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PROGRAMA DE PÓS-GRADUAÇÃO EM CIÊNCIAS DA SAÚDE

VULVODÍNIA: FATORES PSICOSSOCIAIS E ABORDAGENS PSICOTERAPÊUTICAS

JANICE FRANÇA DE QUEIROZ

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Dissertação apresentada ao Programa de Pós-graduação em Ciências da Saúde da Universidade Federal do Rio Grande do Norte como requisito para obtenção do título de Doutor em Ciências da Saúde.

Orientadora: Profa. Dra. Ana Katherine da Silveira Gonçalves de Oliveira

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À minha filha e à mãe.

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“Força de vontade e empenho, são as armas fundamentais para todos que procuram obter algo que consideram difícil ou impossível” (Paulino R. Silva).

RESUMO

Introdução: A vulvodínia, dor vulvar, é uma condição ginecológica comum com prevalência global estimada de aproximadamente 8% da população mundial, afetando tipicamente, mulheres com idade entre 20 e 40 anos. Por se tratar de uma doença multifatorial, pode ser desencadeada por alterações hormonais, infecções recorrentes ou inflamação na região vulvar, traumas na área genital, predisposição genética e fatores psicossociais. Mulheres com vulvodínia apresentam sintomas de disfunção sexual, além de altos níveis de ansiedade e depressão, favorecendo a diminuição da qualidade de vida. Considerando o componente psicológico envolvido no prognóstico da vulvodínia, psicoterapia e técnicas psicoterapêuticas podem oferecer opções de tratamento clinicamente práticas e resolutivas para a dor vulvar.

Objetivos: Identificar os fatores psicossociais associados à vulvodínia e avaliar a eficácia das psicoterapias e técnicas psicoterapêuticas na redução da dor vulvar, na melhoria da função sexual, da saúde mental e do ajustamento psicológico, assim como os impactos na qualidade de vida das mulheres afetadas pela condição.

Materiais e métodos: Foram realizadas duas revisões sistemáticas, sendo uma delas com metanálise. As recomendações do *Preferred Reporting Items for Systematic Review and Meta-Analysis* (PRISMA) foram seguidas. No artigo 1, uma estratégia de busca foi utilizada para estudos observacionais (caso-controle e coorte) que investigaram os fatores psicossociais associados à vulvodínia, seus efeitos na sexualidade, saúde mental e qualidade de vida, avaliando como desfecho primário dor vulvar, nas bases de dados: PubMed, LILACS, Embase, CINAHL, Web of Science, Scopus e PsycINFO. O risco de viés foi avaliado usando a Escala *Newcastle-Ottawa*. No artigo 2, uma estratégia de busca foi utilizada para ensaios clínicos randomizados, que utilizaram psicoterapia e técnicas psicoterapêuticas para vulvodínia, tendo como desfecho primário a intensidade da dor vulvar, nas bases de dados: PubMed, Embase, Scopus, Web of Science, Cochrane Central Register of Controlled Trials, PsycInfo e Clinical Trial Databases. O risco de viés foi avaliado usando a ferramenta *Cochrane Risk of Bias* (RoB 2.0) e o RevMan 5.4 foi usado para a síntese dos dados (metanálise). Em ambos os artigos, dois autores selecionaram e extraíram os dados dos artigos de forma independente, e para classificar a força da evidência, foi utilizada a abordagem Grading of Recommendations Assessment, Development and Evaluation Working Group (GRADE).

Resultados: No artigo 1, um total de 3.182 artigos foram identificados, destes, 22 estudos atenderam aos critérios de elegibilidade e foram incluídos na revisão, compreendendo 2.624 pacientes. Observou-se uma associação dos fatores psicossociais e a vulvodínia, na qual mulheres com dor vulvar possuem mais sintomas de ansiedade e depressão. Em relação à função sexual, os resultados mais frequentes foram dispareunia e a disfunção. Para a qualidade de vida, as mulheres com dor vulvar crônica tiveram maior dificuldade em realizar atividades físicas e experimentaram humores e sentimentos negativos. O risco de viés dos estudos variou de boa (6) a excelente (7). A alta heterogeneidade dos estudos impossibilitou a realização da metanálise. No artigo 2, um total de 1.884 artigos foram identificados, na qual 10 estudos atenderam aos critérios de elegibilidade e foram incluídos na revisão sistemática, compreendendo 951 participantes. Dois estudos foram incluídos na metanálise, estes com 143 participantes. Ao comparar a Terapia de Aceitação e Compromisso (ACT) com o grupo controle, a diferença média (MD) na análise combinada para o Questionário de Aceitação da Dor Crônica não diferiu significativamente entre a ACT e outras terapias, para avaliação pós-tratamento (MD = 0,77; IC 95% -3,45,4, 99) da dor. O risco de viés foi alto em 03 estudos, devido à falta de clareza no processo de mensuração dos resultados. A certeza da evidência para dor vulvar usando ACT foi considerada moderada.

Conclusão: Os resultados sugerem uma associação entre os fatores psicossociais com a vulvodínia. A psicoterapia e as técnicas psicoterapêuticas melhoram significativamente a dor vulvar, o ajuste psicológico e a função sexual e a qualidade de vida em mulheres com vulvodínia. Além disso, nossa metanálise mostrou que ACT e outras intervenções psicoterapêuticas melhoram o ajuste psicológico por meio da aceitação da dor. No entanto, estudos mais rigorosos são necessários para melhorar a qualidade das evidências e melhorar a prática clínica.

Palavras-chave: vulvodínia, vestibulodínia, dor vulvar, fatores psicossociais, psicoterapia.

ABSTRACT

Introduction: Vulvodynia, vulvar pain, is a common gynecological condition with an estimated global prevalence of approximately 8% of the world population, typically affecting women between the ages of 20 and 40. As it is a multifactorial disease, it can be triggered by hormonal changes, recurrent infections or inflammation in the vulvar region, trauma to the genital area, genetic predisposition and psychosocial factors. Women with vulvodynia present symptoms of sexual dysfunction, in addition to high levels of anxiety and depression, favoring a decrease in quality of life. Considering the psychological component involved in the prognosis of vulvodynia, psychotherapy and psychotherapeutic techniques can offer clinically practical and resolute treatment options for vulvar pain.

Objectives: To evaluate the psychosocial factors and psychotherapeutic techniques in the management of vulvodynia.

Materials and methods: Two systematic reviews were conducted, one of which included meta-analysis. The Preferred Reporting Items for Systematic Review and Meta-Analysis (PRISMA) recommendations were followed. In article 1, a search strategy was used for observational studies (case-control and cohort) that investigated the psychosocial factors associated with vulvodynia, its effects on sexuality, mental health and quality of life, evaluating vulvar pain as the primary outcome, in the following databases: PubMed, LILACS, Embase, CINAHL, Web of Science, Scopus and PsycINFO. The risk of bias was assessed using the Newcastle-Ottawa Scale. In article 2, a search strategy was used for randomized clinical trials that used psychotherapy and psychotherapeutic techniques for vulvodynia, with vulvar pain intensity as the primary outcome, in the following databases: PubMed, Embase, Scopus, Web of Science, Cochrane Central Register of Controlled Trials, PsycInfo, and Clinical Trial Databases. The risk of bias was assessed using the Cochrane Risk of Bias (RoB 2.0) tool, and RevMan 5.4 was used for data synthesis (meta-analysis). In both articles, two authors independently selected and extracted data from the articles, and the Grading of Recommendations Assessment, Development and Evaluation Working Group (GRADE) approach was used to classify the strength of the evidence.

Results: In article 1, a total of 3,182 articles were identified, of which 22 studies met the eligibility criteria and were included in the review, comprising 2,624 patients. An association between psychosocial factors and vulvodynia was observed, in which women

with vulvar pain had more symptoms of anxiety and depression. Regarding sexual function, the most frequent results were dyspareunia and dysfunction. For quality of life, women with chronic vulvar pain had greater difficulty performing physical activities and experienced negative moods and feelings. The risk of bias of the studies ranged from good (6) to excellent (7). The high heterogeneity of the studies made it impossible to perform the meta-analysis. In article 2, a total of 1,884 articles were identified, of which 10 studies met the eligibility criteria and were included in the systematic review, comprising 951 participants. Two studies were included in the meta-analysis, these with 143 participants. When comparing Acceptance and Commitment Therapy (ACT) with the control group, the mean difference (MD) in the pooled analysis for the Chronic Pain Acceptance Questionnaire did not differ significantly between ACT and other therapies, for post-treatment assessment (MD = 0.77; 95% CI -3.45, 4, 99) of pain. The risk of bias was high in 03 studies, due to the lack of clarity in the outcome measurement process. The certainty of the evidence for vulvar pain using ACT was considered moderate.

Conclusion: The results suggest an association between psychosocial factors and vulvodynia. Psychotherapy and psychotherapeutic techniques significantly improve vulvar pain, psychological adjustment, and sexual function and quality of life in women with vulvodynia. Furthermore, our meta-analysis showed that ACT and other psychotherapeutic interventions improve psychological adjustment through pain acceptance. However, more rigorous studies are needed to improve the quality of evidence and improve clinical practice.

Keywords: vulvodynia, vestibulodynia, vulvar pain, psychosocial factors, psychotherapy.

LISTA DE ABREVIATURAS E SIGLAS

NOS	*Escala Newcastle-Ottawa*
PRISMA	*Preferred Reporting Items for Systematic Reviews and Meta-Analyses*
PROSPERO	*International Prospective Register of Systematic Reviews*
CRD	*Registration Number*
PICOT	População, Intervenção, Comparador/controle, Resultados
PICOT	População, Intervenção, Controle, Resultados, Tipos de estudo
AASAD	*Center for Health Sciences*
UFRN	Universidade Federal do Rio Grande do Norte
RN	Rio Grande do Norte
LILACS	Literatura Latino-Americana e do Caribe em Ciências da Saúde
MeSH	*Medical Subject Titles*
RevMan	*Review Manager*
MD	*Mean Difference*
CI	*Confidence Intervals*
RCTs	*Randomized clinical trials*
RoB 2	Cochrane Risk of Bias
GRADE	*Grading of Recommendations Assessment, Development and Evaluation*
NRS	Numeral Rating Scale
PCS	*Pain Catastrophizing Scale*
PISES	*Painful Intercourse Self-Efficacy Scale*
MPQ-PRI	*Pain Rating Index of the McGill Pain Questionnaire*
VVG	*Vulvalgesiometer Pain Rating*
VAS	*Visual Analogue Scale*
DSFI	*Derogatis Sexual Functioning Inventory*
SF-MPQ	*Sensory Scale of the McGill Pain Questionnaire*
FSFI	*Female Sexual Function Index*
FSDS-R	*Female Sexual Distress Scale-Revised*
FSDS	*Female Sexual Distress Scale*

BSI-GSI	*Brief Symptom Inventory*
PASS-20	*Pain Anxiety Symptoms Scale*
PVAQ	*Pain and Vigilance Awareness Questionnaire*
CPAQ	*Chronic Pain Acceptance Questionnaire*
FFMQ	*Five Facet Mindfulness Questionnaire, the Self-Compassion Scale*
STAI	*State-Trait Anxiety Inventory*
GAD-7	*Generalized Anxiety Disorder*
BDI	*Beck Depression Inventory*
BDI-PC	*Beck Depression Inventory*
CPAQ-R	*Chronic Pain Acceptance Questionnaire-Revised*
TCCG	Terapia Cognitivo-Comportamental de Grupo
TCCC	Terapia Cognitivo-Comportamental de Casal
TCC	Terapia Cognitivo-Comportamental
M-gCBT	Terapia Cognitivo-Comportamental de Grupo baseada em Mindfulness
ACT	Terapia de Aceitação e Compromisso

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1 INTRODUÇÃO

A vulvodínia é uma condição marcada por dor vulvar, podendo ser crônica, na qual tem duração de três meses ou mais, sem uma causa claramente identificável (1,2,3). É uma dor de origem nervosa que se manifesta ao toque, podendo ser associada a ardência ou queimação (3). De acordo com a Terminologia de Consenso de 2015, a vulvodínia pode ser do tipo generalizada e espontânea (com queixa constante) ou localizada e provocada (estimulada por acontecimentos específicos) (3-8).

A vulvodínia é uma condição ginecológica comum, com uma prevalência global estimada de aproximadamente 8% da população mundial feminina, podendo ser causada por alterações hormonais, infecções recorrentes, lesões ou traumas na área genital, predisposição genética ou inflamação na região vulvar (3,9). A fisiopatologia da vulvodínia é ainda incerta, mas, parece ser multifatorial, englobando fatores de neuroproliferação, miofasciais, hormonais, imunológicos, psicossociais (ansiedade, depressão, vitimização infância e stress pós-traumático, redução do limiar de dor, polimorfismos genéticos, entre outros (3).

Na Europa, sua prevalência é ainda maior, variando de 10% a 16%, conforme relatado pela Sociedade Internacional para o Estudo de Doenças Vulvares (9). Afeta tipicamente, mulheres com idade entre 20 a 40 anos, trazendo sintomas de dor vulvar em quase 10% das mulheres aos 40 anos (2,9,10). Essa condição impacta significativamente a qualidade de vida geral dessas mulheres (1,2,11).

Mulheres com vulvodínia frequentemente acham angustiante e desafiador se submeter a exames ginecológicos ou se envolver em sexo com penetração. As pacientes relatam uma frequência aumentada de pensamentos negativos sobre sexo, o que está associado a uma intensidade de dor, significativa, impactando a saúde sexual e psicológica (4,6). A vulvodínia é comumente associada a uma diminuição na qualidade de vida devido à dor, disfunção sexual, altos níveis de ansiedade e depressão e frequentemente ocorre concomitantemente com transtorno de estresse pós-traumático (6). Estudos sugerem que fatores psicossociais estão associados a causa da vulvodínia, pois o diagnóstico de vulvodínia está significativamente associado a dificuldades psicológicas, emocionais e sexuais da mulher (1,2,12).

2 JUSTIFICATIVA

Existe uma relação bidirecional entre a vulvodínia e fatores psicossociais, como doenças emocionais, a exemplo da depressão e ansiedade. Estudos mostram que mulheres diagnosticadas com vulvodínia são mais propensas a ter sintomas de depressão e ansiedade do que mulheres sem vulvodínia, enquanto mulheres com depressão têm maior probabilidade de serem diagnosticadas com vulvodínia (4,5,7). Embora a depressão não seja a causa da vulvodínia, é uma comorbidade frequente entre as mulheres que a possuem, e o tratamento da dor vulvar geralmente envolve abordar ambos os elementos da doença - mente e corpo, acreditando que os fatores psicossociais, também, desempenham um papel na causa da dor (1,2,5,12).

No entanto, os mecanismos da doença ainda não são completamente compreendidos e, embora haja uma relação clara entre a vulvodínia e ajustamento psicológico, não está claro como o bem-estar mental e a vulvodínia estão relacionados, apesar de haver uma relação bilateral. O risco vitalício de vulvodínia é tão alto quanto 28%, enquanto 8 –12% das mulheres são atualmente afetadas, o que se traduz em milhões de pessoas afetadas (4-7). Um estudo mostrou em seu resultado que a duração média da dor entre as mulheres foi maior que 12 anos, e mais de dois terços não receberam diagnóstico ou tratamento (5). Devido à etiologia incerta e à heterogeneidade clínica da vulvodínia, um tratamento "padrão ouro" não existe atualmente para essa condição, na qual este, muitas vezes, requer ações multidisciplinares como procedimentos médicos, psicoterápicos, fisioterapêuticos, entre outros (3,10,13).

Considerando o componente psicológico significativo envolvido na vulvodínia, psicoterapia e técnicas psicoterapêuticas (atividades específicas de um método psicológico utilizadas para ajudar pacientes a compreender e resolver seus conflitos, e a lidar com dores emocionais e sintomas) podem oferecer opções de tratamento clinicamente práticas. Estas são suporte robusto no tratamento da vulvodínia, sugerindo que os aspectos emocionais podem estar diretamente associados à etiologia da vulvodínia. No entanto, é preciso haver uma compreensão coerente de como os fatores psicossociais impactam os resultados ou interagem com variáveis relevantes da doença (7,14). O tratamento da vulvodínia utilizando a psicoterapia (tratamento realizado por profissional de psicologia que visa resolver problemas

psicológicos e emocionais) e técnicas psicoterapêuticas (métodos de tratamento, embasados em diferentes conceitos teóricos e técnicos) têm demonstrado eficácia na redução da dor vulvar, melhora na sexualidade, no ajustamento psicológico e qualidade de vida. Assim, os autores enfatizaram a necessidade de mais estudos para validar essas descobertas (9).

3 OBJETIVOS

3.1 - Objetivo geral

Identificar os fatores psicossociais associados à vulvodínia e avaliar a eficácia das psicoterapias e técnicas psicoterapêuticas na redução da dor vulvar, na melhoria da função sexual, da saúde mental e do ajustamento psicológico, assim como os impactos na qualidade de vida das mulheres afetadas pela condição.

3.2 - Objetivos específicos

- Descrever os fatores psicossociais, refletindo processos cognitivos, afetivos, comportamentais, depressivos, ansiosos ou interpessoais, associados à vulvodínia.
- Analisar os efeitos dos fatores psicossociais na dor vulvar, função sexual e qualidade de vida das mulheres com vulvodínia.
- Avaliar a eficácia da psicoterapia e técnicas psicoterapêuticas para o tratamento da vulvodínia.
- Identificar a melhora da função sexual, ajustamento psicológico e qualidade de vida após aplicação da psicoterapia e técnicas psicoterapêuticas.

4 MÉTODO

Esse trabalho abrangeu a realização de duas revisões sistemáticas, sendo uma com metanálise. A pesquisa (artigo 1) que utilizou estudos observacionais e a que utilizou ensaios clínicos (artigo 2) foram conduzidas baseada nas recomendações do *Cochrane Handbook for Systematic Reviews of Interventions* (artigo 2) (15,16) e escritas conforme os *Preffered Reporting Itens for Systematic Reviews and Meta-Analysis* (PRISMA) (17,18). As revisões foram registradas na plataforma do PROSPERO (Artigo 1: CRD42022367284 e Artigo 2: CRD42023411450).

4.1 Critérios de inclusão

Foram incluídos, no artigo 1, estudos observacionais (caso-controle e coorte) que investigassem os fatores psicossociais (processos cognitivos, afetivos, comportamentais, depressivos, ansiosos ou interpessoais) associados à vulvodínia, e os efeitos na sexualidade, saúde mental e qualidade de vida, avaliando o desfecho primário dor vulvar, e o desfecho secundário: Disfunção sexual, qualidade de vida e saúde mental. No artigo 2, foram incluídos estudos de ensaios clínicos randomizados, que avaliassem a eficácia da psicoterapia e técnicas psicoterapêuticas para a vulvodínia, com avaliação do desfecho primário a intensidade da dor vulvar, e o desfecho secundário: função sexual, sofrimento sexual, ajuste psicológico. Não houve restrição de data ou idioma na busca.

A pergunta das revisões foi a PECOT (População, Exposição, Comparador, Resultados e Tipos de estudo) e PICOT (População, Intervenção, Controle, Resultados e Tipos de estudo), estando demonstrada nas Tabela 1 e Tabela 2.

P	Mulheres com vulvodínia/dor vulvar
E	Fatores psicossociais
C	Mulheres sem vulvodínia/dor vulvar
O	Dor vulvar, saúde mental e qualidade de vida
T	Estudos observacionais (caso-controle e coorte)

Tabela 1. Estratégia PECOT do artigo 1.

P	Mulheres adultas > 18 anos diagnosticadas com vulvodínia
I	Psicoterapia, abordagens psicoterapêuticas
C	Nenhum tratamento ou outros tratamentos para vulvodínia
O	Intensidade da dor vulvar, função sexual, sofrimento sexual e catastrofização da dor
T	Ensaios clínicos randomizados

Tabela 2. Estratégia PICOT do artigo 2.

