

INPLASY PROTOCOL

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Review Stage at time of this submission: The review has not yet started.

Conflicts of interest:
None declared.

Effectiveness of acupuncture for nocturia: a protocol for systematic review and meta-analysis

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Review question / Objective: 1.Type of studies. All RCTs reported will be included without regional and language restrictions. Animal studies, cohort studies, case-controlled studies, case reports and expert experience will be excluded. 2.Type of participants. Participants in the study were diagnosed with nocturia. On the basis of ICS-2002 report on standardisation of terminology in nocturia“the complaint that the individual has to wake at night one or more times to void” regardless the age, gender, race, country and nocturia type. 3.Type of interventions. The purpose of this study is to observe the clinical study of acupuncture in the treatment of nocturia. Acupuncture treatment were used in the experiment, including body acupuncture, warm acupuncture, electro-acupuncture, auricular acupuncture, fireneedling, elongated needle, moxibustion or herbs-partitioned moxibustion. 4.Type of comparators. The control group that will include non-acupuncture techniques, such as behavioral therapy, sham acupuncture, placebo or other pharmacotherapy. The acupoint numbers, retaining time, and frequency will not be restricted in this protocol. 5.Types of outcome measures The primary outcome measures will be total and frequency of nocturnal urination. Secondary outcomes. Secondary outcomes include the ratio of nocturnal urine volume to daytime urine volume.Urine/blood osmotic pressure ratio, urine specific gravity value. change in N-QoL, Pittsburgh Sleep Quality Index (PSQI) Scale ,as well as a standard battery of blood and urine analyses, vital signs, and physical examinations.

INPLASY registration number: This protocol was registered with the International Platform of Registered Systematic Review and Meta-Analysis Protocols (INPLASY) on 27 March 2021 and was last updated on 27 March 2021 (registration number INPLASY202130100).

INTRODUCTION

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Condition being studied: Nocturia is a common and highly troubled lower urinary tract symptom, which has a wide range of effects. About 33% of patients with lower urinary tract symptoms have been affected by nocturia.Nocturia is mainly manifested as the increase of urination frequency and urine volume at night. It has been proved that acupuncture can reduce the symptoms of nocturia and regulate bladder function in Western countries. Acupuncture may be a promising choice for the treatment of Nocturia.

METHODS

Participant or population: Participants in the study were diagnosed with nocturia. On the basis of ICS-2002 report on

standardisation of terminology in nocturia“the complaint that the individual has to wake at night one or more times to void” regardless the age, gender, race, country and nocturia type.

Intervention: The purpose of this study is to observe the clinical study of acupuncture in the treatment of nocturia. Acupuncture treatment were used in the experiment, including body acupuncture, warm acupuncture, electro-acupuncture, auricular acupuncture, fireneedling, elongated needle, moxibustion or herbs-partitioned moxibustion.

Comparator: The control group that will include non-acupuncture techniques, such as behavioral therapy, sham acupuncture, placebo or other pharmacotherapy. The acupoint numbers, retaining time, and frequency will not be restricted in this protocol.

Study designs to be included: All RCTs reported will be included without regional and language restrictions. Animal studies, cohort studies, case-controlled studies, case reports and expert experience will be excluded.

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Information sources: RCTs of acupuncture for nocturia will be searched in the relevant database, including PubMed, Embase, Cochrane Library, China National Knowledge Infrastructure (CNKI), Wanfang Database, Chinese Biomedical Literature Database (CBM), and Chinese Scientific Journal Database (VIP database). The studies of electronic searches will be exported to EndNote V.9.1 software. We will run meta-analyses using the Review Manager (RevMan) V.5.3 software. Any disagreement will be solved in consultation with a third reviewer.RCTs of acupuncture for nocturia will be searched in the relevant database, including PubMed, Embase, Cochrane Library, China National Knowledge Infrastructure (CNKI), Wanfang Database, Chinese Biomedical Literature Database (CBM), and Chinese Scientific Journal Database (VIP database). The key words include “acupuncture”; "nocturia"; "complementary therapy"; "randomized controlled trial"; "randomized controlled trial, systematic review An equivalent translation of the same search terms will be used to search in the Chinese databases.

Main outcome(s): The primary outcome measures were total and frequency of nocturnal urination.

Additional outcome(s): Secondary outcomes included the ratio of nocturnal

urine volume to daytime urine volume.Urine/blood osmotic pressure ratio, urine specific gravity value. change in N-QoL, Pittsburgh Sleep Quality Index (PSQI) Scale ,as well as a standard battery of blood and urine analyses, vital signs, and physical examinations.

Quality assessment / Risk of bias analysis: The risk of deviation was assessed by 2 reviewers against criteria provided in the Cochrane Intervention Systematic Evaluation Manual. It includes the following seven domains: random sequence generation, allocation concealment, blinding of participants and personnel, blinding of outcome assessment, incomplete outcome data, selective reporting. Any disagreement should be solved in consultation with a third reviewer.

Strategy of data synthesis: We will run meta-analyses using the Review Manager (RevMan) V.5.3 software. If the result of heterogeneity in $P > 0.1$ and $I^2 < 50\%$, the fixed effect model was used; if there was statistical heterogeneity between the studies ($P \leq 0.1$ and $I^2 > 50\%$), the source of heterogeneity was analyzed, and the factors that might lead to heterogeneity were analyzed by subgroup analysis; when there was statistical heterogeneity between the studies but no clinical heterogeneity, the random effect model was used.

Subgroup analysis: If there is significant heterogeneity in the results, we will conduct a subgroup analysis to investigate differences in age, gender, length of disease duration, outcome style, etc.

Sensitivity analysis: We will perform sensitivity analyses to verify robustness of results. It includes the impact of methodological quality, study design and sample size.

Country(ies) involved: China.

Keywords: acupuncture; nocturia; complementary therapy; randomized controlled trial; systematic review.

Contributions of each author:

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