __ / __ __ / __ __

Reposição Hormonal: N[1] S[2] Uso de Anticoncepcional: N[1] S[2] Durante quanto tempo: __ __ anos

HÁBITOS: **ATIVIDADE FÍSICA: Pratica AF: N[1] S[2]** Tempo: __ __ (meses) Frequência: __ __ (semanal) Especificar:_____

Treinamento MAP: N[1] S[2] Frequência: __ __ (semanal) Treinamento Abdome: N[1] S[2] Frequência: __ __ (semanal)

SINTOMAS: Tipo de queixa: **Miciconal[1]** **Intestinal[2]** **Sexual[3]** **Dor Pelvica[4]** **Prolapso genital[5]** **Outra[6]** Duração: __ __ meses

MICCIONAIS: Perda de Urina: Nunca apresentei[1] Já apresentei anteriormente[2] Apresento atualmente[3]

Início da perda de urina: Nunca apresentei[1] Desde a gestação[2]: 1ª 2ª 3ª 4ª ou mais Durante o climatério[3] Não me lembro[4]

Tipo de perda urinária: Aos esforços[1] Situações de urgência[2] Mista[3]

Outros sintomas: Enurese: N[1] S[2] Infecção urinária: N[1] S: Recorrente[2] Atual[3]

Uso de protetores para conter a perda urinária: Não utiliza[1] Utiliza[2] Nº protetores/dia: __ __

Tratamento para incontinência urinária: Nunca realizado[1] Medicamentoso[2] Cirúrgico[3] Fisioterapêutico[4]

Exame Urodinâmico: N[1] S[2] *>> Anexar à ficha* **Diário Miccional**: N[1] S[2] *>> Anexar à ficha*

Os dois próximos questionários avaliam os sintomas da bexiga durante AS ÚLTIMAS 4 SEMANAS.

INTERNATIONAL CONSULTATION ON INCONTINENCE QUESTIONNAIRE URINARY INCONTINENCE – SHORT FORM (ICIQ-UI-SF)

(1) Com que frequência você perde urina? (0) nunca (1) 1x/semana (2) 2-3x/semana (3) 1x/dia (4) diversas vezes/dia (5) o tempo todo

(2) Quantidade de urina perdida: (0) nenhuma (4) moderada (2) pequena (6) grande

(3) Quanto que perder urina interfere em sua vida diária? (0) (1) (2) (3) (4) (5) (6) (7) (8) (9) (10)

0 (não interfere) *10 (interfere muito)*

ICIQ UI – SF (3+4+5) = __ __ (variação de zero a 21) *Tamanini et al., 2004*

Quando você perde urina? (0) nunca (1) Antes de chegar ao banheiro (2) Tosse ou espirro (3) Dormindo (4) Atividades Físicas (5) Terminou de urinar e está se vestindo (6) Sem razão óbvia (7) O tempo todo

SM_V1 atualizado: fevereiro/2017 LABORATORIO DE UroFisioterapia

ANEXO 3 - AVALIAÇÃO UROGINECOLÓGICA

FISIOTERAPIA – UROLOGIA FEMININA

DATA: __ __ / __ __ / __ __   Nome: _

INTERNATIONAL CONSULTATION ON INCONTINENCE QUESTIONNAIRE OVERACTIVE BLADDER (ICIQ-OAB)

(3) Quantas vezes você urina durante o dia? (0) 1-6 vezes (1) 7-8 vezes (2) 9-10 vezes (3) 11-12 vezes (4) 13 vezes ou mais
O quanto isso incomoda você?
(0) (1) (2) (3) (4) (5) (6) (7) (8) (9) (10)

(4) Durante a noite, quantas vezes, em média, você tem que se levantar para urinar? (0) Nenhuma vez (1) 1vez (2) 2 vezes (3) 3 vezes (4) 4 vezes ou mais
O quanto isso incomoda você?
(0) (1) (2) (3) (4) (5) (6) (7) (8) (9) (10)

(5) Você precisa se apressar para chegar ao banheiro para urinar? (0) Nunca (1) Poucas vezes (2) Às vezes (3) Na maioria das vezes (4) Sempre
O quanto isso incomoda você?
(0) (1) (2) (3) (4) (5) (6) (7) (8) (9) (10)