4.2 Critérios de Exclusão

No artigo 1 foram excluídos ensaios clínicos, estudos transversais, além disso, estudos sobre vulvodínia ou causas físicas de dor vulvar associadas à disfunção sexual e com mulheres com idade ≤18 anos. No artigo 2, foram excluídos estudos de pré-impressão, resumos de conferências, comunicações breves, ensaios clínicos randomizados em andamento ou manuscritos com dados incompletos e informações insuficientes, como também que não trouxessem nenhum tratamento ou outros tratamentos para vulvodínia (farmacológico, fisioterapêutico, cirúrgico, entre outros). Além disso, foram excluídos, em ambas as revisões, artigos publicados, não revisados por pares, relatos de caso e outras revisões, assim, nosso estudo focou na vulvodínia clássica.

4.3 Envolvimento de pacientes e do público

Durante toda a realização dessa pesquisa não houve qualquer tipo de envolvimento direto de pacientes. Em se tratando de revisões sistemáticas e metanálise, todos os dados utilizados na pesquisa são provenientes de estudos primários já publicados, não havendo identificação de pacientes.

4.4 Estratégia de Busca

A busca nas bases de dados foi realizada sob orientação de uma bibliotecária experiente do Centro de Ciências da Saúde, registrado no Conselho Regional de Biblioteconomia (CRB-15/474 - UFRN, Natal, RN- Brasil), anexo 1. As seguintes bases de dados foram utilizadas: PubMed/Medline, Latino Americana e do Caribe em

Ciências da Saúde (LILACS), Embase e Cumulative Index to Nursing and Allied Health Cumulative Literature (CINAHL), Web of Science, Scopus and PsycoInfo, no artigo 1. Acrescido às bases de dados Cochrane Register of Controlled Trials e Clinical Trials.gov, para o artigo 2. Os termos do *Medical Subject Headings* (MeSH) foram utilizados conforme a estratégia PICOT ou PECOT definidas sistematicamente para cada objetivo. A estratégia de busca no PUbMed está demonstrada na tabela 3 e 4, e adaptada para cada base de dados.

	MeSh Terms and Keywords
1	Vulvodynia
2	Vestibulodynia
3	Generalized vulvodynia
4	OR / 1–3
5	Psychology
6	Psychosocial factors
7	Emotional
8	Feelings
9	Social factors
10	Behavior
11	Cognition
12	Depression
13	Anxiety
14	OR / 5–13
15	Mental health
16	Quality of life
17	Life quality
18	Pain
19	Burning pain
20	OR / 15–19
21	4 AND 14 AND 20

Tabela 3. Estratégia de busca para o PubMed do artigo 1.

	MeSh Terms and Keywords
1	Vulvodynia
2	Vestibulodynia
3	Generalized Vulvodynia
4	Vulvodynia, Generalized
5	Vulva Pain
6	Pain, Vulva
7	OR / 1-6
8	Psychotherapy
9	Acceptance and Commitment Therapy
10	Cognitive Behavioral Therapy
11	Behavior Therapy
12	Psychology
13	Mindfulness
14	Counseling
15	Psychotherapeutic techniques
16	OR / 8-15
17	7 AND 16

Tabela 4. Estratégia de busca para o PubMed do artigo 2.

4.5 Seleção dos Estudos

Os artigos obtidos a partir da estratégia de busca nas bases de dados foram importados para o Rayyan (Mourad Ouzzani, University of Oxford, UK). Os artigos duplicados foram removidos e três autores avaliaram todos os títulos de forma independente. Os estudos os quais os títulos foram selecionados seguiram então para análise por resumo por três autores de forma independente. Em seguida, foram lidos os textos completos aplicando os critérios de inclusão e exclusão pré-definidos. Durante todo o processo de seleção, se houvesse discordância entre os três autores em relação a inclusão de um artigo, um quarto autor resolveria a discordância. As seleções dos estudos foram apresentadas em fluxogramas PRISMA.

4.6 Extração dos Dados

Os dados dos artigos selecionados foram extraídos de maneira independente por dois autores, quaisquer discrepâncias subsequentes foram resolvidas por meio de discussão com um terceiro revisor. Um formulário padronizado de extração de dados (tabela do Excel) foi usado para coletar as principais características dos estudos e desfechos analisados.

No artigo 1, as variáveis extraídas foram: Autor/Ano; País; Desenho do estudo; Amostra; Idade; Período de acompanhamento; Fatores psicossociais; Fatores sociais e físicos; Ferramenta de análise da dor vulvar; Ferramenta de análise para função sexual/atividade sexual; Ferramenta de medida da qualidade de vida; e, Ferramenta de medida da saúde mental.

No artigo 2, as variáveis extraídas foram: Autor/Ano; País; Intervenção; Controle/ comparador; Participantes; Idade (anos); Conjunto de resultados; Protocolo terapêutico; e, Acompanhamento. Dados suplementares não publicados foram obtidos através de contato por e-mail com o autor correspondente quando necessário.

4.6.1 Dados Perdidos

No caso de falta de dados (estudos incompletos ou valores/medidas faltantes), os autores ou coautores do artigo foram contatados por e-mail ou telefone. Quando as informações faltantes não foram recebidas, os dados foram excluídos da análise e mencionados na seção de discussão.

4.7 Análise dos Dados

Em ambas as revisões, os dados qualitativos foram apresentados de maneira descritiva e em tabelas. No artigo 1, não foi possível a realização da metanálise devido à alta heterogeneidade apresentada entre os estudos incluídos.

No artigo 2, as análises estatísticas foram realizadas usando o software *Review Manager* (*RevMan*), versão 5.4. Para cada ensaio clínico randomizado incluído, a análise da metanálise foi feita através do cálculo dos resultados contínuos apresentados, da média ± desvio padrão, *Mean Difference* (MD), com análise de efeitos aleatórios de inversa variância com *Mantel-Haenszel* e 95% de *Confidence Interval* (CI) para o resultado de aceitação da dor. A análise da heterogeneidade entre

os estudos foi quantificada usando o teste Q de Cochran e o teste de inconsistência I^2. Quando I^2 estava entre 0 e 50%, a heterogeneidade foi considerada aceitável.

4.8 Risco de Viés

Três revisores, avaliaram independentemente o risco de viés dos estudos observacionais (coorte e caso-controle) incluídos, utilizando a ferramenta, Escala *Newcastle-Ottawa* (NOS). Cada estudo foi avaliado a partir de três perspectivas principais: a seleção de grupos de estudo (quatro itens); comparabilidade do grupo (um item); e determinar a exposição ou o resultado de interesse para estudos de caso-controle ou coorte (três itens).

Para os ensaios clínicos, dois autores avaliaram independentemente o risco de viés dos RCTs incluídos, usando a ferramenta *Cochrane Risk of Bias* (RoB 2) (15,16). Assim, cada estudo foi avaliado quanto aos domínios: uso ou ausência de um processo de randomização, desvio de intervenção pretendida, dados de desfechos ausentes, medidas dos desfechos, relato seletivo de resultados e viés geral (19).

4.9 Avaliação da Certeza da Evidência

Para avaliar e classificar a força da evidência dos dados incluídos, foi utilizado o *Grading of Recommendations Assessment, Development, and Evaluation* do (GRADE). A ferramenta GRADE classifica os estudos como de baixa, moderada ou alta qualidade. A qualidade da evidência foi avaliada com base no risco de viés, viés indireto, inconsistência, imprecisão e viés de publicação (20). As diferenças nos julgamentos foram resolvidas por consenso entre os autores.

5. Apresentação dos Resultados

No artigo 1, a alta heterogeneidade observada entre os estudos incluídos na revisão impossibilitou a realização da análise quantitativa (metanálise). Por isto, os resultados foram apresentados de forma narrativa, utilizando tabelas como melhor apresentação dos dados.

Um total de 3.182 artigos foram identificados usando uma estratégia de busca. Destes, 22 estudos (21-42) atenderam aos critérios de elegibilidade e foram incluídos nesta revisão, conforme esquematizado na Figura 1.

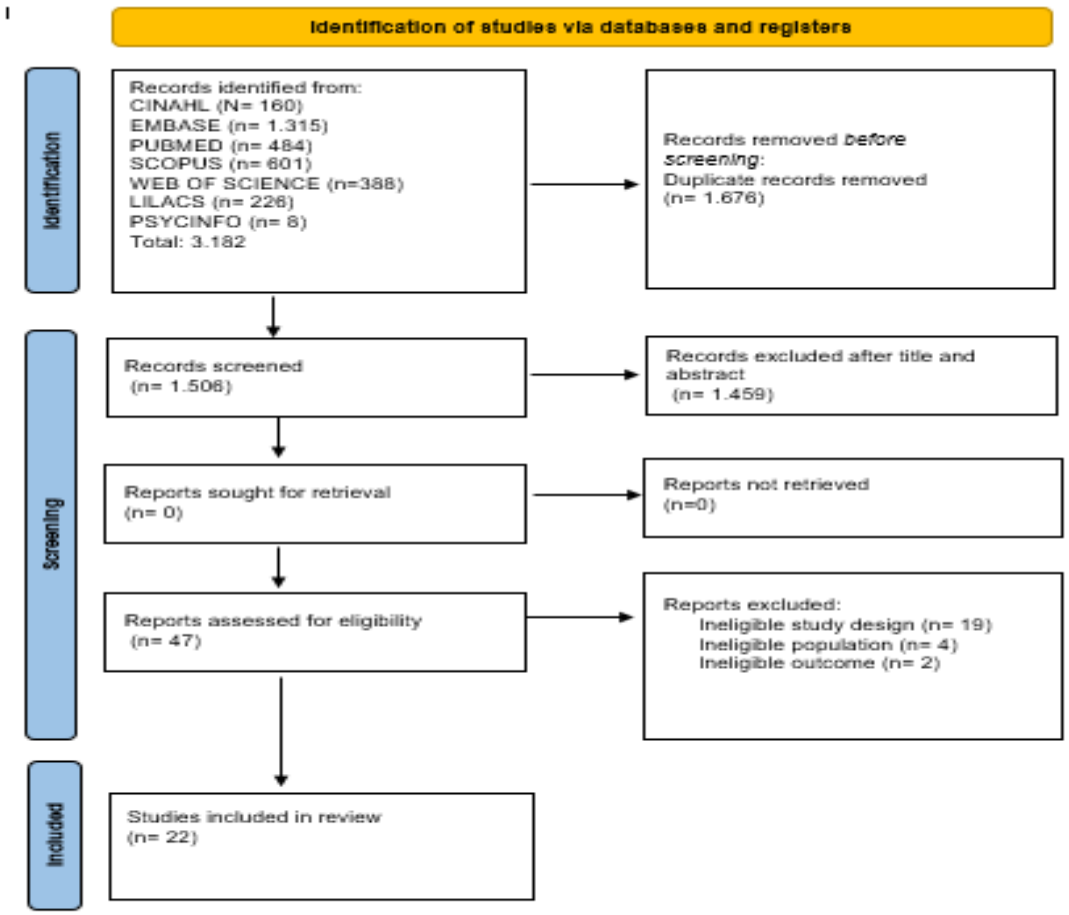

Figure 1. PRISMA flowchart- identification of studies examining psychosocial factors with vulvodynia through databases and registers.

Figura 1 - Fluxograma PRISMA do artigo 1.

Dos 22 estudos observacionais incluídos na revisão, oito foram estudos de coorte (24,26,31,33,34,38,39,41) e 14 foram estudos de caso-controle (21-23,25,27-30,32,35-37,40,42). Nove estudos foram realizados no Canadá, (24,28,29,41,42) oito nos Estados Unidos, (21-23,25,30,31,33,34) dois no Reino Unido, (39,40) um na França, (32) um na Suíça, (26) e um na Bélgica (27). A idade média das mulheres que participaram dos estudos foi de 27 anos, com uma faixa média entre 24 e 48 anos e um total de 2.624 pacientes.

Embora todos os estudos selecionados tenham abordado a vulvodínia, apenas 15 estudos avaliaram a dor vulvar usando instrumentos validados (21,22,24,26-30,34-38,40,41). A vulvodínia tem sido associada a fatores psicológicos, como ansiedade (23,26,27,35,36,38) e depressão (26-30,35,36,38,40,41). Dezoito estudos avaliaram a saúde mental (21-31,33,35,36,38,40-42) e 13 artigos avaliaram a função sexual (24,26-30,32,34-37,40,41).

Os desfechos mais frequentes observados foram dispareunia, (26,27,30,35,41) satisfação sexual, (24,34,37,40) e disfunção sexual (34-37,40). Apenas um estudo avaliou a qualidade de vida. Os dados relatados acima estão descritos na Tabela 5.

Author/ Year	Country	Study design	Sample (n)	Mean age	Follow-up period	Psychological factors	Social and physical factors	Vulvar pain (Analysis tool)	Sexual function (Analysis tool)	Quality of life (Analysis tool)	Mental health (Analysis tool)
Masheb et al. (2002)[10]	United States	Case-control	131	42.9	NA	Affective distress and marital dissatisfaction	Physical disability	WHYMPI	NA	The MOS 36-item SF-36	MHC-SF and LWMAT
Harlow et al (2005)[11]	United States	Case-control	125	24.5	3 years	NA	Childhood exposure to physical and sexual abuse and poor family support	Interviews (Own form)	NA	NA	Survey of Interpersonal Relationships
Khandker et al, (2011)[12]	United States	Case control	240	41.0	55 months	Depression and anxiety	NA	NA	NA	NA	DSM-IV Axis Disorders (SCID)
Rosen et al, (2012[13]	Canada	Cohort	121	30.6	6 months	Anxiety	Pain-inducing behaviors	MPQ	GMSEX, FSFI, SRI: Higher sexual satisfaction was associated with a shorter duration of pain, greater sexual function, less avoidance, and facilitative responses.	NA	STAI
Khandker et al, (2014)[14]	United States	Case control	215	41.0	55 months	Depression and anxiety	NA	NA	NA	NA	DSM-IV Axis I Disorders (SCID)
Leeners et al, (2014)[15]	Switzerl and	Cohort	191	30.0	20 years	Depression, anxiety hostility, obsessive-compulsive, ideation, phobic psychoticism, somatization,	Dissociability	Interviews (Owen form)	Interviews (Own form): Dyspareunia was 26.2% of all reported sexual problems. The prevalence of sexual problems at 35, 41, and 50 years old were 26.1, 32.9 and 25.2%, respectively.	NA	SCL-90, FPI and Scales of Sense of Mastery and Self-esteem from Work

						nervousness, aggressiveness,					
Pasmany et al, (2014)[16]	Belguim	Case control	82	24,9	NA	Depression, anxiety, dyadic adjustment, and distress	NA	Interviews (Own form)	DSC, FSDS, FSFI, and IIEF: Women with dyspareunia reported worse global sexual functioning, more sexual distress, and worse overall sexual functioning.	NA	STAI and BDI-II
Rosen et al, (2014)[17]	Canada	Case control	68	28.1	8 weeks	Depression	NA	NRS	KMS: On days of sexual interaction when women perceived greater negative male partner responses	NA	POMS
Boerner et al, (2015)[18]	Canada	Case control	61	27.9	NA	Depression and anxiety	NA	CPAQ	DISF-SR/GMSEX Women's higher acceptance of their vulvovaginal pain was related to their own higher sexual functioning	NA	STAI and BDI-II
Groven et al, (2015)[19]	United States	Case control	8	27.5	NA	Obedience and stress, non-compliance or effort, and sadness	Recurrent pain, lack of love, frustration	Interviews (Own form)	Interviews (Own form) Women with vulvar pain felt frustrated and sad for not being able to have sexual intercourse without pain	NA	Interviews (own form)
Johnson et al, (2015)[20]	United States	Cohort	18	31,9	2 years	NA	Vulvar pain	Interviews (Own form)	NA	NA	CFS and Fennell Phase Inventory
Wylomanski et al, (2015)[21]	France	Case control	144	48.0	18 months	Well-being		NA	FSFI sub-score was lower in VD patients. Considering the FSFI subscores, a negative	NA	NA
							NA		impact was found for desire, pain lubrication, and orgasm		
Reed et al, (2016)[22]	United States	Cohort	239	47.6	36 months	Depression	Fibromyalgia and Post-Traumatic Stress Disorder	NA	NA	NA	PHQ-8 and PC-PTSD
Vannier et al, (2016)[23]	United States	Cohort	70	28.2	8 weeks	NA	Disturbances in the relationship	NRC	KMS, GMSEX, MF-SSQ: Higher levels of hugging/kissing reported higher sexual satisfaction, and Functioning.	NA	NA
Muise et al, (2017)[24]	Canada	Case control	101	25.6	NA	Depression and anxiety, unpleasantness	NA	PPI, MPQ and FSDS	PPI/MPQ: On days when VD women reported greater sexual strength, they reported less dyspareunia and fewer anxiety symptoms.	NA	POMS
Paquet et al, (2018)[25]	Canada	Case control	127	26.2	NA	Depression and anxiety	NA	NRS	MF-SSQQ/FSDS: On days when VD women felt less depressed and less anxious, they reported better sexual function and less sexual distress.	NA	POMS
Rosen et al, (2018)[26]	Canada	Case control	101	25.6	8 weeks	Anxiety	NA	PPI and MPQ	MF-SSQ: Higher sexual avoidance was related to lower relationship satisfaction and worse sexual function. And closer sexual goals were related to better sexual function	NA	NA
Paquet et al, (2019)[27]	Canada	Cohort	173	31.2	7 years	Depression and anxiety	NA	NRS	NA	NA	STAI and BDI-II

Tabela 5. Características dos estudos incluídos no artigo 1 (continuação).

Chandan et al, (2021) [28]	United Kingdom	Cohort	23	36.1	23 years	Depression, anxiety and serious mental illness,	Domestic abuse, alcohol drinking, smoking, chronic fatigue, syndrome temporomandibular joint disorder, chronic pain, interstitial cystitis, chronic headaches and myofascial pain	NA	NA	NA	NA
Chisari et al, (2022) [29]	United Kingdom	Case control	244	33.0	3 months	Depression, perceived Injustice	Committed action and pain acceptance	CPAQ and BPI	GMSEX/FSFI: Sexual activity and age showed associations with sexual functioning and sexual satisfaction	NA	TOF, CAQ-8, BEASAQQ, PHQ-9 and IEQ
Rossi et al, (2022) [30]	Canada	Cohort	44	29.1	24 months	Depression	Pain, relationship satisfaction, sexual distress, the intensity of pain during intercourse and gynecological exam	PCS and VAS	FSDS: Association between dyspareunia and vestibular pain	NA	EPDS
Smith et al, (2022) [31]	Canada	Case-control	98	32.8	6 months	Fear of childbirth, anxiety, and depression	Pain	NA	NA	NA	PASS-20, W-DEQ, GAD-7 and PHQ

Abbreviations: International Index of Erectile Functioning (IIEF), Dyadic Sexual Communication (DSC), Female Sexual Function Index (FSFI), Marital Satisfaction Scale (KMS), Global Measure of Sexual Satisfaction (GMSEX), Monash Women's Health Program Female Sexual Satisfaction Questionnaire (MF-SSQ), Couples Satisfaction Index (CSI-4), Female Sexual Distress Scale (FSDS), Subscale of the Spouse Response Inventory (SRI), Revised Dyadic Adjustment Scale (RDAS), Present Pain Intensity (PPI), McGill Pain Questionaire (MPQ), Derogatis Interview for Sexual Functioning- Self-Report (DISF-SR), Chronic Pain Acceptance Questionnaire(CPAQ), Brief Pain Inventory Short Form (BPI), West Haven-Yale Multidimensional Pain Inventory (WHYMPI), Numerical Rating Scale (NRS), Pain Catastrophizing Scale (PCS), Visual Analogue Scale (VAS), State-Trait Anxiety Inventory (STAI), Beck Depression Inventory II (BDI-II), Tacting of Function Scale (TOF), Committed Action Questionnaire (CAQ-8), The Body Exposure Anxiety and Avoidance during Sexual Activities Questionnaire (BEASAQQ), Patient Health Questionnaire-9 (PHQ-9), Injustice Experiences Questionnaire (IEQ), Model of Psychosocial Experiences to Chronic Fatigue Syndrome (CFS), Short-form Health Survey-36 (SF-36), Locke-Wallace Marital Adjustment Test (LWMAT), Profile of Mood States (POMS), State-Trait Anxiety Inventory (STAI), Beck Depression Inventory-II (BDI-II), Patient Health Questionnaire (PHQ-8), Primary Care Post-Traumatic Stress Disorder screen (PC-PTSD), Edinburgh Postnatal Depression Scale (EPDS), Pain Anxiety Symptoms Scale (PASS-20), Wijma Delivery Expectancy/Experience Questionnaire (W-DEQ), Generalized Anxiety Disorder-7 (GAD-7) and Patient Health Questionnaire (PHQ)

Tabela 5. Características dos estudos incluídos no artigo 1.

