INPLASY PROTOCOL

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Conflicts of interest:
No conflicts of interest in this work.

Effectiveness of psychological interventions for treating chronic prostatitis/chronic pelvic pain syndrome：a protocol for systematic review and meta-analysis

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Review question / Objective: **With this systematic review and if possible, meta-analysis we urge to further evaluate the effectiveness of psychological as a way to alleviate chronic prostatitis/chronic pelvic pain. The results will offer clinical decisions for urologists and andrologists. So far, the meta-analysis about the effect of CP/CPPS suggested that psychological may be a possible treatment for CP/CPPS, however, more studies with appropriate controls are needed to confirm this finding. Further investigation is warranted given that an increasing number of studies about the effects of psychological intervention for CP/CPPS has been carried out in recent years. Therefore, we will conduct an up-to-date systematic review and meta-analysis for existing RCTs to further assess the effectiveness of the psychological intervention as a way to alleviate CP/CPPS and improve QOL.**

INPLASY registration number: This protocol was registered with the International Platform of Registered Systematic Review and Meta-Analysis Protocols (INPLASY) on 07 August 2020 and was last updated on 07 August 2020 (registration number INPLASY202080021).

INTRODUCTION

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Condition being studied: Chronic prostatitis/chronic pelvic pain syndrome (CP/CPPS) is one of the most common diseases in urology, which 50% of men are infected at some point in their lives. Type III CP/CPPS is the most complex and controversial of all types of prostatitis, the highest incidence rate, uncertain efficacy, the long-term treatment that affects the patient's psychopathic symptoms, increases the psychological burden of patients. Treatment for patients with CP/CPPS, which is difficult to treat with drugs and physics, can effectively improve clinical efficacy and improve the psychological condition. The researchers found a high prevalence of psychosocial problems and catastrophic distress in CP/CPPS patients, such as serious mental disorders, especially depression, anxiety and stress, and the high incidence of pain-devastating illness. In this study, we will evaluate psychological interventions as an effective way to relieve chronic prostatitis.

METHODS

Participant or population: Inclusion criteria: ·pain in penis, testicles, perineum, or lumbosacral region. ·voiding symptoms, such as dysuria, frequency, and sense of incomplete urination. ·prostatic fluid, semen, and urine bacterial culture were negative. ·the minimum duration of these symptoms for inclusion in the study was 3 months.

Intervention: The intervention received may be a psychotherapeutic intervention that was facilitated through a specialized program, or by a registered psychologist, licensed therapist, or other trained and licensed professional credentialed to provide specific counseling. The patients in the treatment group received psychological intervention therapy (include psychological counseling, psychotherapy, psychological support, and psychoeducation, no limit on-one psychotherapy and group therapy and facilitated in person, on the telephone, online, or via distance delivery (method of delivery).

Comparator: The control group could gain routine drug medications or guideline-recommended conventional treatment and health education.

Study designs to be included: All the RCTs of CP/CPPS patients who were treated by psychological interventions will be included and the acceptability of the intervention.

Eligibility criteria: The study will include RCTs and the acceptability of the intervention will also be included.

Information sources: Electronic databases will include English databases (PubMed, MEDLINE, EMBASE, Web of Science, Cochrane Library) and Chinese databases (China National Knowledge Infrastructure, China Biology Medicine Database, Wan fang Database, VIP Database).

Main outcome(s): 1) NIH-CPSI scores decreased (NIH-CPSI to evaluate the patient's symptom score before and after treatment, the scale has a total score of 43 points, including pain or discomfort (21 points), urinary symptoms (10 points), and quality of life (12 points), the higher the score, the more severe the symptoms).

Additional outcome(s): 1)scores of IIEF-5 2)SAS scores, SDS scores (The Anxiety Scale Rating Scale (SAS), and Self-Rating Depression Scale (SDS) are used to assess the patient's psychological status. The total score of both scales is 100 points. The higher the score, the worse the patient's psychological status.) 3)Quality of Life Comprehensive Assessment Questionnaire (QOL).

Quality assessment / Risk of bias analysis: The risk of bias will be independently assessed by two reviewers and any differences will be resolved through consultation or the participation of a third reviewer. The RCTs will be evaluated using the Cochrane "risk of bias assessment" tool. The tool assesses the risk of bias mainly in the following 7 aspects: random sequence generation, allocation concealment, the blinding method for patients, researchers and outcomes assessors, incomplete result data, and selective reports. As recommended by the Cochrane manual, the risk of bias in each of these areas will be assessed as low or high depending on whether the criteria were met or not met, and the lack of information will be recorded as unclear. In most cases, disagreements will be settled by discussion between the 2 reviewers. If disagreement remained after discussion, a third reviewer will be consulted before taking the final decision on the disagreements.

Strategy of data synthesis: We will use RevMan5.3 software for meta-analysis. For dichotomous data (e.g., effective and ineffective), we will calculate risk ratio (RR) and 95% confidence intervals (CIs). For continuous data, when the measurement method and unit are consistent, we will calculate the weighted mean difference (WMD) and 95% CIs. When the measurement methods and units are inconsistent or the mean values of different experiments differ greatly, we will use the standardized mean difference (SMD) and 95% CIs as the composite statistics.

Subgroup analysis: If there is significant heterogeneity in the included trials, we will identify the source of heterogeneity through subgroup analysis and manage the heterogeneity: 1) The duration and severity of CP/CPPS. 2) The severity and duration of the patient's psychological condition. 3) Demographic characteristics of the patients: Age, marital status, course of illness, and education.

Sensibility analysis: A sensitivity analysis will be performed to test the robustness of the review result and to detect the source of heterogeneity. This can be done by excluding trials with a high risk of bias or eliminating each study individually. And, the impact of methodological quality, sample size, and missing data will be assessed. Then the analysis will be repeated after the exclusion of low methodological quality studies and the results compared with the previous meta-analysis.

Country(ies) involved: China.

Keywords: psychological; chronic prostatitis/chronic pelvic pain syndrome; protocol.

Contributions of each author:
Author 1 - Yuanjie Xu - Author 1 drafted the manuscript.
Author 2 - Ling Zhang - The author provided statistical expertise.
Author 3 - Yifeng Shen - The author contributed to the development of the selection criteria.
Author 4 - Hangyu Yao - The author contributed to the risk of bias assessment strategy.
Author 5 - Shanshan Yong - The author provided the software support.
Author 6 - Yaodong You - The author is the guarantor. All authors read, provided feedback and approved the final manuscript.