(6) Você perde urina antes de chegar ao banheiro? (0) Nunca (1) Poucas vezes (2) Às vezes (3) Na maioria das vezes (4) Sempre
O quanto isso incomoda você?
(0) (1) (2) (3) (4) (5) (6) (7) (8) (9) (10)

ICIQ-OAB (3+4+5+6) = __ __(variação de zero a 16) *Pereira et al., 2009*

Pad Test	**Data**	**Número de absorventes**	**Peso Inicial (grs.)**	**Peso Final (grs.)**	**Peso real de perda**
1ª sessão	__ __ / __ __ / __ __	__ __	__ __ __,__ __	__ __ __,__ __	__ __ __,__ __
10ª sessão	__ __ / __ __ / __ __	__ __	__ __ __,__ __	__ __ __,__ __	__ __ __,__ __
20ª sessão	__ __ / __ __ / __ __	__ __	__ __ __,__ __	__ __ __,__ __	__ __ __,__ __
30ª sessão	__ __ / __ __ / __ __	__ __	__ __ __,__ __	__ __ __,__ __	__ __ __,__ __

SINTOMAS INTESTINAIS: Frequência evacuatória: >3x/semana[1] <3x/semana[2]

Sensação de esvaziamento incompleto[1] Presença de hemorróidas[2] Incontinência fecal[3] *(aplicar Fecal Incontinence Quality of Life – FIQL)*

Outras[4] Especificar:____

The Bristol Stool Chart

Tipo 1	Bolinhas duras, difíceis de passar, separadas como nozes.	**Tipos 1 e 2** Considerar constipação aguda ou crônica e impactação fecal.
Tipo 2	Formato de linguiça, untuosas e irregulares, formadas por bolinhas duras.	
Tipo 3	Formado de linguiça com rachaduras na superfície.	
Tipo 4	Formato de linguiça, consistência pastosa.	**Tipos 3, 4 e 5** Considerar consistência como normal.
Tipo 5	Formato mole, com pontas bem definidas, fácil de passar.	
Tipo 6	Pedaços macios com pontas ásperas.	**Tipos 6 e 7** Considerar a impactação fecal com perdas diarreicas.
Tipo 7	Aquosa, sem pedaços sólidos, totalmente líquidas.	

Martinez &Azevedo, 2012

Dor: **N[1]** **S[2]** Disúria[1] Dismenorreia[2] Dispaureunia[3] Local da dor: ausente[1] abdominal[2] vaginal[3] perineal[4] uretral[5]

outra[6] Especificar:____

SINTOMAS SEXUAIS: **Atividade sexual:** **N[1]** **S[2]** Frequência: semanal[1] mensal[2] esporádica[3]

Queixa sexual: Nunca apresentei[1] Já apresentei anteriormente[2] Apresento atualmente[3] Especificar:____________________________

SM_V1 atualizado: fevereiro/2017   LABORATORIO DE UroFisioterapia

ANEXO 3 - AVALIAÇÃO UROGINECOLÓGICA

FISIOTERAPIA – UROLOGIA FEMININA

DATA: __ __ / __ __ / __ __ Nome: _____

O próximo questionário avalia os sintomas vaginais durante AS ÚLTIMAS 4 SEMANAS.

INTERNATIONAL CONSULTATION ON INCONTINENCE – VAGINAL SYMPTOMS ICIQ-VS

1a) **Você percebe uma dor em pressão ou peso no seu abdome inferior (pé da barriga)?**
(0) nunca (1) ocasionalmente (2) às vezes (3) Na maior parte do tempo (4) O tempo todo
1b) **O quanto isso incomoda você?** (0) (1) (2) (3) (4) (5) (6) (7) (8) (9) (10)

2a) **Você percebe que a sua vagina está dolorida?**
(0) nunca (1) ocasionalmente (2) às vezes (3) Na maior parte do tempo (4) O tempo todo
2b) **O quanto isso incomoda você?** (0) (1) (2) (3) (4) (5) (6) (7) (8) (9) (10)