A avaliação do risco de viés mostrou que a qualidade média dos estudos foi boa (8/9) (21,24,25,33,37,39) a excelente (9/9) (22,23,26,31,35,36,38). No entanto, dois estudos apresentaram baixa qualidade (1/9) (34) e (3–9) (42), evidenciado na Tabela 6.

Newcastle - Ottawa	Selection				Comparability	Outcome			Total
Study	1	2	3	4	1	1	2	3	
Masheb et al. (2002)[10]	b)	a)*	a)*	a)*	a)* b)*	b)*	a)*	a)*	8
Harlow et al, (2005)[11]	a)*	a)*	a)*	a)*	a)* b)*	b)*	a)*	a)*	9
Khandker et al, (2011)[12]	a)*	a)*	a)*	a)*	a)* b)*	b)*	a)*	a)*	9
Rosen et al, (2012)[13]	a)*	b)	b) *	a)*	a)* b)*	b)*	a)*	b)*	8
Khandker et al, (2014)[14]	b)*	a)*	a)*	a)*	a)* b)*	b)*	b)	a)*	8
Leeners et al, (2014)[15]	a)*	a)*	b)*	a)*	a)* b)*	b)*	a)*	b)*	9
Pasmany et al, (2014)[16]	a)*	a)*	a)*	a)*	a)*	a)*	a)*	c)	7
Rosen et al, (2014)[17]	a)*	b)	a)*	a) *	a) * b)*	c)	a)*	a)*	7
Boerner et al, (2015)[18]	b)	a)*	a)*	a)*	a)* b)*	c)	a)*	c)	6
Groven et al, (2015)[19]	b)	a)*	b)	a)*	a)* b)*	c)	a)*	a)*	6
Johnson et al, (2015)[20]	a)*	a)*	a)*	a)*	a)* b)*	b)*	a)*	b)*	9
Wylomanski et al, (2015)[21]	a)*	a)*	a)*	a)*	a)*	a)*	a)*	c)	7
Reed et al, (2016)[22]	a)*	a)*	b)*	b)	a)* b)*	b)*	a)*	b)*	8
Vannier et al, (2016)[23]	d)	c)	a)*	b)	c)	c)	b)	d)	1
Muise et al, (2017)[24]	a)*	a)*	a)*	a)*	a)* b)*	b)*	a)*	a)*	9
Paquet et al, (2018)[25]	a)*	a)*	a)*	a)*	a)* b)*	b)*	a)*	a)*	9
Rosen et al, (2018)[26]	a)*	b) *	a) *	a)*	a) * b)*	c)	a)*	a) *	8
Paquet et al, (2019)[27]	b)*	a)*	a)*	a)*	a)* b)*	b)*	a)*	b)*	9
Chandan et al, (2021)[28]	a)*	a)*	a)*	a)*	b)*	a)*	a)*	b)*	8
Chisari et al, (2022)[29]	b)	a)*	a)*	a)*	a)* b)*	c)	a)*	b)	6
Rossi et al, (2022)[30]	a)*	b)	a)*	a)*	a) * b)*	c)	a)*	c)	6
Smith et al, (2022)[31]	b)	b)	a)*	a)*	-	c)	a)*	b)	3

Tabela 6. Avaliação da qualidade dos estudos incluídos usando o NOS do artigo 1.

A certeza da evidência para todos os resultados analisados foi considerada baixa e muito baixa. As principais limitações relacionadas a falhas metodológicas na condução dos estudos foram as seguintes: falha na seleção da coorte não exposta ou grupo controle, falha na descrição dos resultados e uma pequena população de estudo. A não seleção da coorte não exposta ou grupo controle e a não descrição dos resultados impossibilitaram a realização de uma metanálise, como descrito na Tabela 7.

Certainty assessment							Impact	Certainty	Importance
№ of studies	Study design	Risk of bias	Inconsistency	Indirectness	Imprecision	Other considerations			
Vulvar pain									
15	observational studies	serious[a]	serious[b]	serious[c]	serious[d]	none	• Women with vulvar pain reported significantly greater physical disability and affective distress. • Women with vulvar pain versus controls were 2.6 time more likely to report never/rarely receiving childhood family support, such as comfort, encouragement, and love (95% confidence interval (CI): 1.3, 5.1). • Controlling for trait anxiety and avoidance, higher solicitous partner responses were associated with higher vulvovaginal pain intensity (b = 0.20, P = 0.03), and higher facilitative partner responses were associated with lower pain intensity (b=-0.20, P = 0.04). • Dyspareunia was related to psychopathological covariates, especially depression. • Women's greater pain acceptance was associated with their lower self-reported pain during intercourse, controlling for partner's pain acceptance. • Hugging/kissing was unrelated to pain intensity. • On days of sexual activity, when women reported higher anxiety and depressive symptoms (compared to their average), they reported greater pain and lower sexual function. • Women who were older at first pain onset, had pain at another location than the entrance of the vagina, and reported more anxiety were more likely to have a persistent pain trajectory relative to the decreased pain trajectory.	⊕◯◯◯ Very low	CRITICAL

Tabela 7. Avaliação GRADE do artigo 1.

Certainty assessment							Impact	Certainty	Importance
№ of studies	Study design	Risk of bias	Inconsistency	Indirectness	Imprecision	Other considerations			
18	observational studies	serious[a]	serious[b]	serious[c]	serio¦js[d]	none	- Women with vulvar pain reported significantly greater physical disability and affective distress. - Adult-onset vulvodynia was strongly associated with abuse as a child more than a few times physically (odds ratio (OR) 1⁄4 4.1, 95% CI: 1.7, 10.0) or sexually (OR 1⁄4 6.5, 95% CI: 1.2, 35.1). - Vulvodynia was associated with new or recurrent onset of mood or anxiety disorder after adjustment (hazard ratio [HR] 1.7, 95% CI 1.1-2.6). - Among women with no history of childhood abuse, those with vulvodynia had over six times the odds of antecedent mood disorder compared to women without vulvodynia (95% confidence interval: 1.9,19.6). - Dyspareunia was related to psychopathological covariates, especially depression. - Women with dyspareunia reported significantly more impaired psychological and sexual well-being. - On days after women reported higher relationship satisfaction than usual, their perception of greater facilitative male partner responses was associated with their decreased depression. - Greater pain acceptance among women was associated with their own lower anxiety and depression, greater sexual functioning. - On days when women with vulvodynia reported higher sexual communal strength, they reported less pain and anxiety. -Results suggest that daily anxiety and depressive symptoms play a role in women's experience of vulvodynia-related pain, women's sexual function and the couple's sexual distress. -There were significant decreases in pain severity, pain interference, present moment awareness, committed action and a significant increase in depression at 3 months.	⊕◯◯◯ Very low	CRITICAL

a. Failure of selection of the non-exposed cohort or control group / b. High heterogeneity / c. Failure to describe the results / d. Small population

Tabela 7. Avaliação GRADE do artigo 1. (continuação)

Certainty assessment							Impact	Certainty	Importance
№ of studies	Study design	Risk of bias	Inconsistency	Indirectness	Imprecision	Other considerations			
Sexual dysfunction									
13	observational studies	serious[a]	serious[b]	serious[c]	serious[d]	none	- Controlling for sexual function, trait anxiety, and avoidance, higher facilitative partner responses were associated with higher sexual satisfaction (b = 0.15, P = 0.05). - As dyspareunia is experienced by about 20 % of all women, it represents a frequent sexual problem. - Women with dyspareunia reported significantly poorer dyadic sexual communication, a difference not found between partners of women with dyspareunia and control partners. - Women's greater pain acceptance was associated with their lower self-reported pain during intercourse, controlling for partner's pain acceptance. - On the FSFI subscores, VD had significant impacts on items related to "arousal", "pain", "lubrication", "satisfaction", and "desire". When comparing the VD groups, the total FSFI score seemed lower for (pre)malignant VD. - Hugging/kissing was positively associ- ated with sexual satisfaction, relationship satisfaction, and sexual functioning with in any given day and when predicting the next day. - On days of sexual activity, when women reported higher depressive symptoms, they reported greater levels of sexual distress.	⨁◯◯◯ Very low	CRITICAL
Quality of life									
1	observational studies	not serious	not serious	not serious	not serious	none	- Women with vulvar pain reported significantly greater physical disability and affective distress.	⨁⨁◯◯ Low	IMPORTANT
Mental health									

Tabela 7. Avaliação GRADE do artigo 1.

No artigo 2, foram identificados por meio da estratégia de busca um total de 1.884 artigos, dos quais 1.021 duplicatas foram excluídas. Após a leitura dos títulos e resumos, 845 artigos foram excluídos e 18 estudos foram revisados. Oito estudos (43-50) preencheram os critérios de elegibilidade e foram incluídos na revisão sistemática, como mostrado na Figura 2.

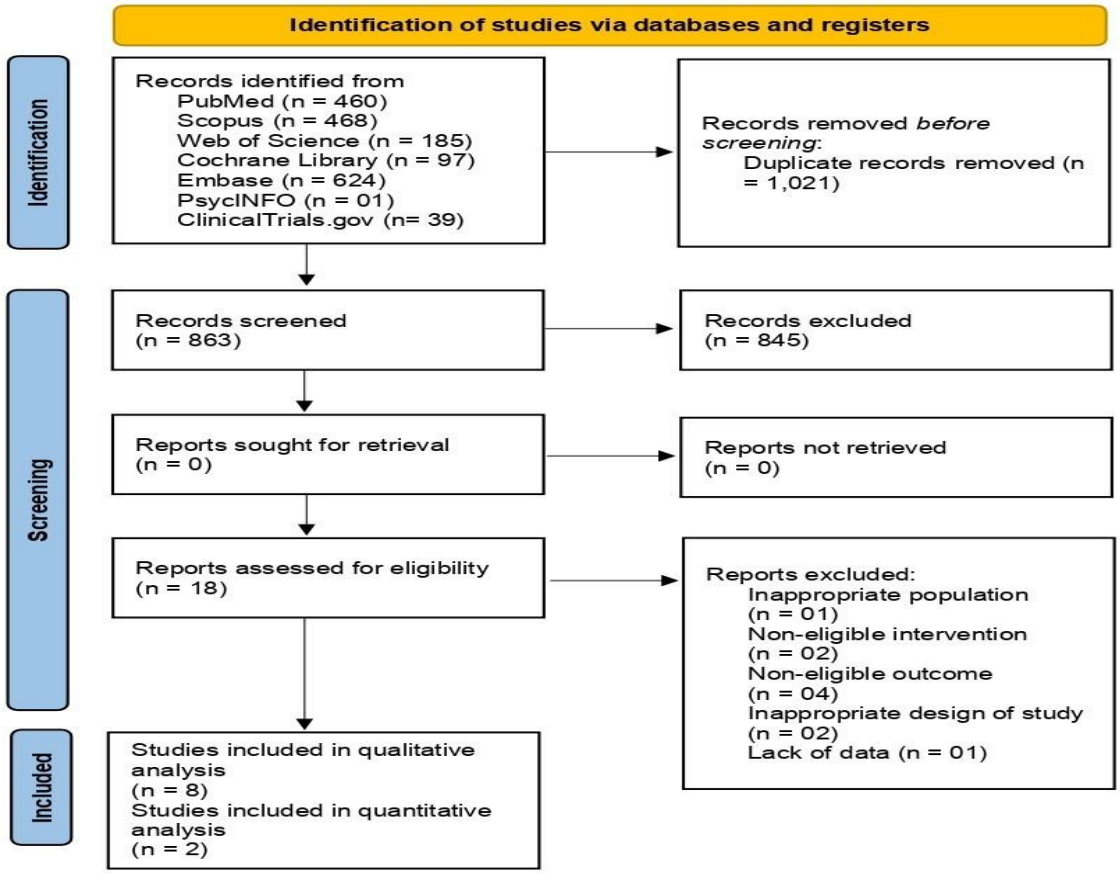

Figura 2. Fluxograma PRISMA do artigo 2.

Os oito ensaios clínicos incluídos na revisão, foram randomizados para receber intervenção ou controle, na qual envolveu um total de 689 participantes, com idade média variando de 24,2 a 43,4 anos. Destes, quatro foram realizados no Canadá (43-46), dois nos Estados Unidos (47,50) e dois na Suécia (48,49). O período de acompanhamento variou de 6 meses (43-45,47), 12 meses (46,50) e de 6-7 semanas (48) de duração, como mostrado na Tabela 8.

Table 2. Characterization of the included Studies

Author, year	Country	Intervention	Control/ comparator	Participants Enrollment		Mean age (years)		Core outcome set[8]	Therapeutic protocol	Follow-up
				Intervention	Control	Intervention	Control			
Bergeron et al. (2016)[14]	Canada	Group cognitive-behavior therapy	Topical corticosteroid	52	45	27.79	26.07	1. Insertional pain (nonsexual) 2. Insertional pain (sexual) 3. Pain-related interference on one's life 4. Provoked vulvar pain by pressure/contact 5. Pain interference on sexual life 6. Sexual function	10 sessions over a 13-week period	6 months
Bergeron et al. (2021)[15]	Canada	Cognitive-behavioral couple therapy	Topical lidocaine	53	55	26.51	27.60	1. Insertional pain (sexual) 2. Pain-related interference on one's life 3. Provoked vulvar pain by pressure/contact 4. Pain interference on sexual life 5. Sexual function	12 weekly 75-min sessions	6 months
Brotto et al. (2019)[16]	Canada	Cognitive-behavior therapy	Mindfulness-based cognitive therapy	63	67	31.24	33.72	1. Insertional pain (sexual) 2. Pain-related interference on one's life 3. Provoked vulvar pain by pressure/contact 4. Pain interference on sexual life 5. Sexual function	8 weekly 2h25min sessions	6 months
Brotto et al. (2020)[17]	Canada	Cognitive-behavior therapy	Mindfulness-based cognitive therapy	63	67	31.24	31.24	1. Insertional pain (sexual) 2. Pain-related interference on one's life 3. Provoked vulvar pain by pressure/contact 4. Pain interference on sexual life 5. Sexual function	8 weekly 2h25min sessions	12 months
Guillet et al. (2019)[18]	USA	Mindfulness-based group cognitive behavior therapy	Education support group therapy	14	17	34.4	29.1	1. Insertional pain (nonsexual) 2. Insertional pain (sexual) 3. Pain-related interference on one's life 4. Provoked vulvar pain by pressure/contact 5. Pain interference on sexual life 6. Sexual function	8 weekly 2.5h sessions	6 months
Hess Engstrom et al. (2022)[19]	Sweden	Acceptance and Commitment Therapy (Online)	Waitlist control	52	47	24.2	24.7	1. Insertional pain (nonsexual); 2. Insertional pain (sexual) 3. Pain-related interference on one's life 4. Provoked vulvar pain by pressure/contact 5. Pain interference on sexual life 6. Sexual function.	6 modules 1 for week	6 -7 weeks
Maathz et al.	Sweden	Acceptance and	Waitlist control	22	22	25.13	28.24	1. Insertional pain (nonsexual)	6 modules	NA

Tabela 8. Caracterização dos estudos incluídos no artigo 2.

Os instrumentos de avaliação utilizados nos estudos para avaliar a dor vulvar foram: Numeral Rating Scale (NRS) (43-46,48), Painful Sexual Intercourse Self-Efficacy Scale (PISES) (43), McGill Pain Questionnaire Pain Assessment Index (MPQ-PRI) (43), Vulvalgesiometer Pain Assessment (VVG) (45,46), e Tampon Test (47,48). Para mensurar a função sexual foram utilizados os seguintes instrumentos: Female Sexual Function Index (FSFI) (43-45,47,49,50), a Female Sexual Distress Scale-Revised (FSDS-R) (44-46) e a Female Sexual Distress Scale (FSDS) (47). Os instrumentos de avaliação para mensurar o ajuste psicológico foram: Pain Catastrophizing Scale (PCS) (43-49), Pain Anxiety Symptoms Scale (PASS-20) (44), o Pain and Vigilance Awareness Questionnaire (PVAQ) (45), o Five Facet Mindfulness Questionnaire, a Self-Compassion Scale (FFMQ) (46), Generalized Anxiety Disorder (GAD-7) (47), o Beck Depression Inventory (BDI) (50), o Beck Depression Inventory (BDI-PC) (47), o Chronic Pain Acceptance Questionnaire (CPAQ) (45,46) e o Chronic Pain Acceptance Questionnaire Revised (CPAQ-R) (48).

As técnicas psicoterapêuticas utilizadas nos estudos foram Terapia Cognitivo-Comportamental de Grupo (TCCG) (43), Terapia Cognitivo-Comportamental de Casal (TCCC) (44), Terapia Cognitivo-Comportamental (TCC) (45,46,50), Terapia Cognitivo-Comportamental de Grupo baseada em Mindfulness (M-gCBT) (46) e Terapia de Aceitação e Compromisso (ACT) (Online) (48,49). Os grupos de comparação/controles do estudo e tipos de tratamento, também, estão descritos na Tabela 8.

A metanálise foi realizada em dois estudos (48,49). A análise conjunta desses estudos, ao comparar o grupo ACT e o grupo controle para aceitação da dor crônica pelo CPAQ, mostrou que não houve diferença significativa entre os dois grupos (MD = 0,77; IC 95% -3,45,4,99; I^2=0%; p = 0,90), conforme mostrado na Figura 2. Nos estudos em que a metanálise não foi viável devido à alta heterogeneidade nas medidas de desfecho, foi realizada uma análise qualitativa, como demonstrada na Figura 3.

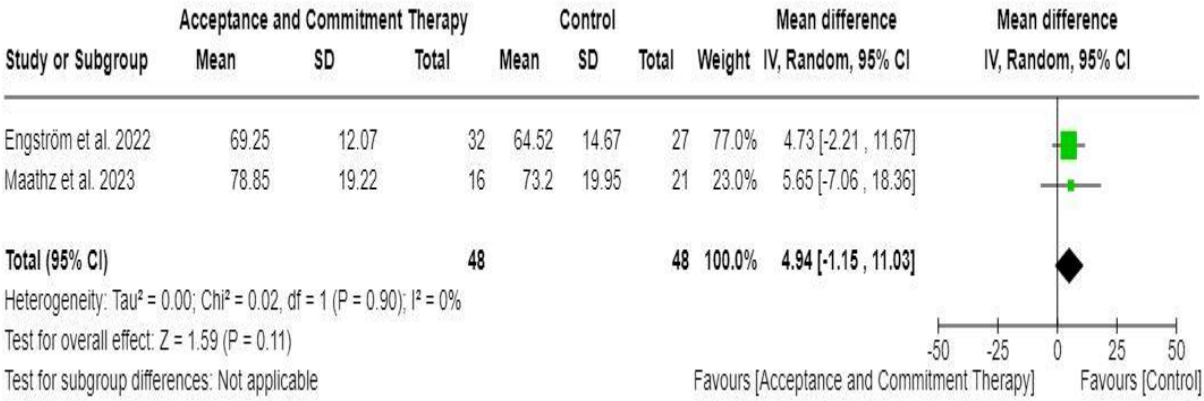

Figura 3. Metanálise comparando o ACT vs. Controle para aceitação da dor do artigo 2.