3a) **Você sente que tem um redução de sensibilidade ou amortecimento na sua vagina ou em volta dela?**
(0) nunca (1) ocasionalmente (2) às vezes (3) Na maior parte do tempo (4) O tempo todo
3b) **O quanto isso incomoda você?** (0) (1) (2) (3) (4) (5) (6) (7) (8) (9) (10)

Prolapso (bexiga caída) é um problema comum que afeta a sustentação normal dos órgãos pélvicos, e que resulta na descida ou "queda" das paredes vaginais ou dos próprios órgãos pélvicos. Isto pode incluir a bexiga, o intestino e o útero. Os sintomas são geralmente piores em pé ou fazendo força (por exemplo: carregar peso, tossir, fazer exercícios) e geralmente melhoram ao deitar e relaxar.

O prolapso pode causar vários problemas. Nós estamos tentando descobrir quantas pessoas apresentam prolapso e quanto isso as incomoda. Ficaríamos agradecidos se você pudesse responder as seguintes perguntas, pensando em como você tem passado, em média, nas ***ÚLTIMAS QUATRO SEMANAS***

4a) **Você sente a sua vagina muito frouxa ou larga?**
(0) nunca (1) ocasionalmente (2) às vezes (3) Na maior parte do tempo (4) O tempo todo
4b) **O quanto isso incomoda você?** (0) (1) (2) (3) (4) (5) (6) (7) (8) (9) (10)

5a) **Você percebe um "caroço" ou "bola" descendo na sua vagina?**
(0) nunca (1) ocasionalmente (2) às vezes (3) Na maior parte do tempo (4) O tempo todo
5b) **O quanto isso incomoda você?** (0) (1) (2) (3) (4) (5) (6) (7) (8) (9) (10)

6a) **Você sente um "caroço ou bola" sair da sua vagina, de modo que você pode sentir isso do lado de fora ou vê-lo do lado de fora?**
(0) nunca (1) ocasionalmente (2) às vezes (3) Na maior parte do tempo (4) O tempo todo
6b) **O quanto isso incomoda você?** (0) (1) (2) (3) (4) (5) (6) (7) (8) (9) (10)

7a) **Você sente que a sua vagina é muito seca?**
(0) nunca (1) ocasionalmente (2) às vezes (3) Na maior parte do tempo (4) O tempo todo
7b) **O quanto isso incomoda você?** (0) (1) (2) (3) (4) (5) (6) (7) (8) (9) (10)

8a) **Você tem que colocar o dedo na vagina para ajudar a evacuar (fazer cocô)?**
(0) nunca (1) ocasionalmente (2) às vezes (3) Na maior parte do tempo (4) O tempo todo
8b) **O quanto isso incomoda você?** (0) (1) (2) (3) (4) (5) (6) (7) (8) (9) (10)

9a) **Você sente que a sua vagina é muito apertada?**
(0) nunca (1) ocasionalmente (2) às vezes (3) Na maior parte do tempo (4) O tempo todo
9b) **O quanto isso incomoda você?** (0) (1) (2) (3) (4) (5) (6) (7) (8) (9) (10)

QUESTÕES SEXUAIS

10) **Atualmente você tem vida sexual?**
(0) sim (1) Não, por causa dos meus sintomas vaginais (2) Não, por outros motivos
Se NÃO, vá para a questão 14.

11a) **Seu problema de vagina interfere na sua vida sexual?**
(0) de jeito nenhum (1) muito pouco (2) moderadamente (3) muito
11b) **O quanto isso incomoda você?** (0) (1) (2) (3) (4) (5) (6) (7) (8) (9) (10)

12a) **Você sente que seu relacionamento com seu parceiro é afetado pelos sintomas vaginais?**
(0) de jeito nenhum (1) muito pouco (2) moderadamente (3) muito
12b) **O quanto isso incomoda você?** (0) (1) (2) (3) (4) (5) (6) (7) (8) (9) (10)

13) **Quanto você acha que sua vida sexual tem sido prejudicada pelos seus sintomas vaginais?**
(0) (1) (2) (3) (4) (5) (6) (7) (8) (9) (10)

14) **Em geral, quanto seus sintomas vaginais interferem na sua vida diária?**
(0) (1) (2) (3) (4) (5) (6) (7) (8) (9) (10)