Para o Risco de viés, no geral, dois RCTs tiveram um baixo risco de viés de relato (43,50), cinco tiveram algumas preocupações (44,45,47-49), e apenas um teve um alto risco de viés (46). A maioria dos ensaios levantou algumas preocupações devido à falta de clareza sobre o processo de medição de resultados (Figura 4).

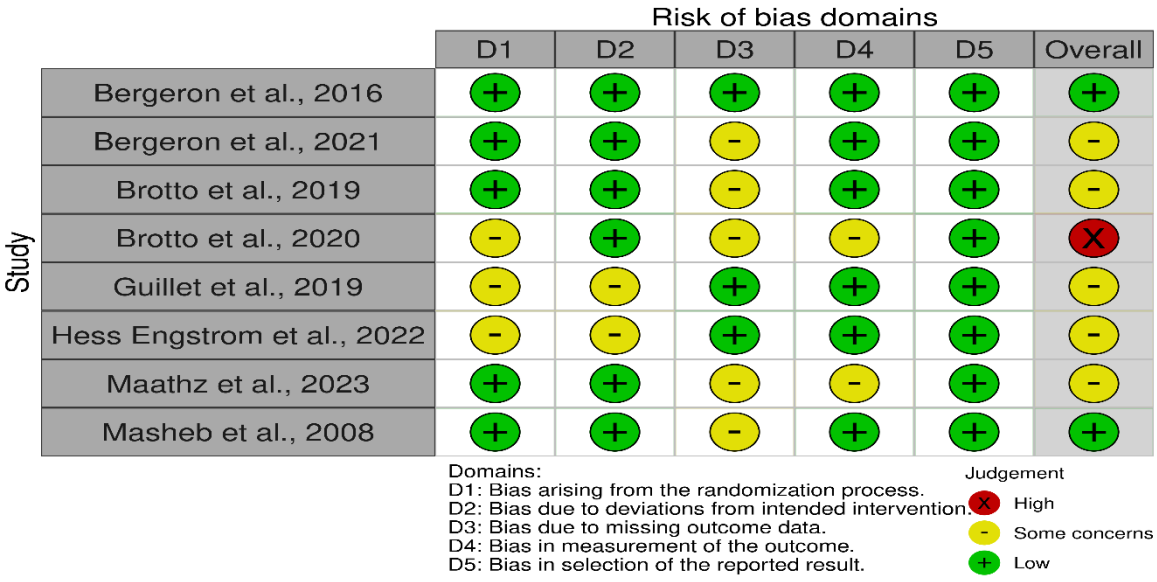

Figura 4. Risco de viés dos estudos incluídos no artigo 2.

A classificação GRADE para a certeza da evidência para a aceitação da dor usando ACT foi considerada baixa, como demonstrada na Tabela 9.

Certainty assessment							№ of patients		Effect		Certainty	Importance
№ of studies	Study design	Risk of bias	Inconsistency	Indirectness	Imprecision	Other considerations	Acceptance and Commitment therapy	Control	Relative (95% CI)	Absolute (95% CI)		
Pain acceptance												
2	randomised trials	serious	not serious	not serious	serious[a]	none	48	48	-	mean **4.94 higher** (1.15 lower to 11.03 higher)	⊕⊕◯ ◯ Low	CRITICAL

CI: confidence interval; a. large confidence interval

Tabela 9 - Avaliação GRADE do artigo 2.

6. ARTIGOS PRODUZIDOS

6.1 O artigo *Psychosocial Factors Associated with Vulvodynia*, aceito para publicação no *Journal of Lower Genital Tract Disease* que possui fator de impacto 2.4 e segundo a nova qualificação por Percentil 89%, Qualis CAPES A1 para área Medicina II.

SYSTEMATIC REVIEW, META-ANALYSIS, NARRATIVE REVIEW

Psychosocial Factors Associated With Vulvodynia

Janice F. Queiroz, MD,[1] Antonio C.Q. Aquino, MD,[1] Ayane C.A. Sarmento, PhD,[1,2] Beatriz B. Siqueira, MS,[3] Heitor D. Medeiros, MS,[3] Megan L. Falsetta, PhD,[4] Tracey Maurer, PhD,[5] and Ana Katherine Gonçalves, PhD[4,6]

Objectives: We set out to identify the psychosocial factors associated with vulvodynia and the effects on sexuality, mental health, and quality of life.

Materials and Methods: PubMed, LILACS, Embase, CINAHL, Web of Science, Scopus, and PsycINFO were searched in August 2023. Two authors selected and extracted the data independently. The risk of bias was assessed using the Newcastle-Ottawa Scale for Observational Studies. To rank the strength of evidence, the Grading of Recommendations Assessment, Development and Evaluation Working Group (GRADE) approach was utilized.

Results: A total of 3,182 articles were identified. Twenty-two observational studies (8 cohorts and 14 case-controls) met the eligibility criteria and were included, comprising 2,624 patients. Vulvodynia has been associated with psychological factors (anxiety and depression) and social factors (childhood exposure to physical and sexual abuse, posttraumatic stress, and domestic abuse). Concerning sexual function, the most frequent outcomes were dyspareunia and sexual dysfunction. Only one study assessed quality of life, which showed that women with chronic vulvar pain had greater difficulty performing physical activities and experienced negative moods and feelings. The assessment of the risk of bias showed that the average quality of studies was good to excellent. However, the studies failed to select the nonexposed cohort or control group to describe the results, and often, the study population was rather small, which made it impossible to carry out a meta-analysis.

Conclusions: The certainty of evidence for the associations between anxiety and depression, vulvodynia, and sexual functioning suggests that combating these factors could improve overall quality of life in vulvodynia patients.

Key Words: vulvodynia, vestibulodynia, vulvar pain, psychology

(*J Low Genit Tract Dis* 2024;28: 264–275)

Vulvodynia is a debilitating condition defined as chronic, persistent, and agonizing vulvar pain, lasting for 3 months or longer, all without a clearly identifiable cause. Vulvodynia detrimentally impacts the patient's overall quality of life. According to the 2015 Consensus Terminology, vulvodynia is vulvar pain that lasts at least 3 months without a clear identifiable cause, which may have potentially associated factors (localized, provoked, onset, and temporal pattern).[1–5]

The lifetime risk of vulvodynia is as high as 28%, while 8–12% of women are currently affected, translating to millions of affected persons.[1–4] In a population-based sample, the mean duration of pain among women was greater than 12 years, and more than two-thirds received no diagnosis or treatment.[2]

Vulvodynia is commonly associated with a decrease in quality of life due to pain, sexual dysfunction, high levels of anxiety, and poor mood and often concomitantly occurs with posttraumatic stress disorder.[3] Women with vulvodynia often find it distressing and challenging to undergo gynecological examinations or engage in penetrative sex. Patients report an increased frequency of negative thoughts about sex, which is associated with significant pain intensity, impacting both sexual and psychological health.[1,3] However, the mechanisms of disease are incompletely understood, and although there is a clear relationship between vulvodynia and patient quality of life, it is not clear how mental wellness and vulvodynia are related. There is a bidirectional relationship between vulvodynia and depression. Women diagnosed with vulvodynia are more likely to report depression and anxiety than women without vulvodynia, and these symptoms typically present after the diagnosis.[1] Additionally, studies have shown that women with vulvodynia are more likely to have symptoms of depression, believing that psychosocial factors may also play a role in causing pain.[2]

Psychotherapy approaches have received robust support in the vulvodynia treatment, suggesting that emotional aspects may be directly associated with the etiology of vulvodynia. However, there needs to be a coherent understanding of how psychosocial factors impact the results or interact with relevant variables of the disease.[4,6] Identifying and understanding the psychosocial factors associated with vulvodynia are important to improve the effectiveness of treatments, which could greatly benefit this patient population. Therefore, this study aims to identify the psychosocial factors associated with vulvodynia and the effects on sexuality, mental health, and quality of life based on the available literature in which patient quality of life was assessed.

METHODS

The systematic review was designed based on the Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA)[7] and registered with the PROSPERO database.

Ethical Considerations

Secondary data were used in this study, so obtaining approval from the ethics committee was not necessary.

Search Strategy

A comprehensive search was performed in August 18, 2023, using the following databases: PubMed/Medline, Literatura Latino-Americana e do Caribe em Ciências da Saúde (LILACS), Embase, Cumulative Index to Nursing and Allied Health Cumulative Literature (CINAHL), Web of Science, Scopus, and PsycInfo. In addition, reference lists of retrieved articles were manually searched to identify eligible studies. No language, publication period restrictions, or other filters were imposed.

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The authors have declared they have no conflicts of interest.

Statement of patient consent: Consent was obtained from the patient, and the document is maintained by the author.

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PROSPERO registration: CRD42022367284

DOI: 10.1097/LGT.0000000000000822

The terms of the Medical Subject Titles (MeSH) and keywords were (Vulvodynia OR Vestibulodynia OR Generalized vulvodynia) AND (Psychology OR Psychosocial factors OR Emotional OR Feelings OR Social factors OR Behavior OR Cognition OR Depression OR Anxiety) AND (Mental health OR Quality of life OR Pain OR Burning pain). The search strategy used in PubMed is shown in Table 1.

Study Selection

After searching the databases, all identified articles were exported to Rayyan software, and duplicates were removed. Based on the inclusion criteria, titles and abstracts were read independently by at least three reviewers (JFQ, BBS, and HDM). The full texts of these potentially eligible studies were independently retrieved and considered for eligibility by the two reviewers (ACQA and ACS). Only studies identified by both reviewers were included in the systematic review. In case of discrepancy, a fourth reviewer (AKQ) made the final decision on inclusion.

Inclusion Criteria

We included observational studies (case-control and cohort) evaluating psychosocial factors related to sexually active adult women with vulvodynia or vulvar pain. Women aged ≥18 years were considered adults.

Exclusion Criteria

Published but not peer-reviewed articles, clinical trials, cross-sectional studies, meta-analyses, review articles, reports, and case series were excluded. Furthermore, studies on vulvodynia or physical causes of vulvar pain associated with sexual dysfunction, and with women aged ≤18 years, were also excluded.

TABLE 1. Search Strategy of Studies Examining Psychosocial Factors Associated With Vulvodynia

	Mesh terms and keywords
1	Vulvodynia
2	Vestibulodynia
3	Generalized vulvodynia
4	OR / 1–3
5	Psychology
6	Psychosocial factors
7	Emotional
8	Feelings
9	Social factors
10	Behavior
11	Cognition
12	Depression
13	Anxiety
14	OR / 5–13
15	Mental health
16	Quality of life
17	Life quality
18	Pain
19	Burning pain
20	OR / 15–19
21	4 AND 14 AND 20

Patients, Intervention/Exposure, Comparison, Outcome Strategy, and Study Types

The PECOT strategy was used as follows: population - women with vulvodynia/ vulvar pain; intervention/exposure - psychosocial factors; comparator/control - women without vulvodynia/ vulvar pain; outcomes - vulvar pain, mental health, and quality of life; and types of study to be included - observational studies (case-control and cohort).

Primary Outcome

Vulvar pain.

Secondary Outcomes

Sexual dysfunction, quality of life, and mental health.

Data Extraction

A standardized data extraction form was developed and tested. Two reviewers (JFQ and ACS) independently extracted data for each included study, and any subsequent discrepancies were resolved through discussion with a third reviewer (AKG). Extracted data included information such as authors; year and country of publication; study design; sample; mean age; follow-up; psychosocial measure/psychosocial factors; pain measure/vulvovaginal pain; sexual intercourse pain/sexual activity, and quality of life measure.

Missing Data

In the case of a lack of data (incomplete studies or missing values/measures), the authors or coauthors of the article were contacted by telephone or e-mail. When the missing information was not received, the data were excluded from analysis and mentioned in the discussion section.

Data Synthesis

Because of the high heterogeneity presented between the studies, it was not possible to carry out qualitative analysis (meta-analysis). Study characteristics and results were summarized narratively.

Quality Assessment

Three reviewers (JFQ, BBS, and HDM) independently assessed the risk of bias in the included studies using the Newcastle-Ottawa Scale for Observational Studies (NOS).[8] This tool exists in separate versions for cohort studies and case-control, in which a study is judged from three main perspectives: the selection of study groups (four items); group comparability (one item); and determining the exposure or outcome of interest for case-control or cohort studies (three items).[8]

Assessing Certainty in the Findings

To rank the strength of evidence from the included data, the Grading of Recommendations Assessment, Development and Evaluation Working Group (GRADE) approach was utilized. The GRADE tool classifies studies as low, moderate, or high quality. The quality of evidence was assessed based on the risk of bias, indirect bias, inconsistency, imprecision, and publication bias.[9]

RESULTS

In this systematic review, a total of 3,182 articles were identified using our comprehensive search strategy of the following databases: PubMed, LILACS, Embase, CINAHL, Web of Science, Scopus, and PsycInfo, which yielded 1,676 duplicates that were subsequently excluded. After reading titles and abstracts,

1,459 were excluded, because they did not meet our inclusion criteria; the majority did not examine patient quality of life. Forty-seven full-length articles were then read to determine eligibility. Twenty-two studies[10–31] met the eligibility criteria and were included in this review, which included data from a total of 2,624 patients (see Figure 1).

Of the 22 observational studies included in the review, eight were cohort[13,15,20,22,23,27,28,30] and 14 were case-control[10–12,14,16–19,21,24–26,29,31] studies. Nine studies were carried out in Canada,[13,17,18,30,31] eight in the United States,[10–12,14,19,20,22,23] two in the United Kingdom,[28,29] one in France,[21] one in Switzerland,[15] and one in Belgium.[16] The average age of the women who participated in the studies was 27 years old, with an average range between 24 and 48 years old (see Table 2).

Although all selected studies addressed vulvodynia, only 15 studies assessed vulvar pain using validated instruments.[10,11,13,15–19,23–27,29,30] The main instrument used in the studies to assess vulvar pain was the interview (with its own form and questionnaire in each study),[11,15,16,19,20] followed by the NRS (Numerical Rating Scale)[17,26,27] (see Table 2).

Vulvodynia has been associated with psychological factors, such as anxiety[12,15,16,24,25,27] and depression.[15–19,24,25,27,29,39] Eighteen studies have assessed mental health[10–20,22,24,25,27,29–31] using mainly the following instruments: DSM-IV Axis Disorders (SCID),[12,14] Profile of Mood States.[17,24,25] State-Trait Anxiety Inventory (STAI),[13,16,18,27] and Beck Depression Inventory-II and (BDI-II)[16,18,27] (see Table 2). Additionally, social factors such as childhood exposure to physical and sexual abuse,[11] posttraumatic stress,[22] and domestic abuse[28] were associated with vulvodynia (see Table 2).

Thirteen articles assessed sexual function.[13,15–19,21,23–26,29,30] mainly by the Global Measure of Sexual Satisfaction[13,18,23,29] and the Female Sexual Function Index.[13,16,21,29] The most frequent outcomes observed were dyspareunia,[15,16,19,24,30] sexual satisfaction,[13,23,26,29] and sexual dysfunction.[23–26,29] Just one study has assessed quality of life. Masheb et al. (2002)[10] was a case-control that correlated vulvar pain with quality of life using the Medical Outcomes Study-SF 36-item tools (Short Form).

The assessment of the risk of bias showed that the average quality of studies was good (8/9)[10,13,14,22,26,28] to excellent (9/9).[11,12,15,20,24,25,27] However, two studies showed poor quality (1/9),[23] and (3–9)[31] (see Table 3). The quality of evidence for all outcomes analyzed was considered low and very low. The main limitations related to methodological flaws in the conduct of studies were as follows: failure to select the nonexposed cohort or control group, failure to describe the results, and a small study population (see Table 4). The nonselection of the unexposed cohort or control group and the nondescription of the results made it impossible to carry out a meta-analysis.

DISCUSSION

This systematic review identified numerous psychosocial factors associated with vulvodynia. Our study highlights the need

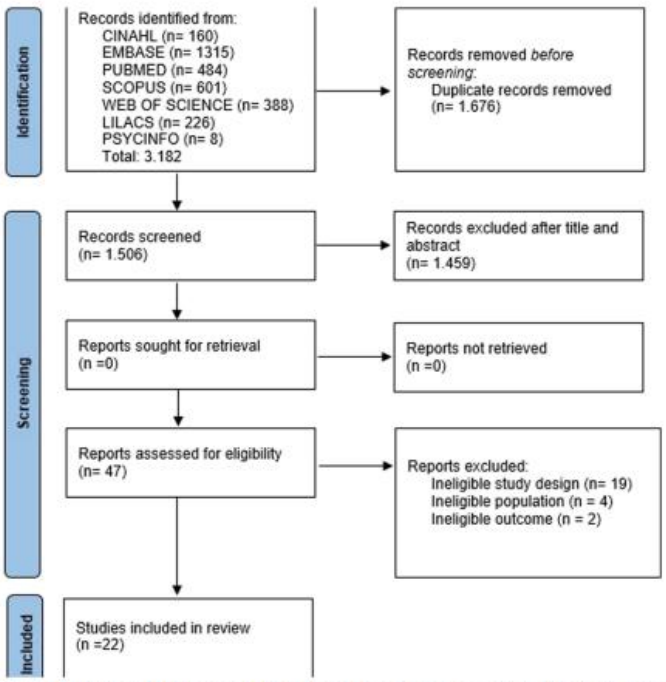

FIGURE 1. PRISMA flowchart – identification of studies examining psychosocial factors associated with vulvodynia through databases and registers.

TABLE 2. Characteristics of the Studies Included in the Systematic Review Examining Psychosocial Factors Associated With Vulvodynia

Author/ Year	Country	Study design	Sample (*n*)	Mean age	Follow-up period	Psychological factors	Social and physical factors	Vulvar pain (analysis tool)	Sexual function (analysis tool)	Quality of life (analysis tool)	Mental health (analysis tool)
Masheb et al. (2002)[10]	United States	Case-control	131	42.9	NA	Affective distress and marital dissatisfaction	Physical disability	WHYMPI	NA	The MOS 36-item SF-36	MHC-SF and LWMAT
Harlow et al. (2005)[11]	United States	Case-control	125	24.5	3 y	NA	Childhood exposure to physical and sexual abuse and poor family support	Interviews (Own form)	NA	NA	Survey of Interpersonal Relationships
Khandker et al, (2011)[12]	United States	Case control	240	41.0	55 mo.	Depression and anxiety	NA	NA	NA	NA	DSM-IV Axis Disorders (SCID)
Rosen et al. (2012)[13]	Canada	Cohort	121	30.6	6 mo	Anxiety	Pain-inducing behaviors	MPQ	GMSEX, FSFI, SRI: Higher sexual satisfaction was associated with a shorter duration of pain, greater sexual function, less avoidance, and facilitative responses.	NA	STAI
Khandker et al. (2014)[14]	United States	Case control	215	41.0	55 mo	Depression and anxiety	NA	NA	NA	NA	DSM-IV Axis I Disorders (SCID)
Leeners et al. (2014)[15]	Switzerland	Cohort	191	30.0	20 y	Depression, anxiety hostility, obsessive-compulsive, ideation, phobic psychoticism, somatization, nervousness, aggressiveness,	Dissociability	Interviews (Owen form)	Interviews (Own form): Dyspareunia was 26.2% of all reported sexual problems. The prevalence of sexual problems at 35, 41, and 50 y old were 26.1, 32.9 and 25.2%, respectively.	NA	SCL-90, FPI, and Scales of Sense of Mastery and Self-esteem from Work
Pasmany et al. (2014)[16]	Belgium	Case control	82	24.9	NA	Depression, anxiety, dyadic adjustment, and distress	NA	Interviews (Own form)	DSC, FSDS, FSFI, and IIEF: Women with dyspareunia reported worse global sexual functioning, more sexual distress, and worse overall sexual functioning.	NA	STAI and BDI-II

Continued next page

TABLE 2. *(Continued)*

Author/ Year	Country	Study design	Sample (n)	Mean age	Follow-up period	Psychological factors	Social and physical factors	Vulvar pain (analysis tool)	Sexual function (analysis tool)	Quality of life (analysis tool)	Mental health (analysis tool)
Rosen et al. (2014)[17]	Canada	Case control	68	28.1	8 wk	Depression	NA	NRS	KMS: On days of sexual interaction when women perceived greater negative male partner responses	NA	POMS
Boerner et al. (2015)[18]	Canada	Case control	61	27.9	NA	Depression and anxiety	NA	CPAQ	DISF-SR/GMSEX Women's higher acceptance of their vulvovaginal pain was related to their own higher sexual functioning	NA	STAI and BDI-II
Groven et al. (2015)[19]	United States	Case control	8	27.5	NA	Obedience and stress, noncompliance or effort, and sadness	Recurrent pain, lack of love, frustration	Interviews (Own form)	Interviews (Own form) Women with vulvar pain felt frustrated and sad for not being able to have sexual intercourse without pain	NA	Interviews (own form)
Johnson et al. (2015)[20]	United States	Cohort	18	31.9	2 y	NA	Vulvar pain	Interviews (Own form)	NA	NA	CFS and Fennell Phase Inventory
Wylomanski et al. (2015)[21]	France	Case control	144	48.0	18 mo	Well-being	NA	NA	FSFI subscore was lower in VD patients. Considering the FSFI subscores, a negative impact was found for desire, pain lubrication, and orgasm	NA	NA
Reed et al. (2016)[22]	United States	Cohort	239	47.6	36 mo	Depression	Fibromyalgia and posttraumatic stress disorder	NA	NA	NA	PHQ-8 and PC-PTSD
Vannier et al. (2016)[23]	United States	Cohort	70	28.2	8 wk	NA	Disturbances in the relationship	NRC	KMS, GMSEX, MF-SSQ: Higher levels of hugging/kissing reported higher sexual satisfaction, and Functioning.	NA	NA

Muise et al. (2017)[24]	Canada	Case control	101	25.6	NA	Depression and anxiety, unpleasantness	NA	PPI,MPQ and FSDS	PPI/MPQ: On days when VD women reported greater sexual strength, they reported less dyspareunia and fewer anxiety symptoms.	NA	POMS
Paquet et al. (2018)[25]	Canada	Case control	127	26.2	NA	Depression and anxiety	NA	NRS	MF-SSQQ/FSDS: On days when VD women felt less depressed and less anxious, they reported better sexual function and less sexual distress.	NA	POMS
Rosen et al. (2018)[26]	Canada	Case control	101	25.6	8 weeks	Anxiety	NA	PPI and MPQ	MF-SSQ: Higher sexual avoidance was related to lower relationship satisfaction and worse sexual function. And closer sexual goals were related to better sexual function	NA	NA
Paquet et al. (2019)[27]	Canada	Cohort	173	31.2	7 y	Depression and anxiety	NA	NRS	NA	NA	STAI and BDI-II
Chandan et al. (2021)[28]	United Kingdom	Cohort	23	36.1	23 y	Depression, anxiety and serious mental illness,	Domestic abuse, alcohol drinking, smoking, chronic fatigue, syndrome temporomandibular joint disorder, chronic pain, interstitial cystitis, chronic headaches and myofascial pain	NA	NA	NA	NA
Chisari et al. (2022)[29]	United Kingdom	Case control	244	33.0	3 mo	Depression, perceived Injustice	Committed action and pain acceptance	CPAQ and BPI	GMSEX/FSFI: Sexual activity and age showed associations with sexual functioning and sexual satisfaction	NA	TOF, CAQ-8, BEASAQQ, PHQ-9 and IEQ

Continued next page

TABLE 2. *(Continued)*

Author/ Year	Country	Study design	Sample (*n*)	Mean age	Follow-up period	Psychological factors	Social and physical factors	Vulvar pain (analysis tool)	Sexual function (analysis tool)	Quality of life (analysis tool)	Mental health (analysis tool)
Rossi et al. (2022)[30]	Canada	Cohort	44	29.1	24 mo	Depression	Pain, relationship satisfaction, sexual distress, the intensity of pain during intercourse and gynecological exam	PCS and VAS	FSDS: Association between dyspareunia and vestibular pain	NA	EPDS
Smith et al. (2022)[31]	Canada	Case-control	98	32.8	6 mo	Fear of childbirth, anxiety, and depression	Pain	NA	NA	NA	PASS-20, W-DEQ, GAD-7 and PHQ

BEASAQQ indicates The Body Exposure Anxiety and Avoidance during Sexual Activities Questionnaire; BPI, Brief Pain Inventory Short Form; CAQ-8, Committed Action Questionnaire; CFS, Model of Psychosocial Experiences to Chronic Fatigue Syndrome; CPAQ, Chronic Pain Acceptance Questionnaire; CSI-4, Couples Satisfaction Index; DISF-SR, Derogatis Interview for Sexual Functioning-self-report; DSC, Dyadic Sexual Communication; EPDS, Edinburgh Postnatal Depression Scale; FSDS, Female Sexual Distress Scale; FSFI, Female Sexual Function Index; GAD-7, Generalized Anxiety Disorder-7; GMSEX, Global Measure of Sexual Satisfaction; IEQ, Injustice Experiences Questionnaire; IIEF, International Index of Erectile Functioning; KMS, Marital Satisfaction Scale; LWMAT, Locke-Wallace Marital Adjustment Test; MF-SSQ, Monash Women's Health Program Female Sexual Satisfaction Questionnaire; MPQ, McGill Pain Questionnaire; NRS, Numerical Rating Scale; PASS-20, Pain Anxiety Symptoms Scale; PC-PTSD, primary care posttraumatic stress disorder screen; PCS, pain catastrophizing scale; PHQ-9, Patient Health Questionnaire 9; POMS, Profile of Mood States; PPI, present pain intensity; RDAS, Revised Dyadic Adjustment Scale; SF-36, Short-form Health Survey-36; SRI, Subscale of the Spouse Response Inventory; TOF, Tacting of Function Scale; VAS, visual analog scale; W-DEQ, Wijma Delivery Expectancy/Experience Questionnaire; WHYMPI, West Haven-Yale Multidimensional Pain Inventory.

for additional investigation into the mental health, wellbeing, and quality of life of persons living with chronic vulvar pain. After scanning several thousand articles, only 22 met our inclusion criteria. Many simply did not address quality of life or the psychological sequelae of disease. However, we can draw some important conclusions from the limited available data that will help us inform patient care and future much-needed studies to better elucidate the impact of vulvar pain on quality of life.

Depression and anxiety were the most frequent psychological symptoms observed in 15[12–18,22,24,25,27–31] of the 22 studies. Fourteen of twenty-two studies explored depression in relation to pain[12,14–18,22,24,25,27–31] and eight[15–18,24,25,29,30] in relation to sexual dysfunction. Concerning anxiety, 12 studies explored general anxiety in relation to vulvodynia.[12–16,18,24–28,31] In some studies, depression and anxiety were associated with hostility, obsessive-compulsive behaviors, ideation, phobic psychoticism, somatization,[15] and serious mental illness.[28] Masheb et al. (2002)[10] found that affective distress and marital dissatisfaction were associated with vulvodynia, while Groven et al. (2015)[19] observed that noncompliance or effort and sadness were associated with recurrent pain, lack of love, and frustration. However, it was not possible in any of these studies to establish whether psychological factors occurred in response to vulvodynia symptoms or were present before or precipitated disease onset. This is a limitation of the available data set and thus our systematic review. Nonetheless, there are ample data to show that psychological distress and vulvodynia go hand in hand.

Additionally, social factors such as posttraumatic stress disorder,[22] domestic abuse, and alcohol consumption[28] were associated with psychological symptoms in persons diagnosed with vulvodynia. Harlow et al. (2005)[11] associated childhood exposure to physical and sexual abuse and poor family support with vulvodynia, but without exploring or discussing the psychological aspects.

This systematic review also evaluated the effects of vulvodynia on sexuality. Thirteen articles assessed sexual function.[13,15–19,21,23–26,29,30] The most frequent outcomes observed were dyspareunia,[15,16,19,24,30] sexual satisfaction (or lack thereof),[13,23,26,29] and sexual dysfunction.[23–26,29] Rosen et al. (2012)[13] found that higher sexual satisfaction was associated with a shorter duration of pain, greater sexual function, less avoidance, and facilitative responses. Pasmany et al. (2014)[16] found that women with dyspareunia reported worse global sexual functioning, more sexual distress, and worse overall sexual functioning. Boerner et al. (2015)[18] showed that in vulvodynia patients, acceptance of their vulvovaginal pain was related to higher sexual functioning. Groven et al. (2015)[19] observed that women with vulvar pain felt frustrated and sad because of their inability to engage in sexual intercourse without pain. Vannier et al. (2016)[23] found that other forms of intimacy, such as hugging and kissing, resulted in higher sexual satisfaction and functioning.

Just one study has assessed the quality of life in women with vulvodynia. Masheb et al. (2002)[10] demonstrated that women with chronic vulvar pain had greater difficulty performing physical activities including walking and dressing, had greater problems with work and other daily activities, reported feeling more tired and worn down, and experienced more negative moods than women without vulvar pain, thus compromising the overall quality of life. In addition, the authors suggested that the experience of persistent vulvar pain, rather than the level of intensity of that pain, accounts for disturbances in functioning and emotional well-being. Despite the suffering caused by vulvar pain and painful sexual intercourse, more than 80% of women with vulvodynia continue to attempt intercourse regularly despite their pain, possibly to maintain intimacy or avoid conflict.[32,33]

TABLE 3. Quality Assessment of the Included Studies Examining Psychosocial Factors Associated With Vulvodynia Using the Newcastle-Ottawa Scale

Newcastle-Ottawa	Selection				Comparability	Outcome			
Study	1	2	3	4	1	1	2	3	Total
Masheb et al. (2002)[10]	b)	a)*	a)*	a)*	a)* b)*	b)*	a)*	a)*	8
Harlow et al. (2005)[11]	a)*	a)*	a)*	a)*	a)* b)*	b)*	a)*	a)*	9
Khandker et al. (2011)[12]	a)*	a)*	a)*	a)*	a)* b)*	b)*	a)*	a)*	9
Rosen et al. (2012)[13]	a)*	b)	b)*	a)*	a)* b)*	b)*	a)*	b)*	8
Khandker et al. (2014)[14]	b)*	a)*	a)*	a)*	a)* b)*	b)*	b)	a)*	8
Leeners et al. (2014)[15]	a)*	a)*	b)*	a)*	a)* b)*	b)*	a)*	b)*	9
Pasmany et al. (2014)[16]	a)*	a)*	a)*	a)*	a)*	a)*	a)*	c)	7
Rosen et al. (2014)[17]	a)*	b)	a)*	a)*	a)* b)*	c)	a)*	a)*	7
Boerner et al. (2015)[18]	b)	a)*	a)*	a)*	a)* b)*	c)	a)*	c)	6
Groven et al. (2015)[19]	b)	a)*	b)	a)*	a)* b)*	c)	a)*	a)*	6
Johnson et al. (2015)[20]	a)*	a)*	a)*	a)*	a)* b)*	b)*	a)*	b)*	9
Wylomanski et al. (2015)[21]	a)*	a)*	a)*	a)*	a)*	a)*	a)*	c)	7
Reed et al. (2016)[22]	a)*	a)*	b)*	b)	a)* b)*	b)*	a)*	b)*	8
Vannier et al. (2016)[23]	d)	c)	a)*	b)	c)	c)	b)	d)	1
Muise et al. (2017)[24]	a)*	a)*	a)*	a)*	a)* b)*	b)*	a)*	a)*	9
Paquet et al. (2018)[25]	a)*	a)*	a)*	a)*	a)* b)*	b)*	a)*	a)*	9
Rosen et al. (2018)[26]	a)*	b)*	a)*	a)*	a)* b)*	c)	a)*	a)*	8
Paquet et al. (2019)[27]	b)*	a)*	a)*	a)*	a)* b)*	b)*	a)*	b)*	9
Chandan et al. (2021)[28]	a)*	a)*	a)*	a)*	b)*	a)*	a)*	b)*	8
Chisari et al. (2022)[29]	b)	a)*	a)*	a)*	a)* b)*	c)	a)*	b)	6
Rossi et al. (2022)[30]	a)*	b)	a)*	a)*	a)* b)*	c)	a)*	c)	6
Smith et al. (2022)[31]	b)	b)	a)*	a)*	—	c)	a)*	b)	3

*Score assigned.

Comparison With Other Reviews

The findings of a previous review[34] highlighted a set of psychosocial factors that appear to promote distress and avoidance, specifically around sex or intimacy in women. Despite these interesting findings, several limitations warrant consideration. First, this study did not follow PRISMA guidelines, compromising the quality of the findings. Second, many of studies included in the review were cross-sectional, so the direction of the relationships among factors is unclear. Third, all the included studies were conducted in a single country, Canada. It may be that different psychosocial factors are present in different sociocultural contexts. Fourth, essential steps of the systematic review methodology, such as quality assessment and assessing certainty in the findings, were not adequately described, compromising the quality of the evidence.

Another review and meta-analysis conducted by Ferraz et al. (2024) showed a significant association between vulvodynia and depression, anxiety, and somatization. However, the review only included studies published between 1993 and 2017.[35]

A recent scoping review highlights the numerous barriers that people with vulvodynia may experience. While anxiety, depression, catastrophizing, and fear can intensify sexual dysfunction, this review suggests that intrapersonal, environmental, structural, and cultural barriers play an important role in an individual's well-being and may limit one's ability to seek treatment.[36]

Strengths and Limitations of This Systematic Review

The strength of this study was the rigorous search criteria, careful selection of articles, quality assessment, and assessing certainty in the findings. The main limitations were related to methodological flaws in the conduct of the included studies. They failed to select the nonexposed cohort or control group to describe the results and often the study population was rather small, which made it impossible to carry out a meta-analysis. Additionally, the quality of evidence for all outcomes analyzed was considered low and very low. Another key limiting factor in applying a systematic review to this research question is the overall limited number of publications concerning chronic vulvar pain and psychosocial factors. Nonetheless, our findings are contribute to the existing literature by summarizing what little is known and helping to identify areas of investigation that are needed. The evidence obtained is strong enough to demonstrate a connection between psychological factors and the experience of chronic vulvar pain, although the directionality of this relationship is currently unclear.

Clinical Implication of the Findings

The certainty of the association between anxiety and depression with vulvodynia and sexual functioning suggests that addressing these comorbidities could improve overall quality of life and even lessen symptoms or the experience of those symptoms. It is essential to identify and recognize the psychosocial factors associated with vulvodynia to improve the available therapeutic approaches.

CONCLUSIONS

Although there is a consistent association between psychosocial factors and vulvodynia, a direct cause-and-effect relationship could not be established, perhaps due to the need to clarify the mechanisms involved in the genesis of vulvodynia and limited data currently available.

TABLE 4. GRADE Assessment of the Included Studies Examining Psychosocial Factors Associated With Vulvodynia

Certainty assessment										
No. studies	Study design	Risk of bias	Inconsistency	Indirectness	Imprecision	Other considerations	Impact	Certainty	Importance
Vulvar pain									
15	Observational studies	Serious[a]	Serious[b]	Serious[c]	Serious[d]	None	- Women with vulvar pain reported significantly greater physical disability and affective distress. - Women with vulvar pain versus controls were 2.6 time more likely to report never/rarely receiving childhood family support, such as comfort, encouragement, and love (95% CI = 1.3, 5.1). - Controlling for trait anxiety and avoidance, higher solicitous partner responses were associated with higher vulvovaginal pain intensity (b = 0.20, p = .03), and higher facilitative partner responses were associated with lower pain intensity (b = −0.20, p = .04). - Dyspareunia was related to psychopathological covariates, especially depression. - Women's greater pain acceptance was associated with their lower self-reported pain during intercourse, controlling for partner's pain acceptance. - Hugging/kissing was unrelated to pain intensity. - On days of sexual activity, when women reported higher anxiety and depressive symptoms (compared to their average), they reported greater pain and lower sexual function. - Women who were older at first pain onset, had pain at another location than the entrance of the vagina, and reported more anxiety were more likely to have a persistent pain trajectory relative to the decreased pain trajectory.	⊕○○○ Very low	CRITICAL
Sexual dysfunction									

13	Observational studies	Serious[a]	Serious[b]	Serious[c]	Serious[d]	None	- Controlling for sexual function, trait anxiety, and avoidance, higher facilitative partner responses were associated with higher sexual satisfaction (b = 0.15, p = .05). - As dyspareunia is experienced by about 20% of all women, it represents a frequent sexual problem. - Women with dyspareunia reported significantly poorer dyadic sexual communication, a difference not found between partners of women with dyspareunia and control partners. - Women's greater pain acceptance was associated with their lower self-reported pain during intercourse, controlling for partner's pain acceptance. - On the FSFI subscores, VD had significant impacts on items related to "arousal," "pain," "lubrication," "satisfaction," and "desire." When comparing the VD groups, the total FSFI score seemed lower for (pre) malignant VD. - Hugging/kissing was positively associated with sexual satisfaction, relationship satisfaction, and sexual functioning with in any given day and when predicting the next day. - On days of sexual activity, when women reported higher depressive symptoms, they reported greater levels of sexual distress.	⊕○○○ Very low	CRITICAL
Quality of life											
1	observational studies	not serious	not serious	not serious	not serious	none	- Women with vulvar pain reported significantly greater physical disability and affective distress.	⊕⊕○○ Low	IMPORTANT
Mental health											

Continued next page

TABLE 4. *(Continued)*

Certainty assessment										
No. studies	Study design	Risk of bias	Inconsistency	Indirectness	Imprecision	Other considerations	Impact	Certainty	Importance
18	Observational studies	Serious[a]	Serious[b]	Serious[c]	Serious[d]	None	- Women with vulvar pain reported significantly greater physical disability and affective distress. - Adult-onset vulvodynia was strongly associated with abuse as a child more than a few times physically (odds ratio [OR]: 1/4 4.1, 95% CI = 1.7, 10.0) or sexually (OR = 1/4 6.5, 95% CI = 1.2, 35.1). - Vulvodynia was associated with new or recurrent onset of mood or anxiety disorder after adjustment (hazard ratio = 1.7, 95% CI = 1.1–2.6). - Among women with no history of childhood abuse, those with vulvodynia had over six times the odds of antecedent mood disorder compared to women without vulvodynia (95% CI = 1.9, 19.6). - Dyspareunia was related to psychopathological covariates, especially depression. - Women with dyspareunia reported significantly more impaired psychological and sexual well-being. - On days after women reported higher relationship satisfaction than usual, their perception of greater facilitative male partner responses was associated with their decreased depression. - Greater pain acceptance among women was associated with their own lower anxiety and depression, greater sexual functioning. - On days when women with vulvodynia reported higher sexual communal strength, they reported less pain and anxiety. -Results suggest that daily anxiety and depressive symptoms play a role in women's experience of vulvodynia-related pain, women's sexual function and the couple's sexual distress. -There were significant decreases in pain severity, pain interference, present moment awareness, committed action and a significant increase in depression at 3 mo.	⊕○○○ Very low	CRITICAL

[a]Failure of selection of the nonexposed cohort or control group.
[b]High heterogeneity.
[c]Failure to describe the results.
[d]Small population.

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6.2 O artigo *Psychotherapy and psychotherapeutic techniques for the treatment of vulvodynia: a systematic review and meta-analysis*, com o aceite no *Journal of Lower Genital Tract Disease* que possui fator de impacto 2.4 e segundo a nova qualificação por Percentil 89%, Qualis CAPES A1 para área Medicina II.