Tamanini et al., 2008

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ANEXO 3 - AVALIAÇÃO UROGINECOLÓGICA

FISIOTERAPIA – UROLOGIA FEMININA

ÍNDICE DE FUNÇÃO SEXUAL FEMININA – IFSF

1) *Durante as últimas 4 semanas, com que frequência você sentiu desejo ou interesse sexual?*

Sempre ou quase sempre[5] | Muitas vezes (mais da metade do tempo)[4]
Às vezes (aproximadamente a metade do tempo)[3] | Poucas vezes (menos do que a metade do tempo)[2]
Nunca ou quase nunca[1]

2) *Durante as últimas 4 semanas, como você classificaria seu nível (grau) de desejo ou interesse sexual?*

Muito Alto[5] | Alto[4] | Moderado[3] | Baixo[2] | Muito baixo ou nenhum[1]

Desejo: (x 0,6) _____

3) *Durante as últimas 4 semanas, com que frequência você se sentiu excitada durante o ato ou atividade sexual?*

Sem atividade sexual[0] | Sempre ou quase sempre[5]
Muitas vezes (mais da metade do tempo)[4] | Algumas vezes (aproximadamente metade do tempo)[3]
Poucas vezes (menos do que a metade do tempo)[2] | Nunca ou quase nunca[1]

4) *Durante as últimas 4 semanas, como você classificaria seu nível (grau) de excitação sexual durante a atividade sexual?*

Sem atividade sexual[0] | Muito Alto[5] | Alto[4] | Moderado[3] | Baixo[2] | Muito baixo ou nenhum[1]

5) *Durante as últimas 4 semanas, qual foi seu grau de confiança sobre sentir-se excitada durante a atividade sexual?*

Sem atividade sexual[0] | Altíssima confiança[5] | Alta confiança[4]
Moderada confiança[3] | Baixa confiança[2] | Baixíssima ou nenhuma confiança[1]

6) *Durante as últimas 4 semanas, com que frequência você ficou satisfeita com seu nível (grau) de excitação durante a atividade sexual?*

Sem atividade sexual[0] | Sempre ou quase sempre[5]
Muitas vezes (mais da metade do tempo)[4] | Algumas vezes (aproximadamente metade do tempo)[3]
Poucas vezes (menos do que a metade do tempo)[2] | Nunca ou quase nunca[1]

Excitação: (x 0,3) _____

7) *Durante as últimas 4 semanas, com que frequência você ficou lubrificada ("molhada") durante a atividade sexual?*

Sem atividade sexual[0] | Sempre ou quase sempre[5]
Muitas vezes (mais da metade do tempo)[4] | Algumas vezes (aproximadamente metade do tempo)[3]
Poucas vezes (menos do que a metade do tempo)[2] | Nunca ou quase nunca[1]

8) *Durante as últimas 4 semanas, qual foi o grau de dificuldade para ficar lubrificada ("molhada") durante a atividade sexual?*

Sem atividade sexual[0] | Extremamente difícil ou impossível[1] | Muito difícil[2]
Difícil[3] | Pouco difícil[4] | Nada difícil[5]

9) *Durante as últimas 4 semanas, com que frequência você manteve sua lubrificação até o final da atividade sexual?*

Sem atividade sexual[0] | Sempre ou quase sempre[5]
Muitas vezes (mais da metade do tempo)[4] | Algumas vezes (aproximadamente metade do tempo)[3]
Poucas vezes (menos do que a metade do tempo)[2] | Nunca ou quase nunca[1]

10) *Durante as últimas 4 semanas, qual foi o grau de dificuldade para manter sua lubrificação até terminar a atividade sexual?*

Sem atividade sexual0 | Extremamente difícil ou impossível[1] | Muito difícil[2]
Difícil[3] | Pouco difícil[4] | Nada difícil[5]

Lubrificação: (x0,3) _____

11) *Durante as últimas 4 semanas, na atividade sexual ou quando sexualmente estimulada, com que frequência você atingiu o orgasmo (clímax)?*

Sem atividade sexual[0] | Sempre ou quase sempre[5]
Muitas vezes (mais da metade do tempo)[4] | Algumas vezes (aproximadamente metade do tempo)[3]
Poucas vezes (menos do que a metade do tempo)[2] | Nunca ou quase nunca[1]