Journal of Lower Genital Tract Disease

Psychotherapy and psychotherapeutic techniques for the treatment of vulvodynia: a systematic review and meta-analysis

--Manuscript Draft--

Manuscript Number:	
Full Title:	Psychotherapy and psychotherapeutic techniques for the treatment of vulvodynia: a systematic review and meta-analysis
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Abstract:	Objectives: We set out to assess the effectiveness of psychotherapy and psychotherapeutic techniques for vulvodynia. Material and methods: The Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) guidelines were followed. PubMed, Embase, Scopus, Web of Science, Cochrane Central Register of Controlled Trials, PsycInfo, and Clinical Trial Databases were searched on July 19, 2024. We included randomized controlled trials (RCTs) comparing psychotherapy interventions and psychotherapeutic techniques for vulvodynia. The studies were selected, and data were extracted by two authors independently. The risk of bias was assessed using the Cochrane Risk of Bias (RoB 2.0) tool. RevMan 5.4. was used for data synthesis. The Grading of Recommendations Assessment Development (GRADE) and Evaluation method was used to assess the strength of the evidence. This systematic review was registered with the International Prospective Register of Systematic Reviews (PROSPERO), register (CRDXXXXXXXXXX). Results: A total of 1.884 articles were retrieved. Ten studies met the eligibility criteria and were included in the systematic review, and two studies were included in the meta-analysis. A total of 951 participants were included. When comparing the Acceptance and Commitment Therapy (ACT) with the control group, the mean difference in the pooled analysis for the Chronic Pain Acceptance Questionnaire did not differ significantly between ACT therapy and other therapies for post-treatment assessment

	(MD = 0.77; 95% CI -3.45.4, 99). Three studies were at high risk of bias due to a lack of clarity about the outcome measurement process. The GRADE rating for the certainty of the evidence for vulvar pain using ACT was considered moderate. Conclusions: The studied interventions (ACT and treatments incorporating other psychotherapeutic approaches) seem to reduce pain and improve sexual function and quality of life. However, the heterogeneity of the studies prevented meta-analysis. In addition, well-designed trials are needed to improve the certainty of this evidence.

COVER LETTER

August 10, 2024

Dear Editor-in-Chief

We would like to send for your evaluation the manuscript: "Psychotherapy and psychotherapeutic techniques for the treatment of vulvodynia: a systematic review and meta-analysis" to publish in *The Journal of Lower Genital Tract Disease* as Review Article.

This study aims to summarize the evidence on Psychotherapy and psychotherapeutic techniques for the treatment of vulvodynia.

This systematic review was registered with the PROSPERO database: CRD42023411450.

Concerning the ethical considerations, just secondary published data were used in this study, so obtaining approval from the ethics committee was not necessary.

We certify that there is no conflict of interest with any organization regarding the material discussed in the manuscript.

The manuscript has not been published and is not under consideration in another journal.

All authors approved the manuscript and submission.

We would appreciate publishing our paper in this prestigious journal.

Yours sincerely,

Ana Katherine Gonçalves

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JLGTD Checklist

I read the Journal of Lower Genital Tract Disease Instruction to Authors and made certain that my submission complies with all relevant instructions:

☒ Cover Letter included, and in compliance with instructions

☒ Manuscript included; has minimum elements of Title page, Précis, Abstract (if original research), Key words, Body of the Text, Disclosure statements, References, and is Line-Numbered.

☒ If human and non-human investigation/experimentation was conducted, manuscript and cover letter states that the appropriate institutional review body granted approval before the study began. For human research, manuscript and cover letter state that signed patient consents were obtained and maintained by the investigators. The type of nonhuman subjects must be stated in the title, abstract, key words, and Methods section of the report.

☒ If a case report or image of a patient is submitted, the cover letter states that signed informed consent was obtained from the patient, and the document is maintained by the author.

☒ If applicable, Role of the Funding Source, List of Abbreviations and Acronyms, and Permissions included and in compliance

☒ If applicable, Tables, Figures, Artwork, Photographs & Illustrations, Legends and Supplementary Data and Digital Content included and are in compliance, and submitted as individual items (separate from manuscript)

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Title: Psychotherapy and Psychotherapeutic Techniques for Treating Vulvodynia: A Systematic Review and Meta-Analysis

Précis: Acceptance and Commitment Therapy and other psychotherapeutic approaches show promise in reducing pain and enhancing sexual function and quality of life in women with vulvodynia.

ABSTRACT

Objectives: To assess the effectiveness of psychotherapy and psychotherapeutic techniques for reduction of vulvar pain and the improvement of sexual function and psychological adjustment in vulvodynia. **Material and methods:** The Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) guidelines were followed. PubMed, Embase, Scopus, Web of Science, Cochrane Central Register of Controlled Trials, PsycInfo, and Clinical Trial Databases were searched on July 19, 2024. We included randomized controlled trials comparing psychotherapy interventions and psychotherapeutic techniques for vulvodynia. The risk of bias was assessed using the Cochrane Risk of Bias (RoB 2.0) tool. RevMan 5.4. was used for data synthesis. The Grading of Recommendations Assessment Development (GRADE) and Evaluation method was used to assess the strength of the evidence. **Results:** A total of 1,884 articles were retrieved. Eight studies met the eligibility criteria and were included in the systematic review, comprising 689 participants. Two studies were included in the meta-analysis, these with 143 participants. When comparing the Acceptance and Commitment Therapy (ACT) with the control group, the mean difference (MD) in the pooled analysis for the Chronic Pain Acceptance Questionnaire did not differ significantly between ACT therapy and other therapies for post-treatment assessment (MD = 0.77;95% CI -3.45.4, 99). Only one study was at high risk of bias due to a lack of clarity about the outcome measurement process. The GRADE rating for the certainty of the evidence for vulvar pain acceptance using ACT was considered low. **Conclusions**: Psychotherapy significantly improves vulvar pain, psychological adjustment, and sexual function in women with vulvodynia. Additionally, our meta-analysis showed that ACT and other psychotherapeutic interventions improve psychological adjustment through pain acceptance. However, more rigorous studies are needed to improve the quality of evidence and inform clinical practice.

Keywords: Vulvodynia; Vestibulodynia; Psychotherapy; Psychotherapeutic techniques.

INTRODUCTION

Vulvodynia is a common gynecological condition characterized by chronic (lasting ≥3 months) burning and debilitating vulvar pain. This pain may be localized to the vulvar vestibule (the tissue surrounding the vaginal opening) and/or generalized across the entire vulvar region, with a global prevalence estimated at around 8%. In Europe, the prevalence is even higher, ranging from 10% to 16%.[1] These symptoms may occur spontaneously or be triggered by activities such as touch, pressure, or vaginal intercourse, with no clear underlying medical pathology or identifiable cause.[2-7].

Women diagnosed with vulvodynia report significantly higher rates of depression and anxiety, suggesting that psychosocial factors play a role in the pain experience.[3-5] However, the relationship between depression and vulvodynia is bi-directional. Women with vulvodynia are more likely to be diagnosed with depression. Similarly, women with depression are more likely to develop vulvodynia. Although depression is not the cause of vulvodynia, it is a common comorbidity, and effective treatment often requires addressing both the physical and psychological aspects of the condition.[3]

Psychotherapy has been used to help reduce vulvar pain.[8] However, a recent systematic review suggests that the effectiveness of psychotherapy for vulvodynia may vary depending on individual patient characteristics, highlighting the need for further research to validate these findings.[8] Therefore, this study aims to assess the effectiveness of psychotherapy in managing vulvodynia symptoms.

METHODS

The systematic review was designed based on the Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA)[9,10]. The protocol was prospectively registered at the International Prospective Register of Systematic Reviews (PROSPERO), with the registration number (CRDXXXXXXXXX).

Ethical considerations

Secondary data were used in this study, so obtaining approval from the ethics committee was not necessary.

Search strategy

The search in the databases was carried out under the guidance of an experienced librarian from the Center of Health Sciences, registered with the Regional Council of Librarianship (CRB-15/474 - UFRN, Natal, RN- Brazil).

A comprehensive search was performed in the following databases: PubMed, Embase, Scopus, Web of Science, Cochrane Central Register of Controlled Trials, ClinicalTrials. gov, and PsycINFO on July 19, 2024. Additionally, the reference lists of retrieved articles were manually searched to identify eligible studies. No language restrictions, publication period or other filters were imposed. Medical Subject Titles (MeSH) terms and keywords were (Vulvodynia OR Vestibulodynia OR “Generalized Vulvodynia” OR “Vulvodynia, Generalized” OR “Vulva Pain” OR “Pain, Vulva”) AND (Psychotherapy OR “Acceptance and Commitment Therapy” OR “Cognitive Behavioral Therapy” OR “Behavior Therapy” OR Psychology OR Mindfulness OR Counseling OR “Psychotherapeutic techniques”). The search strategy used in PubMed is shown in Table 1. The detailed search for each database is described in Supplementary file S1.

Study selection

After searching the databases, all identified articles were exported to Rayyan software and the duplicates were removed. Based on the inclusion criteria, titles and abstracts were read independently by at least three reviewers. The full texts of these potentially eligible studies were retrieved independently and considered for eligibility by the two reviewers. Only studies identified by both reviewers were included in the systematic review. In case of discrepancy, a third reviewer made the final decision on inclusion. We maintained a record of the reasons for excluding clinical trials at all stages of review. The results of the inclusion or exclusion of studies is reported using the PRISMA flowchart (Figure 1).

Inclusion criteria

Randomized clinical trials (RCTs) that evaluated psychotherapy, in any format applied by professionals or trainees, such as cognitive behavioral therapy, mindfulness-based therapy, psychological counseling, and treatments incorporating other psychotherapeutic approaches such as educational support group therapy and acceptance and commitment therapy for the treatment of vulvodynia were included.

Exclusion criteria

Studies evaluating the use of pharmacological treatment, physiotherapy or other non-psychotherapeutic treatment options were excluded. Published but not peer-reviewed articles, preprint studies, case reports, systematic reviews, conference abstracts, brief communications, ongoing RCTs or manuscripts with incomplete data and insufficient information were also excluded from the review.

Patients, Intervention/Exposure, Comparison, Outcome Strategy, and Study Types

The PICOT strategy was used as follows: Population – Adult women > 18 years old diagnosed diagnosed with any type of vulvodynia (localized vulvodynia, provoked vulvar pain, and provoked vestibulodynia); Intervention — psychotherapy, psychotherapeutic approaches; Comparator/control — no treatment or other treatments for vulvodynia; Outcomes – intensity of vulvar pain, sexual function and psychological adjustment; and Types of studies to be included – RCTs.

Primary Outcome

The intensity of any type of vulvar pain, including nonsexual, during sexual activities, provoked vulvar pain by pressure/contact, during the cotton-swab test, and spontaneous pain.

Secondary Outcomes

The following were considered as secondary outcomes: sexual function, and psychological adjustment (symptoms of depression, anxiety, subjective improvement, mindfulness, self-compassion, and pain acceptance).

Data collection and analysis

Data Extraction

A standardized data extraction form was developed and tested. Two reviewers independently extracted data from each included study, and any subsequent discrepancies were resolved through discussion with a third reviewer. A standardized data extraction form was used to collect the following data: names of authors, year of publication, country, study design, sample size, mean age (in years), therapeutic protocol, follow-up, and outcomes of interest.

Missing Data

In the case of a lack of data (incomplete studies or missing values/measures), the authors or co-authors of the article were contacted by or e-mail. When the missing information was not received, the data was excluded from analysis and mentioned in the discussion section.

Data Synthesis

Statistical analyses were performed using Review Manager (RevMan) software version 5.4 (Cochrane Collaboration, 2020). For each included RCTs, continuous outcomes were presented as mean ± standard deviation, mean differences (MD) with inverse-variance random-effects analysis with Mantel-Haenszel and 95% confidence intervals (CI) for pain acceptance outcome. The heterogeneity among studies was quantified using Cochran's Q test and the inconsistency I^2 test. When I^2 was between 0 and 50%, the heterogeneity was considered acceptable.

Quality Assessment

Two authors independently judged the risk of bias in the included studies using the Cochrane Risk of Bias (RoB 2) tool for RCTs[11]. Thus, studies were evaluated based on the use or lack of a randomization process, deviations from intended interventions, missing outcome data, how the outcome was measured, selection of reported outcomes, and overall bias. We used Shiny app-robbins as a visualization tool to develop risk of bias numbers. Disagreements were resolved by consensus by a third author[12].

Assessing Certainty in the Findings

The Grading of Recommendations Assessment, Development and Evaluation (GRADE) methodology was used for grading the strength of the evidence for psychological adjustment assessed by the Chronic Pain Acceptance Questionnaire (CPAQ) outcome, which classifies studies as very low, low, moderate, or high certainty of evidence, based on risk of bias, indirectness, inconsistency, imprecision, and publication bias[13].

RESULTS

A total of 1,884 articles were identified through the search strategy, of which 1,021 duplicates were excluded. After reading the titles and abstracts, 845 articles were excluded. 18 studies were reviewed. Eight studies[14-21] met the eligibility criteria and were included in the systematic review, involving 689 participants who were randomized to receive intervention or control, with a mean age ranging from 24.2- to 43.4-years-old (Table 2).

Of the eight clinical trials included in the review, six were carried out in Canada[14-17], two in the United States[18,21] and two in Sweden[19,20]. The follow-up period ranged from 6[14-16,18-20,] to 12 months[17,21] of duration (Table 2).

The assessment instruments used in the studies to assess vulvar pain were: The Numeric Rating Scale (NRS)[14-17,19], the Painful Intercourse Self-Efficacy Scale

(PISES)[14], the Pain Rating Index of the McGill Pain Questionnaire (MPQ-PRI)[14], the Vulvalgesiometer Pain Rating (VVG)[16,17] and the Tampon Test[18,19]. To measure sexual function the following instruments were used: the Female Sexual Function Index (FSFI)[14-16,18,20,21], the Female Sexual Distress Scale-Revised (FSDS-R)[15-17] and the Female Sexual Distress Scale (FSDS)[18]. Assessment instruments to measure psychological adjustment were: the Pain Catastrophizing Scale (PCS)[14-20], the Pain Anxiety Symptoms Scale (PASS-20)[15], the Pain Vigilance Awareness Questionnaire (PVAQ)[16], the Five Facet Mindfulness Questionnaire, the Self-Compassion Scale (FFMQ)[17], Generalized Anxiety Disorder (GAD-7)[18], the Beck Depression Inventory (BDI)[21], the Beck Depression Inventory (BDI-PC)[18], the Chronic Pain Acceptance Questionnaire (CPAQ)[16,17] and the Chronic Pain Acceptance Questionnaire-Revised (CPAQ-R)[19]. The summary of these data is described in Table 2.

The psychotherapeutic techniques used in the studies were Cognitive-Behavioral Group Therapy (CBGT)[14], Cognitive-Behavioral Couple Therapy (CBCT)[15], Cognitive-Behavioral Therapy (CBT)[16,17,21], Cognitive-Behavioral Group Therapy based on Mindfulness (M-gCBT)[17], and Acceptance and Commitment Therapy (Online)[19,20] (Table 2). For the comparison group, study controls received treatment through Topical Corticosteroid[14], Topical Lidocaine[15], Educational Support Group Therapy[18], Mindfulness-based Cognitive Therapy (MBCT)[16,17], Waitlist Control[19,20], and Supportive Psychotherapy (SPT)[21].

Meta-analysis was carried out in two studies[19,20]. The pooled analysis of these studies, when comparing the Acceptance and Commitment Therapy (ACT) and control group for chronic pain acceptance by CPAQ, showed that it did not significantly differ between both groups (MD = 0.77; 95% CI -3.45.4. 99; I^2=0%; p = 0.90), as shown in Figure 2. In studies where meta-analysis was not feasible due to high heterogeneity in outcome measurements, a qualitative analysis was conducted.

Bergeron (2016) [14] utilized cognitive-behavioral group therapy (CBGT) as an intervention and compared its effectiveness to topical corticosteroids. The authors showed that both groups reported a decrease in vulvar pain from baseline to post-treatment during the 6-month follow-up, although the CBGT group showed a significantly greater reduction in the intensity of vulvar pain as measured by the McGill Pain Questionnaire (68.6% of participants). Additionally, both groups presented with significant improvements in psychological adjustment and sexual function, but the CBGT group had a larger magnitude of reduction in pain catastrophizing coupled with better sexual performance ($p < 0.05$) post-treatment.

Bergeron (2021) [15] studied patients allocated to a CBCT intervention arm compared to topical lidocaine (control arm), showing that CBCT led to significant improvements in catastrophizing (p = 0.026) and anxiety and vulvar pain intensity (p = 0.001) compared to topical lidocaine. There was a concomitant reduction in sexual distress (p = 0.018). The authors concluded that at the 6-month follow-up women in CBCT reported significantly greater improvements in their sexual function than women treated with topical lidocaine.

Two studies used the CBT intervention and compared it with the same control, MBCT[20,21]. Brotto (2019) [16] showed that participants in both treatment groups reported a decrease in vulvar pain (68% in the CBT group and 58% in the MBCT group) and improvement in quality of sexual life. Fifty-nine% of participants reported moderate or great improvement (60% in the CBT group and 59% in the MBCT group) for results measured after six months of follow-up. The study conducted by Brotto (2020) [17] also showed that both psychotherapies, CBT and MBCT, improved vulvar pain during intercourse and penetrative sex, reduced pain catastrophizing, and fostered decentralization and chronic pain acceptance at a 12-month follow-up.

Masheb's (2008) [21] study also compared the CBT intervention to SPT. CBT reduced vulvar pain intensity (p <0.001), with 42% of trial participants presenting with a clinical improvement. CBT also reduced vulvar pain intensity during the medical examination (p = 0.014), increased sexual function (p = 0.034), and improved satisfaction (p <0.05). Guillet (2019) [18] compared participants in an intervention arm with M-gCBT to women that received Educational Support Group Therapy as ac control. By 6-months, participants in the M-gCBT group presented a statistically significant improvement in their FSFI, Generalized Anxiety Disorder (p = 0.001), and Beck Depression Index (p = 0.004) scores. However, the vaginal insertion pain (p < 0.001) decreased in both groups.

Risk of Bias

Overall, two RCTs had a low risk of reporting bias[14,21], five had some concerns[15,16,18-20], and only one had a high risk of bias[17]. Most trials raised some concerns due to a lack of clarity about the outcome measurement process (Figure 3).

Quality of evidence - GRADE

The GRADE rating for the certainty of the evidence for pain acceptance using ACT was considered low (Table 3).

DISCUSSION

The studies included in this systematic review show a decrease in vulvar pain following psychotherapeutic treatment. Additionally, the studies reported improvements in sexual function and psychological adjustment that were associated with psychotherapy. However, there was no significant difference in chronic pain acceptance in women treated with ACT therapy versus control, with only a moderate certainty of evidence. [19,20]

Various therapies have been proposed for treating vulvar pain, which is why a multidisciplinary approach is always recommended. This approach includes localized treatments (e.g., topical lidocaine and physiotherapy), systemic treatments (e.g., tricyclic antidepressants and anticonvulsants), psychotherapeutic treatments (including cognitive-behavioral therapy and sexual therapy), and surgical interventions (e.g., vestibulectomy). [22,23,8]

Depression and anxiety are linked to worsening pain, decreased sexual activity, and lower relationship satisfaction. Women with vulvodynia are four times more likely to report depression, anxiety, and a negative self-image than women without vulvodynia. These symptoms are more common after diagnosis, and these women also face greater difficulty expressing their feelings and communicating with their partners.[8,24] Factors such as domestic violence, fear of pain, and limited understanding of the condition can exacerbate pain intensity, leading to catastrophic interpretations, fear, and avoidance behaviors, which disrupt healthy emotional and sexual relationships. Interpersonal factors have also been shown to be related to pain and sexual outcomes. [25,26,27]

Wilson et al. (2020) [28] describe that fear of vulvar pain and low acknowledgment of the issue create a pattern of disengagement in women, increasing pain and disrupting healthy sexual functioning in relationships.[15,16,29] Research by Smith et al. (2011) [30] and Stefano et al. (2018) [31] suggests that living with vulvar pain is a distressing experience. They extend their study beyond the biological aspect to a biopsychosocial model of pain, emphasizing the importance of psychosocial factors as robust predictors of pain and its associated disability.

Considering the quality of life and mental health of women with vulvodynia is crucial, as these aspects contribute to high rates of comorbidities, increased vulnerability to other diseases, functional difficulties, and low quality of life. [23,32] Van Reijn-Baggen et al. (2021) [33] found that quality of life, measured with different instruments in various studies, showed significant improvement from pre- to post-treatment.