12) *Durante as últimas 4 semanas, na atividade sexual ou quando sexualmente estimulada,qual foi o grau de dificuldade para atingir o orgasmo (clímax)?*

Sem atividade sexual[0] | Extremamente difícil ou impossível[1] | Muito difícil[2]
Difícil[3] | Pouco difícil[4] | Nada difícil[5]

13) *Durante as últimas 4 semanas, qual foi o grau de satisfação com sua habilidade de chegar ao orgasmo (clímax) durante a atividade sexual?*

Sem atividade sexual[0] | Muito satisfeita[5] | Moderadamente satisfeita[4]
Indiferente[3] | Moderadamente insatisfeita[2] | Muito insatisfeita[1]

Orgasmo: (x 0,4) _____

ANEXO 3 - AVALIAÇÃO UROGINECOLÓGICA

FISIOTERAPIA – UROLOGIA FEMININA

14) *Durante as últimas 4 semanas, qual foi o grau de satisfação com a quantidade de envolvimento emocional entre você e seu parceiro durante a atividade sexual?*

Sem atividade sexual[0] Muito satisfeita[5] Moderadamente satisfeita[4]
Indiferente[3] Moderadamente insatisfeita[2] Muito insatisfeita[1]

15) *Durante as últimas 4 semanas, qual foi o grau de satisfação na relação sexual com seu parceiro?*

Sem atividade sexual[0] Muito satisfeita[5] Moderadamente satisfeita[4]
Indiferente[3] Moderadamente insatisfeita[2] Muito insatisfeita[1]

16) *Durante as últimas 4 semanas, de forma geral, qual foi o grau de satisfação com sua vida sexual?*

Sem atividade sexual[0] Muito satisfeita[5] Moderadamente satisfeita[4]
Indiferente[3] Moderadamente insatisfeita[2] Muito insatisfeita[1]

Satisfação: (x 0,4) _____

17) *Durante as últimas 4 semanas, com que frequência você sentiu desconforto ou dor durante a penetração vaginal?*

Não houve tentativa de penetração[0] Sempre ou quase sempre[1]
Muitas vezes (mais da metade do tempo)[2] Algumas vezes (aproximadamente metade do tempo)[3]
Poucas vezes (menos do que a metade do tempo)[4] Nunca ou quase nunca[5]

18) *Durante as últimas 4 semanas, com que frequência você sentiu desconforto ou dor após a penetração vaginal?*

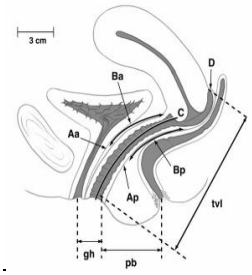
Sem atividade sexual[0] Sempre ou quase sempre[1]
Muitas vezes (mais da metade do tempo)[2] Algumas vezes (aproximadamente metade do tempo)[3]
Poucas vezes (menos do que a metade do tempo)[4] Nunca ou quase nunca[5]

19) *Durante as últimas 4 semanas,como você classificaria seu nível (grau) de desconforto ou dor durante ou após a penetração vaginal?*

Não houve tentativa de penetração[0] Altíssimo[1] Alto[2]
Moderado[3] Baixo[4] Baixíssimo ou nenhum[5]

Dor: (x 0,4) _____ *Hentschel et al., 2007*

REAV EXAME FISICO:



HALF WAY SYSTEM

PROLAPSO ANTERIOR: 0 1 2 3 4 PROLAPSO POSTERIOR: 0 1 2 3 4

PROLAPSO APICAL: 0 1 2 3 4 ROTURA PERINEAL: 0 1 2 3 4

POP-Q		
Aa	Ba	C
Gh	Pb	TVL
Ap	Bp	D

	12	11	10	9	8	7	6	5	4	3	2	1	0	-1	-2	-3	-4	-5	-6	-7	-8	-9	-10	-11	-12
Aa																									
Ba																									
C																									
D																									
Bp																									
Ap																									

EXAME DO ABDÔMEN:

Circunferência abdominal: __ __ cm **Diástase do Reto Abdome**: __ __ cm **Cicatriz** N[1] S[2] **Fibrose** N[1] S[2] Localização: _____

Circunferência quadril: __ __ cm

INSPEÇÃO

Coloração: Sem alterações Rosa pálido Avermelhada Assaduras **Secreção:** Ausente Transparente Leitosa Escurecida

Odor: Ausente Urina Fétido **Sensibilidade:** Presente Ausente **Corpo perineal:** Sem alterações Abaulado

Intróito vaginal: Sem alterações Estreito Aumentado Prolapso evidente Labiações Trauma

Esfíncter anal: Sem alterações Labiações Fístula Hemorroida

Contração voluntária: Presente Ausente **Uso de musculatura acessória:** N[1] S[2] Glúteos Adutores Abdominais Apneia inspiratória

Teste de Esforço: positivo[1] negativo[2] não realizado[3] inconclusivo[4] Posição: Dec. Dorsal Ortostática

PALPAÇÃO

Cicatriz N[1] S[2] Localização: _____ Fibrose N[1] S[2] Localização: _____

Tonicidade:

Posterior: Hipertônica Normotônica Hipotônica

Lateral Direita: Hipertônica Normotônica Hipotônica

Lateral Esquerda: Hipertônica Normotônica Hipotônica

Contratilidade:

Global: Presente Deficitária Ausente

Seletiva: Presente Deficitária Ausente

Escala Modificada de Oxford: 0 1 2 3 4 5

Coordenação: Presente Deficitária Ausente **Contração Reflexa:** Presente Deficitária Ausente P___E___R___F___

SM_V1 atualizado: fevereiro/2017 **LABORATORIO DE UroFisioterapia**

Anexo 4: Termo de Consentimento Livre e Esclarecido

ANEXO 4 – TERMO DE CONSENTIMENTO LIVRE E ESCLARECIDO

Treinamento dos músculos do assoalho pélvico feminino
por meio de terapia de exposição à realidade virtual nos sintomas miccionais de IUE e IUM
Anita Bellotto Leme Nagib
Número do CAAE: 41304914.9.00005404

Você está sendo convidado a participar como voluntário de um estudo. Este documento, chamado Termo de Consentimento Livre e Esclarecido, visa assegurar seus direitos como participante e é elaborado em duas vias, uma que deverá ficar com você e outra com o pesquisador. Por favor, leia com atenção e calma, aproveitando para esclarecer suas dúvidas. Se houver perguntas antes ou mesmo depois de assiná-lo, você poderá esclarecê-las com o pesquisador. Se preferir, pode levar para casa e consultar seus familiares ou outras pessoas antes de decidir participar. Se você não quiser participar ou retirar sua autorização, a qualquer momento, não haverá nenhum tipo de penalização ou prejuízo.

Justificativa e objetivos: Os músculos do assoalho pélvico são popularmente conhecidos como períneo. Eles são responsáveis pela sustentação dos órgãos pélvicos, como bexiga e útero, além de auxiliar no controle da urina e das fezes, bem como na função sexual da mulher. Esta pesquisa tem por finalidade estudar os efeitos do treinamento dos músculos do assoalho pélvico (exercícios físicos) sobre a função dos músculos do assoalho pélvico e os sintomas uroginecológicos, como perda de urina, funcionamento do intestino, função sexual e presença de distopias genitais (posicionamento da bexiga, útero e de outros órgãos).

Procedimentos: Participando do estudo você está sendo convidado a preencher um questionário com perguntas sobre sua saúde, além de fazer exame para avaliação da contratilidade (força) dos músculos do assoalho pélvico e abdômen e investigação do posicionamento da bexiga e do útero para verificar se existe queda desses órgãos. Os exames serão feitos por profissional capacitado e constam de ultrassonografia vaginal, palpação vaginal e introdução de uma sonda vaginal manipulada cuidadosamente, que registrará suas condições musculares. Esses dados serão armazenados no computador para posterior análise. Após a avaliação, se for de seu interesse, você participará de um programa de 10 sessões de treinamento dos músculos do assoalho pélvico, por reabilitação virtual com o console *Wii™* (jogo na televisão) e, será reavaliada após o término do tratamento. Para isso, haverá necessidade de deslocamento para o laboratório de UroFisioterapia durante todas as sessões, com duração total de uma hora para a avaliação (preenchimento do questionário e realização dos exames) ou para a realização dos exercícios. O tratamento será realizado durante cinco semanas consecutivas, com frequência de duas vezes por semana.