Comparison with Other Reviews

Few systematic reviews have been conducted on this topic, and those that have included only a limited number of clinical trials that employed psychotherapeutic techniques or psychotherapies as interventions for vulvar pain, sexual function, and psychological adjustment. Our systematic review provides a comprehensive update on the use of only psychotherapies and psychotherapeutic techniques in the treatment of vulvodynia.

Pérez-López et al. (2019)[35] investigated various therapeutic approaches for vulvodynia, including vaginal cream with conjugated estrogens, oral desipramine (alone or combined with topical lidocaine), standalone topical lidocaine, laser therapy, and transcranial direct current stimulation. However, their meta-analysis did not demonstrate significant efficacy of these interventions in alleviating patient-reported symptoms.

More recently, Bohm-Starke et al. (2022)[8] found that multimodal physiotherapy, compared to lidocaine treatment, was the only intervention with some level of scientific evidence supporting its clinical use in patients with vulvar pain.

It is important to note that previously published systematic reviews included studies with diverse methodological designs, such as prospective and retrospective studies, cross-sectional studies, randomized controlled trials (RCTs), non-randomized studies, and those combining psychotherapeutic and clinical approaches with other treatment modalities. This methodological heterogeneity limits the assessment of the quality and certainty of the results, thereby compromising the overall strength of the evidence.

Strengths and Limitations of This Systematic Review and Meta-analyses

The strengths of this study include its rigorous search criteria, careful selection, and thorough quality assessment of articles, which provide a robust quality of evidence. However, there were notable limitations, primarily concerning the clarity of the results measurement process. Most clinical trials did not use consistent interventions and controls, and the study populations were often quite small, limiting the ability to perform more extensive meta-analyses.

Clinical Implication of the Findings

The available evidence provides promising results regarding the effectiveness of psychotherapy and psychotherapeutic techniques for vulvodynia. However, these results need to be confirmed through well-designed clinical trials with larger sample sizes. An important consideration is the development of baseline outcome studies for vulvodynia, vulvar pain, sexual function, and psychological adjustment. This would

facilitate more comprehensive systematic reviews and meta-analyses in future research.

CONCLUSIONS

Our systematic review demonstrated that psychotherapy and psychotherapeutic techniques, especially CBT and its variations, significantly improve vulvar pain, psychological adjustment, and sexual function in individuals with vulvodynia. Furthermore, our meta-analysis of two studies showed that ACT compared to control both appear to improve psychological adjustment through pain acceptance. However, this review highlights the need for more studies with rigorous methodology to enhance the certainty of evidence and better inform clinical practice for treating vulvodynia.

LISTA DE ABREVEATURAS E SIGLAS

PRISMA	Preferred Reporting Items for Systematic Reviews and Meta-Analyses
PROSPERO	International Prospective Register of Systematic Reviews
CRD	Registration Number
AASAD	Center for Health Sciences
UFRN	Universidade Federal do Rio Grande do Norte
RN	Rio Grande do Norte
MeSH	Medical Subject Titles
RCTs	Randomized clinical trials
PICOT	Population, Intervention, Comparator/control, Outcomes
RevMan	Review Manager
MD	Mean differences
CI	Confidence intervals
RoB 2	Cochrane Risk of Bias
GRADE	Grading of Recommendations Assessment, Development and Evaluation
CPAQ	Chronic Pain Acceptance Questionnaire
NRS	Numeral Rating Scale
PCS	Pain Catastrophizing Scale
PISES	Painful Intercourse Self-Efficacy Scale
MPQ-PRI	Pain Rating Index of the McGill Pain Questionnaire
VVG	Vulvalgesiometer Pain Rating

VAS	Visual Analogue Scale
DSFI	Derogatis Sexual Functioning Inventory
SF-MPQ	Sensory Scale of the McGill Pain Questionnaire
FSFI	Female Sexual Function Index
FSDS-R	Female Sexual Distress Scale-Revised
FSDS	Female Sexual Distress Scale
BSI-GSI	Brief Symptom Inventory
PASS-20	Pain Anxiety Symptoms Scale
PVAQ	Pain and Vigilance Awareness Questionnaire
FFMQ	Five Facet Mindfulness Questionnaire, the Self-Compassion Scale
STAI	State-Trait Anxiety Inventory
GAD-7	Generalized Anxiety Disorder
BDI	Beck Depression Inventory
BDI-PC	Beck Depression Inventory
CPAQ-R	Chronic Pain Acceptance Questionnaire-Revised
CBGT	CognitiveBehavioral Group Therapy
CBCT	Cognitive-Behavioral Couple Therapy
CBT	Cognitive-Behavioral Therapy
M-gCBT	Cognitive-Behavioral Group Therapy based on Mindfulness
MBCT	Mindfulness-based Cognitive Therapy
SPT	Supportive Psychotherapy
ACT	Acceptance and Commitment Therapy

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Legends and Titles

Table 1. Search Strategy of PubMed database.

Table 2. Characterization of the included Studies.

Table 3. GRADE assessment.

Figure 1. PRISMA flow chart.

Figure 2. Meta-analysis comparing the ACT vs. control for pain acceptance.

Figure 3. Risk of Bias included studies.

Supplementary file S1. Detailed search strategy for each database.

Table 1

Table 1. Search Strategy of PubMed database.

	MeSH Terms and Keywords
1	Vulvodynia
2	Vestibulodynia
3	Generalized Vulvodynia
4	Vulvodynia, Generalized
5	Vulva Pain
6	Pain, Vulva
7	OR / 1–6
8	Psychotherapy
9	Acceptance and Commitment Therapy
10	Cognitive Behavioral Therapy
11	Behavior Therapy
12	Psychology
13	Mindfulness
14	Counseling
15	Psychotherapeutic techniques
16	OR / 8-15
17	7 AND 16

Table 2. Characterization of the included Studies

Author, year	Country	Intervention	Control/ comparator	Participants Enrollment		Mean age (years)		Core outcome set[8]	Therapeutic protocol	Follow-up
				Intervention	Control	Intervention	Control			
Bergeron et al. (2016)[14]	Canada	Group cognitive-behavior therapy	Topical corticosteroid	52	45	27.79	26.07	1. Insertional pain (nonsexual) 2. Insertional pain (sexual) 3. Pain-related interference on one's life 4. Provoked vulvar pain by pressure/contact 5. Pain interference on sexual life 6. Sexual function	10 sessions over a 13-week period	6 months
Bergeron et al. (2021)[15]	Canada	Cognitive-behavioral couple therapy	Topical lidocaine	53	55	26.51	27.60	1. Insertional pain (sexual) 2. Pain-related interference on one's life 3. Provoked vulvar pain by pressure/contact 4. Pain interference on sexual life 5. Sexual function	12 weekly 75-min sessions	6 months
Brotto et al. (2019)[16]	Canada	Cognitive-behavior therapy	Mindfulness-based cognitive therapy	63	67	31.24	33.72	1. Insertional pain (sexual) 2. Pain-related interference on one's life 3. Provoked vulvar pain by pressure/contact 4. Pain interference on sexual life 5. Sexual function	8 weekly 2h25min sessions	6 months
Brotto et al. (2020)[17]	Canada	Cognitive-behavior therapy	Mindfulness-based cognitive therapy	63	67	31.24	31.24	1. Insertional pain (sexual) 2. Pain-related interference on one's life 3. Provoked vulvar pain by pressure/contact 4. Pain interference on sexual life 5. Sexual function	8 weekly 2h25min sessions	12 months
Guillet et al. (2019)[18]	USA	Mindfulness-based group cognitive behavior therapy	Education support group therapy	14	17	34.4	29.1	1. Insertional pain (nonsexual) 2. Insertional pain (sexual) 3. Pain-related interference on one's life 4. Provoked vulvar pain by pressure/contact 5. Pain interference on sexual life 6. Sexual function	8 weekly 2.5h sessions	6 months
Hess Engstrom et al. (2022)[19]	Sweden	Acceptance and Commitment Therapy (Online)	Waitlist control	52	47	24.2	24.7	1. Insertional pain (nonsexual); 2. Insertional pain (sexual) 3. Pain-related interference on one's life 4. Provoked vulvar pain by pressure/contact 5. Pain interference on sexual life 6. Sexual function.	6 modules 1 for week	6 -7 weeks
Maathz et al.	Sweden	Acceptance and	Waitlist control	22	22	25.13	28.24	1. Insertional pain (nonsexual)	6 modules	NA

Table 3. GRADE assessment

Certainty assessment							№ of patients		Effect		Certainty	Importance
№ of studies	Study design	Risk of bias	Inconsistency	Indirectness	Imprecision	Other considerations	Acceptance and Commitment therapy	Control	Relative (95% CI)	Absolute (95% CI)		
Pain acceptance												
2	randomised trials	serious	not serious	not serious	serious[a]	none	48	48	-	mean **4.94 higher** (1.15 lower to 11.03 higher)	⊕⊕◯ ◯ Low	CRITICAL

CI: confidence interval; a. large confidence interval

Figure 1. PRISMA flowchart

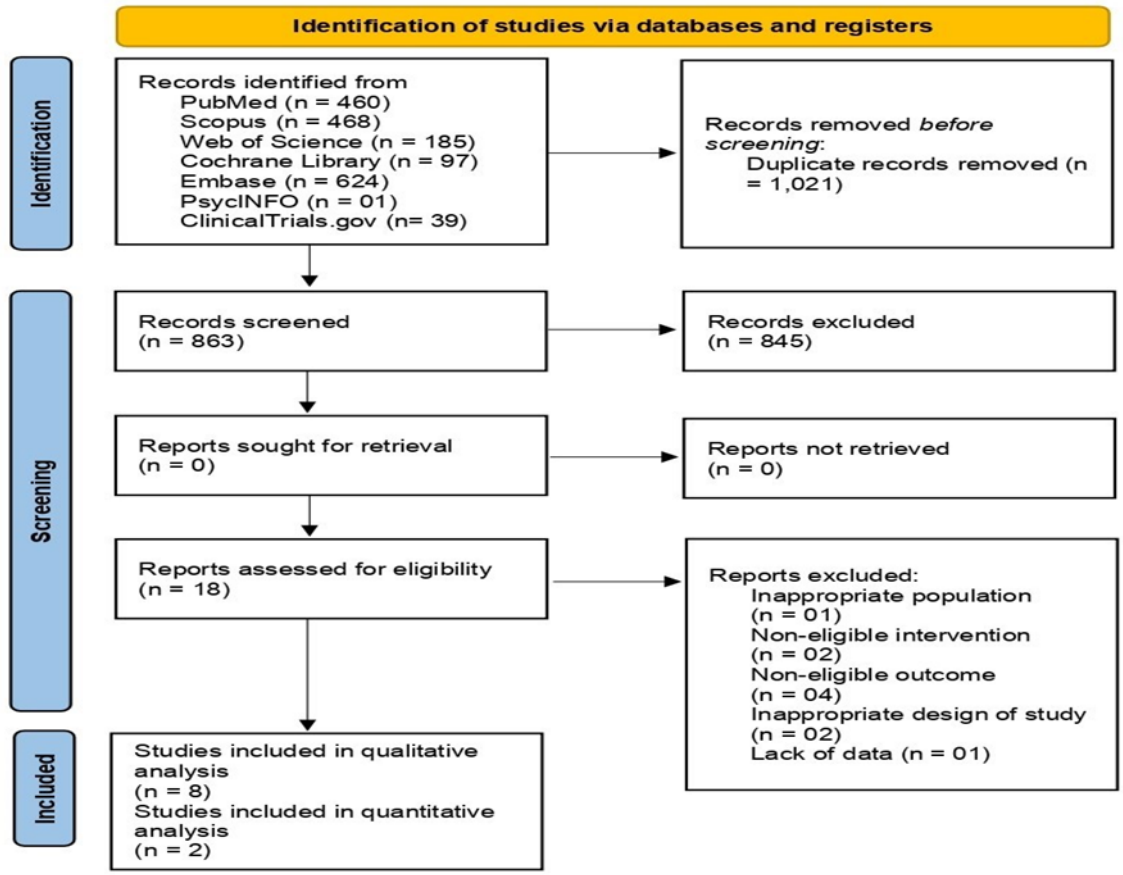


Figure 2

Click here to access/download;Figure;Figure 2. Meta-analysis.jpeg

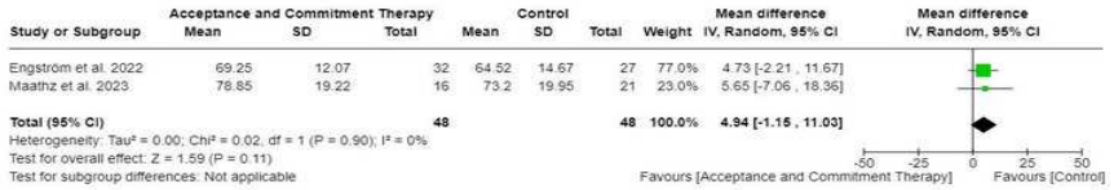
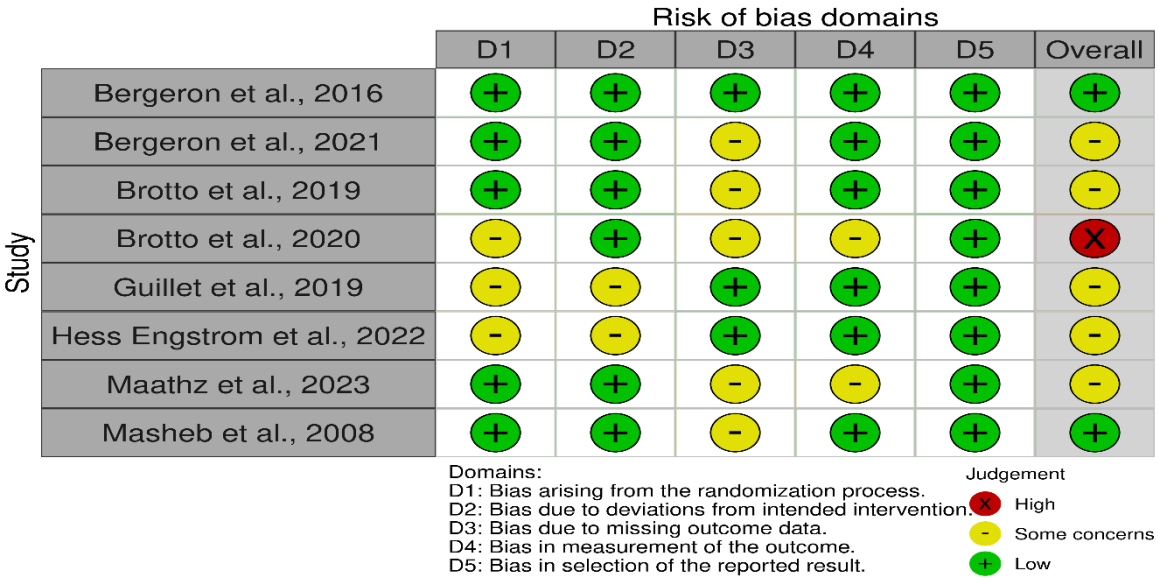


Figure 3. Risk of Bias included studies.



7. CONCLUSÕES

- A vulvodínia tem sido associada a fatores psicológicos, como ansiedade e depressão, na qual estes foram os sintomas psicológicos mais frequentes observados nos estudos.
- Fatores psicossociais foram associados à vulvodínia (frustação, violência doméstica, estresse pós-traumático, dores crônicas, realcionamentos conturbados entre outros). Para a função sexual foi ressaltado a presença de dispareunia, satisfação e disfunção sexual, influenciando no funcionamento sexual da mulher. Para a qualidade de vida observou-se que mulheres com dor vulvar crônica possuem maior dificuldade em realizar atividades físicas e outras atividades diárias, também, experimentando humores e sentimentos negativos.
- Nossa revisão sistemática demonstrou que a psicoterapia e as técnicas psicoterapêuticas, especialmente a TCC e suas variações, melhoram significativamente a dor vulvar, o ajuste psicológico e a função sexual em indivíduos com vulvodínia. E a metanálise (dois estudos) mostrou que a ACT, em comparação ao controle (lista de espera), ambos parecem melhorar o ajuste psicológico por meio da aceitação da dor.
- Esta revisão destaca a necessidade de haver mais estudos sobre a temática estudada, com metodologia rigorosa para melhorar a qualidade das evidências e corroborar com a prática clínica para o tratamento da vulvodínia.

8. COMENTÁRIOS, CRÍTICAS E SUGESTÕES

O doutorado em Ciências da Saúde consistiu em um aprofundamento robusto sobre pesquisa e ensino no âmbito da saúde da mulher, saúde ginecológica, psicológica e saúde baseada em evidências. A trajetória acadêmica é desafiadora e apaixonante. O contexto atual de velocidade de novas informações pode nos deixar atordoados, ao mesmo tempo que nos impulsiona à busca pelo crescimento.

Associado ao período do doutorado, a conciliação do vínculo empregatício com a progressão acadêmica representou o maior desafio. Fui Psicóloga Hospitalar da Maternidade Escola Januário Cicco/RN, realizando atendimento com mulheres que vivenciam clinicamente sobre o tema estudado no doutorado. No meu percurso, em particular, posso afirmar que foi desafiador fazer pesquisa com uma filha recém-nascida e em pleno puerpério. Tive a felicidade de fazer novos amigos, e reencontrar antigos que me acompanharam desde o mestrado, que foram catalisadores no meu desenvolvimento. Por fim, no campo pessoal, a conclusão do doutorado simbolizou uma enorme superação; e no campo profissional, me proporcionou especialidade sobre o tema me fazendo realizar atendimentos mais robustos e de maior qualidade técnica as mulheres.

A elaboração dessa tese exigiu esforço, dedicação, paciência e perseverança. A temática acerca da qual foi desenvolvida é um tópico de extrema relevância para a ciência e para a comunidade. A vulvodínia é uma condição clínica com grande prevalência e impacto na saúde íntima da mulher que permanece subdiagnosticada e uma grande parcela das que têm diagnóstico, ainda ficam sem tratamento adequado.

Na construção dos estudos percebemos, nas revisões sistemáticas, uma grande associação dos fatores psicossociais com a vulvodínia e seu tratamento, através de técnicas psicoterápicas, como meio de cuidar da mulher com dor vulvar no seu âmbito clínico, sexual e também emocional. A revisão sistemática e a metanálise são ferramentas fundamentais na produção de sínteses confiáveis da literatura, fornecendo evidências para auxiliar profissionais de saúde e gestores nas tomadas de decisão, baseadas em evidências científicas.

Com a finalização do doutorado, espero poder continuar contribuindo com o programa, com a universidade e com a comunidade, fazendo pesquisas que gerem impacto real na saúde e qualidade de vida das pessoas.

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APÊNDICE

Apêndice 1- Registro do Protocolo no PROSPERO do artigo 1

NIHR | National Institute for Health Research

PROSPERO
International prospective register of systematic reviews

Psychosocial factors associated with vulvodynia: a systematic review and meta-analysis

Citation

Ana Katherine GonÃ§alves, Janice França Queiroz, Ayane Cristine Alves Sarmento, Kleyton Santos Medeiros. Psychosocial factors associated with vulvodynia: a systematic review and meta-analysis. PROSPERO 2022 CRD42022367284 Available from: https://www.crd.york.ac.uk/prospero/display_record.php?ID=CRD42022367284

Review question

What are the psychosocial factors associated with vulvodynia?

- Population/participants: women with vulvodynia/ vulvar pain
- Exposure(s): psychosocial factors
- Comparator/control: women without vulvodynia/ vulvar pain
- Outcomes: vulvar pain, mental health and quality of life
- Type: Observational studies (case control and cohort)

Searches

To carry out the research, the following databases will be consulted: PubMed, LILACS, Embase, CINAHL, Web of Science, and Scopus. The gray literature was searched using appropriate databases (e.g. OpenGrey). Eligible studies may also be selected from their reference list so free retrieved articles. No language or publication period restrictions will be imposed.