Desconfortos e riscos: Você **não** deve participar deste estudo se tiver a pressão arterial descontrolada (pressão alta sem controle médico ou alguma limitação física que impossibilite a execução dos exercícios). Para realização do exame perineal, será colocado uma geléia antialérgica para evitar o desconforto gerado pelo exame de palpação e introdução da sonda vaginal.

Benefícios: Você receberá avaliação e acompanhamento gratuito, instruções fisioterapêuticas preventivas sobre possíveis cuidados com o assoalho pélvico e desenvolverá atividades de treinamento, com o objetivo de melhorar o controle da bexiga, do intestino, da função sexual e do posicionamento dos órgãos pélvicos. Além disso, irá contribuir com o conhecimento cientifico sobre o efeito dos exercícios para a função dos músculos do assoalho pélvico feminino.

Acompanhamento e assistência: Durante as atividades ou após o encerramento da pesquisa nossa instituição continuará a lhe prestar assistência à saúde sempre que necessário, por meio de carta de encaminhamento feita pelos pesquisadores responsáveis aos serviços de saúde.

Sigilo e privacidade: Você tem a garantia de que sua identidade será mantida em sigilo e nenhuma informação será dada a outras pessoas que não façam parte da equipe de pesquisadores. Na divulgação dos resultados desse estudo, seu nome não será citado.

Ressarcimento: Não haverá ressarcimento de despesas de transporte, alimentação ou diárias. Se houver necessidade de solicitação de transporte junto à secretaria de saúde de seu município ou outro órgão, os pesquisadores poderão justificar a necessidade de sua participação por meio de relatório clinico.

Métodos alternativos: Apos realizar sua avaliação inicial, você recebera orientações preventivas e deverá segui-las por um período de cinco semanas (período controle). Logo após, será reavaliada e poderá ser incluída no grupo de tratamento, se for de seu interesse. O grupo de tratamento realiza cinco semanas consecutivas de exercícios físicos por reabilitação virtual com o console *Wii™* (jogo na televisão).

Contato: Em caso de dúvidas sobre o estudo, você poderá entrar em contato com a pesquisadora Anita Bellotto Leme Nagib por meio do e-mail urofisio.lab@gmail.com, ou no endereço: *LabUro - Laboratório de Urodinâmica e Estudos da Incontinência Urinária - Andar térreo do prédio do CIPED, Rua Tessália Vieira de Camargo, 126 – Cidade Universitária Zeferino Vaz. – Campinas.* Em caso de denúncias ou reclamações sobre sua participação e sobre questões éticas do estudo, você pode entrar em contato com a secretaria do Comitê de Ética em Pesquisa (CEP) da UNICAMP: Rua: Tessália Vieira de Camargo, 126; CEP 13083-887 Campinas – SP; telefone (19) 3521-8936; fax (19) 3521-7187; e-mail: cep@fcm.unicamp.br

Consentimento livre e esclarecido: Após ter sido esclarecimento sobre a natureza da pesquisa, seus objetivos, métodos, benefícios previstos, potenciais riscos e o incômodo que esta possa acarretar, aceito participar:

Responsabilidade do Pesquisador: Asseguro ter cumprido as exigências da resolução 466/2012 CNS/MS e complementares na elaboração do protocolo e na obtenção deste Termo de Consentimento Livre e Esclarecido. Asseguro, também, ter explicado e fornecido uma cópia deste documento ao participante. Informo que o estudo foi aprovado pelo CEP perante o qual o projeto foi apresentado. Comprometo-me a utilizar o material e os dados obtidos nesta pesquisa exclusivamente para as finalidades previstas neste documento ou conforme o consentimento dado pelo participante.

Nome da participante: _____ Data: ___/___/___
RG: _____ HC: _____
Endereço: _____

_____ _____
Assinatura da participante
Anita Bellotto Leme Nagib
Pesquisadora

Página **1** de **1**

Anexo 5: Autorização da Editora John Wiley and Sons

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Apr 03, 2020

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