Keywords: Database searches were conducted using key terms tailored for each database and included terms for: "vulvodynia" OR "vestibulodynia" OR "veneralized vulvodynia" AND "psychology" OR "psychosocial factors" OR "emotional" OR "feelings" OR "social factors" OR "behavior" OR "cognition" OR "depression" OR "anxiety" AND "mental health" OR "quality of life" OR "life quality" OR "pain" OR "burning pain"

Types of study to be included

Observational studies (case control and cohort).

Condition or domain being studied

Vulvodynia is a prevalent condition characterized by persistent vulval pain, described as sharp, burning and "knifelike". Vulvodynia can be categorized based on pain location (generalized to the whole vulva, localized or mixed), situations that elicit the pain (spontaneous, upon contact or mixed), temporal pattern (e.g. intermittent/constant) and onset (primary/secondary). The most common subtype, 'Provoked Vestibulodynia (PVD)', refers to pain that is elicited when pressure is applied to the vulvar vestibule, representing 80% of cases of Vulvodynia. To date, Vulvodynia represents the

most common form of dyspareunia, and spontaneous pain can occur during daily activities such as walking and sitting, significantly affecting women's quality of life, mental and physical health.

Participants/population

Women with vulvodynia/ vulvar pain.

Intervention(s), exposure(s)

Psychosocial factors, reflecting cognitive, affective, behavioral, depressive, anxious or interpersonal processes.

Comparator(s)/control

Women without vulvodynia/ vulvar pain.

Main outcome(s)

The primary outcome of this review is the vulvar pain evaluated using: (1) pain scale or the McGill Pain Questionnaire; (2) Psychophysical measure (tampon insertion pain and vestibular testing pain rating, both judged on a 0–10 scale); (3) Pain upon pressure or touch- pain ratings (VAS, NRS).

Additional outcome(s)

The secondary outcome is quality of life that was evaluated using:

- Mental health (Mental distress): (1) Beck Depression Inventory, Generalized Anxiety Disorder) and (2) State Trait Anxiety Inventory of Spielberger;

- Quality of life: (1): Skin-related quality of life was measured with a vulvar-specific version of Skindex-29 and (2) Dermatology Life Quality Index (DLQI) questionnaire to measure the impact of vulvodynia on the quality

of life.

Data extraction (selection and coding)

A standardized after searching the databases, the articles will be imputed to the Rayyan software and the duplicates will be removed. Initially, two independent authors (JFQ and KMS) will be selected the articles according to the titles and abstracts. Then the full texts of these articles will be retrieved for eligibility independently for two researchers (JFQ and KMS). Any discrepancies will be resolved by a third author (ACAS).

Data from each included study will be extracted independently by two reviewers (JFQ and KSM), and any subsequent discrepancies will be resolved through discussion with a third reviewer (ACAS). The following data will then be extracted from the studies selected: authors, publication year, study design, country, sample size, age, clinical characteristics, disease severity, rates pain duration, quality of live and mental health.

Risk of bias (quality) assessment

Two review authors (JFQ and KMS) will independently assess the risk of bias in the included studies. The quality of cohort and case-control studies will be assessed using the Newcastle-Ottawa Scale for observational studies (http://www.ohri.ca/programs/clinical_epidemiology/oxford.asp).

Strategy for data synthesis

This systematic review will be performed using the Review Manager (RevMan 5.2). After data extraction, the authors

will determine whether a meta-analysis is possible. For dichotomous data's, we will derive the odds ratio (OR) and the 95% confidence interval (CI). Heterogeneity will be assessed using the I^2 statistic, which is a quantitative measure of inconsistency between studies. If there is high heterogeneity (I^2 >50%), a random effects model will be used to combine study results to calculate OR and 95% CI.

In addition, when possible, we will use the Egger funnel plot to assess possible publication bias. The strength of evidence will be assessed according to the Grading of Recommendations Assessment, Development and Evaluation (GRADE) rated evidence as high, moderate, low or very low.

Analysis of subgroups or subsets

In the case of high levels of statistical heterogeneity (as tested using the χ^2 test and the I^2 statistic, with p>0.10 and I^2>50% being indicative of high levels of heterogeneity, respectively), we will perform a subgroup investigation and a target -random effects regression to examine characteristics such as study design, setting, and sample characteristics.

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Type and method of review

Systematic review

Anticipated or actual start date

05 December 2022

Anticipated completion date

05 December 2023

Funding sources/sponsors

None

Conflicts of interest

Language

English

Country

Brazil

Stage of review

Review Ongoing

Subject index terms status

Subject indexing assigned by CRD

Subject index terms

Case-Control Studies; Female; Humans; Mental Health; Pain; Quality of Life; Vulvodynia

Date of registration in PROSPERO

24 October 2022

Date of first submission

The review has not started

Stage	Started	Completed
Preliminary searches	No	No
Piloting of the study selection process	No	No
Formal screening of search results against eligibility criteria	No	No
Data extraction	No	No
Risk of bias (quality) assessment	No	No
Data analysis	No	No

The record owner confirms that the information they have supplied for this submission is accurate and complete and they understand that deliberate provision of inaccurate information or omission of data may be construed as scientific misconduct.

The record owner confirms that they will update the status of the review when it is completed and will add publication details in due course.

Versions

24 October 2022

24 October 2022

Apêndice 2- Registro do Protocolo no PROSPERO do artigo 2

NIHR | National Institute for Health Research

PROSPERO
International prospective register of systematic reviews

Psychotherapy and psychotherapeutic techniques for vulvodynia: a systematic review and meta-analysis.

Citation

Ana Katherine GonÃ§alves, Janice França Queriroz, Ayane Cristine Sarmento. Psychotherapy and psychotherapeutic techniques for vulvodynia: a systematic review and meta-analysis.. PROSPERO 2023 CRD42023411450 Available from: https://www.crd.york.ac.uk/prospero/display_record.php?ID=CRD42023411450

Review question

To assess the efficacy of Psychotherapy and psychotherapeutic techniques for vulvodynia

P- Women with Vulvodynia

I-Psychotherapy and psychotherapeutic techniques for Vulvodynia

C- No treatment

O- Reduction of vulvar pain, improved sexual function, and quality of life

T- Clinical trial

Searches

A comprehensive search of the following databases was carried out: PubMed, Embase, Scopus, Web of Science, SciELO, the Cochrane Central Register of Controlled Trials (CENTRAL), CINAHL, and of clinical trials databases (www.trialscentral.org; www.controlled-trials.com).

A combination of free-text and medical subject heading (MeSH) search terms, text words, and keywords were used, based on each database characteristic:

(Vulvodynia OR Vestibulodynia OR Generalized Vulvodynia) AND Psychology OR Cognitive Behavioral Therapy OR OR Mindfulness OR Counseling)

Types of study to be included

This review will include studies: Clinical Trials, Controlled Clinical Trials, and Randomized Controlled Trials.

Condition or domain being studied

Vulvodynia is a vulvar pain of at least three months without an identifiable cause, which may have potential associated factors. Despite its prevalence, economic burden, and personal impact, the exact etiology of Vulvodynia remains unknown. The complexity of the disease and the diversity of factors associated with Vulvodynia suggest a

biopsychosocial etiology associated with the development and persistence of this condition. Considering the multiplicity of factors involved in vulvodynia, the etiological diagnosis is essential to establish the most effective treatment. Within this context, excluding vulvar pain caused by a specific disorder, we will have vulvar pain without a clearly identifiable cause that is often associated with Psychosocial factors such as anxiety, depression, childhood victimization, and posttraumatic stress.

Participants/population

Adult women over 18 years of age were diagnosed with vulvodynia.

Intervention(s), exposure(s)

Psychology OR Cognitive Behavioral Therapy OR Mindfulness OR Counseling

Comparator(s)/control

No treatment for vulvodynia

Main outcome(s)

Reduction of vulvar pain

Additional outcome(s)

Improvement of sexual function and quality of life

Data extraction (selection and coding)

After a standardized database search, the articles will be imputed to the Rayyan software, and we will remove the duplicates. Two independent authors (JF and ACAS) will initially select the articles according to the titles and abstracts. Then the full texts of these articles will be retrieved for eligibility independently for two researchers (JF and ACAS). Any discrepancies will be resolved by a third author (AKG). The following data will be extracted from selected studies: authors, publication year, study design, country, sample size, age, clinical characteristics, disease severity, rates of pain duration, sexual function, quality of life, and mental health.

Risk of bias (quality) assessment

Two authors will independently JF and ACAS assess the risk of bias in the included studies using the Cochrane Risk of Bias tool, which evaluates the survey according to Sequence Generation, allocation concealment, blinding, incomplete outcome data, blinding of participants, personnel and outcome assessors and selective outcome reporting. Bias will be assessed as a judgment (high, low, or unclear). We will attempt to obtain missing data by contacting an article's first or corresponding authors or coauthors via phone, email, or post. If we receive any necessary information, the data will be included in our analysis and addressed in the discussion section.

Strategy for data synthesis

The latter will be carried out using the RevMan Analyses statistical package in Review Manager V.5.1. For dichotomous outcomes, we will derive the OR and 95% CI for each study. The heterogeneity between the trial results will be evaluated using a standard test with a significance level of p 0.1 and the I^2 statistic, which is a quantitative measure of inconsistency across studies, with a value of 0% indicating no observed heterogeneity, and values of 50% indicating substantial levels are present. If there is heterogeneity (I^2 75%), a random-effects model will be used to combine the trials to calculate the relative risk (RR) and 95% CI, using the DerSimonian-Laird algorithm in meta for the package, a meta-analysis package for R. Other study characteristics and results will be summarised narratively if a meta-analysis cannot be performed for all or some of the included studies. If possible, funnel plots will also be used to assess the presence of potential reporting

biases, and a linear regression approach will be used to evaluate funnel plot asymmetry.

Analysis of subgroups or subsets

In the event of high levels of statistical heterogeneity (as tested using the $\chi 2$ test and the I^2 statistic, with $p>0.10$ and $I^2>50\%$ being indicative of high levels of heterogeneity, respectively), we will conduct an investigation of subgroups and a random-effect meta-regression to examine characteristics such as study design, setting, and sample characteristics.

Contact details for further information

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Organisational affiliation of the review

Universidade Federal do Rio Grande do Norte

Review team members and their organisational affiliations

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Type and method of review

Systematic review

Anticipated or actual start date

03 July 2023

Anticipated completion date

03 July 2024

Funding sources/sponsors

None

Conflicts of interest

Language

English

Country

Brazil

Stage of review

Review Ongoing

Subject index terms status

Subject indexing assigned by CRD

Subject index terms

Female; Humans; Pain Measurement; Plastic Surgery Procedures; Psychotherapy; Quality of Life; Vulvodynia

Date of registration in PROSPERO

06 April 2023

Date of first submission

26 March 2023

Stage of review at time of this submission

The review has not started

Stage	Started	Completed
Preliminary searches	No	No
Piloting of the study selection process	No	No
Formal screening of search results against eligibility criteria	No	No
Data extraction	No	No
Risk of bias (quality) assessment	No	No
Data analysis	No	No

The record owner confirms that the information they have supplied for this submission is accurate and complete and they understand that deliberate provision of inaccurate information or omission of data may be construed as scientific misconduct.

The record owner confirms that they will update the status of the review when it is completed and will add publication details in due course.

Versions

06 April 2023
06 April 2023

ANEXO

Anexo 1- Revisão por pares de estratégias de busca eletrônica

Peer Review of Electronic Search Strategies

***PRESS Guideline* — Search Submission & Peer Review Assessment**

SEARCH SUBMISSION: July 19, 2024

Searcher: Antonio Carlos Queiroz de Aquino	E-mail: carlos.queiroz.069@ufrn.edu.br
Date submitted: July 19, 2024	Date requested by: July 19, 2024

Systematic Review Title:

Psychotherapy and psychotherapeutic techniques for the treatment of vulvodynia: a systematic review and meta-analysis

This search strategy is…

X	My PRIMARY (core) database strategy — First time submitting a strategy for search question and database
	My PRIMARY (core) strategy — Follow-up review NOT the first time submitting a strategy for search question and database. If this is a response to peer review, itemize the changes made to the review suggestions
	SECONDARY search strategy— First time submitting a strategy for search question and database
	SECONDARY search strategy — NOT the first time submitting a strategy for search question and database. If this is a response to peer review, itemize the changes made to the review suggestions

Database

(i.e., MEDLINE, CINAHL…): *[mandatory]*

PubMed/MEDLINE, *ClinicalTrials.gov, Embase, Web of Science, PsycInfo, PEDro, Cochrane, and Scopus.*
PubMed/MEDLINE *will be used as basis for validation of the strategy.*

Interface

(i.e., Ovid, EBSCO…): *[mandatory]*

PubMed

Research Question
(Describe the purpose of the search) *[mandatory]*

What are the Psychotherapeutic techniques for treatment of vulvodynia?

PICO Format
(Outline the PICOs for your question — i.e., Patient, Intervention, Comparison, Outcome, and Study Design — as applicable)

P	Adult women > 18 years old diagnosed with vulvodynia
I	psychotherapy, psychotherapeutic approaches
C	No treatment or other treatments for vulvodynia
O	Intensity of vulvar pain, sexual function, sexual distress, and pain catastrophizing
S	randomized clinical trials

Inclusion Criteria
(List criteria such as age groups, study designs, etc., to be included) *[optional]*

Randomized Clinical Trials (RCTs) that compared Psychotherapeutic techniques for treatment of vulvodynia were included.

Exclusion Criteria
(List criteria such as study designs, date limits, etc., to be excluded) *[optional]*

Cohort studies, systematic reviews, pilot studies, observational studies, under 18 years of age, studies that do not specifically Psychotherapeutic techniques for treatment of vulvodynia. Studies that do not have a control group. Furthermore, studies that do not report the expected results will not be analyzed.

Was a search filter applied?

Yes **X** No ☐

If YES, which one(s) (e.g., Cochrane RCT filter, PubMed Clinical Queries filter)? Provide the source if this is a published filter. *[mandatory if YES to previous question — textbox]*

None

Other notes or comments you feel would be useful for the peer reviewer? ***[optional]***

None

Please copy and paste your search strategy here, exactly as run, including the number of hits per line. ***[mandatory]***

(Add more space, as necessary.)

	MESH AND SYNONYM*	STRATEGY LINES	NUMBER OF STUDIES LOCATED
P	Vulvodynia (MeSH) Vestibulodynia Generalized Vulvodynia Vulvodynia, Generalized Vulva Pain Pain, Vulva	(Vulvodynia OR Vestibulodynia OR Generalized Vulvodynia OR Vulvodynia, Generalized OR Vulva Pain OR Pain, Vulva)	-
	AND	**AND**	
I	Psychotherapy (MeSH) Acceptance and Commitment Therapy (MeSH) Cognitive Behavioral Therapy (MeSH) Behavior Therapy (MeSH) Psychology (MeSH) Mindfulness (MeSH) Counseling (MeSH) Psychotherapeutic techniques	(Psychotherapy OR Acceptance and Commitment Therapy OR Cognitive Behavioral Therapy OR Behavior Therapy OR Psychology OR Mindfulness OR Counseling OR Psychotherapeutic techniques)	-
	AND	**AND**	
C	-	-	-
	AND	**AND**	
O	-	-	-
	AND	**AND**	
S	-	-	-

*Use adaptations of the acronym as necessary.

DATABASES	STRATEGY*	NUMBER OF STUDIES LOCATED
PubMed/MEDLINE	(Vulvodynia OR Vestibulodynia OR "Generalized Vulvodynia" OR "Vulvodynia, Generalized" OR "Vulva Pain" OR "Pain, Vulva") AND (Psychotherapy OR "Acceptance and Commitment Therapy" OR "Cognitive Behavioral Therapy" OR "Behavior Therapy" OR Psychology OR Mindfulness OR Counseling OR "Psychotherapeutic techniques")	460
Scopus	Vulvodynia OR Vestibulodynia OR "Generalized Vulvodynia" OR "Vulvodynia, Generalized" OR "Vulva Pain" OR "Pain, Vulva" AND Psychotherapy OR "Acceptance and Commitment Therapy" OR "Cognitive Behavioral Therapy" OR "Behavior Therapy" OR Psychology OR Mindfulness OR Counseling OR "Psychotherapeutic techniques"	468
Embase	(Vulvodynia OR Vestibulodynia OR "Generalized Vulvodynia" OR "Vulvodynia, Generalized" OR "Vulva Pain" OR "Pain, Vulva") AND (Psychotherapy OR "Acceptance and Commitment Therapy" OR "Cognitive Behavioral Therapy" OR "Behavior Therapy" OR Psychology OR Mindfulness OR Counseling OR "Psychotherapeutic techniques")	624
Cochrane	(Vulvodynia OR Vestibulodynia OR "Generalized Vulvodynia" OR "Vulvodynia, Generalized" OR "Vulva Pain" OR "Pain, Vulva") AND (Psychotherapy OR "Acceptance and Commitment Therapy" OR "Cognitive Behavioral Therapy" OR "Behavior Therapy" OR Psychology OR Mindfulness OR Counseling OR "Psychotherapeutic techniques")	97
Web of Science	(Vulvodynia OR Vestibulodynia OR "Generalized Vulvodynia" OR "Vulvodynia, Generalized" OR "Vulva Pain" OR "Pain, Vulva") AND (Psychotherapy OR "Acceptance and Commitment Therapy" OR "Cognitive Behavioral Therapy" OR "Behavior Therapy" OR Psychology OR Mindfulness OR Counseling OR "Psychotherapeutic techniques")	185
ClinicalTrials.gov	(Vulvodynia OR Vestibulodynia OR "Generalized Vulvodynia" OR "Vulvodynia, Generalized" OR "Vulva Pain" OR "Pain, Vulva") AND (Psychotherapy OR "Acceptance and Commitment Therapy" OR "Cognitive Behavioral Therapy" OR "Behavior Therapy" OR Psychology OR Mindfulness OR Counseling OR "Psychotherapeutic techniques")	39
PsycINFO	(Vulvodynia OR Vestibulodynia OR "Generalized Vulvodynia" OR "Vulvodynia, Generalized" OR "Vulva Pain" OR "Pain, Vulva") AND	01

	(Psychotherapy OR "Acceptance and Commitment Therapy" OR "Cognitive Behavioral Therapy" OR "Behavior Therapy" OR Psychology OR Mindfulness OR Counseling OR "Psychotherapeutic techniques")	

PEER REVIEW ASSESSMENT: THIS SECTION TO BE FILLED IN BY THE REVIEWER

Reviewer: Adriana Alves da Silva Alves Dias / CRB-15/474	**E-mail:** biblioteca@ccs.ufrn.br	**Date completed:** 24/07/2024

1. TRANSLATION			
	A. No revisions	☑	
	B. Revision(s) suggested	☐	
	C. Revision(s) required	☐	

If "B" or "C," please provide an explanation or example:

2. BOOLEAN AND PROXIMITY OPERATORS			
	A. No revisions	☑	
	B. Revision(s) suggested	☐	
	C. Revision(s) required	☐	

If "B" or "C," please provide an explanation or example:

3. SUBJECT HEADINGS			
	A. No revisions	☑	
	B. Revision(s) suggested	☐	
	C. Revision(s) required	☐	

If "B" or "C," please provide an explanation or example:

4. TEXT WORD SEARCHING			
	A. No revisions	☑	
	B. Revision(s) suggested	☐	
	C. Revision(s) required	☐	

If "B" or "C," please provide an explanation or example:

5. SPELLING, SYNTAX, AND LINE NUMBERS			
	A. No revisions	☑	
	B. Revision(s) suggested	☐	
	C. Revision(s) required	☐	

If "B" or "C," please provide an explanation or example:

6. LIMITS AND FILTERS

	A. No revisions	☑	
	B. Revision(s) suggested	☐	
	C. Revision(s) required	☐	

If "B" or "C," please provide an explanation or example:

7. OVERALL EVALUATION (Note: If one or more "revision required" is noted above, the response below must be "revisions required".)			
	A. No revisions	☑	
	B. Revision(s) suggested	☐	
	C. Revision(s) required	☐	

Additional comments:
