INPLASY PROTOCOL

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Review Stage at time of this submission: **Preliminary searches.**

Conflicts of interest:
None declared.

Establishing a core outcome set for neurogenic bladder trials: study protocol for a scoping review, and Delphi surveys

Chen, YM[1]; Yu, HJ[2]; Niu, MM[3]; Li, YY[4]; Tian, JH[5].

Review question / Objective: **The health condition for this study is on NGB. Patients with NGB aged 18 and above will be included. This COS will cover all interventions. The COS is designed for use in both research and routine clinical care, in any health care system. We plan to involve patients, carers, healthcare professionals and researchers in developing the COS in order to identify the outcomes of most importance to all stakeholders.**
Information sources: **The following eight databases will be searched for relevant studies: Web of Science, PubMed, Embase.com, Cochrane Library, CINAHL, Wanfang database, CNKI, and Chinese BioMedical Database. ClinicalTrials.gov, International Standard Randomized Controlled Trial Number Register, Chinese Clinical Trial Registry, the World Health Organization's International Clinical Trials Registry Platform, PROSPERO and INPLASY will also be searched for relevant, ongoing trials. Relevant key search terms will include "neurogenic bladder", "neurogenic urinary bladder", "neurogenic dysfunction of the urinary bladder", "urinary bladder neurogenic dysfunction", "neuropathic bladder", "bladder neurogenesis", "neurogenic lower urinary tract dysfunction", "neurogenic overactive bladder", "neurogenic detrusor overactivity" and "overactive bladder syndrome".**

INPLASY registration number: This protocol was registered with the International Platform of Registered Systematic Review and Meta-Analysis Protocols (INPLASY) on 02 January 2022 and was last updated on 02 January 2022 (registration number INPLASY202210007).

INTRODUCTION

Review question / Objective: **The health condition for this study is on NGB. Patients with NGB aged 18 and above will be included. This COS will cover all interventions. The COS is designed for use in both research and routine clinical care, in any health care system. We plan to involve patients, carers, healthcare**

professionals and researchers in developing the COS in order to identify the outcomes of most importance to all stakeholders.

Condition being studied: Neurogenic bladder (NGB) is a chronic and disabling condition with a high prevalence rate, which can cause economic burden on patients and their families and reduce the quality of life of patients. Researchers have carried out a large number of clinical trials on the effectiveness and safety of different interventions for the treatment of NGB. The published clinical trials of NGB generally suffered from inconsistent and irregular reporting of outcome indicators. To facilitate future research studies of NGB, a core outcome set (COS) is required, which helps translate the results into high-quality evidence.This mixed-method project has four phases instrument. In phase 1, a scopoing review of the literature to identify outcomes that have been reported in clinical trials and systematic reviews of clinical trials of interventions for NGB. In phase 2, a qualitative component using interviews to obtain the views of NGB patients, families and their caregivers. In phase 3, delphi survey among stakeholders to prioritise the core outcomes. In phase 4, a face-to-face consensus meeting to discuss and agree on the final NBG COS.We will develop a COS that should be reported in future clinical trials of NGB.

METHODS

Participant or population: Patients with NGB aged 18 and above will be included..

Intervention: Any.

Comparator: Any.

Study designs to be included: Randomised or non-randomised studies, prospective and retrospective studies, will be included.

Eligibility criteria: Randomised or non-randomised studies, prospective and retrospective studies, will be included. We will exclude cohort studies, case–control studies, case series, case reports, qualitative research, economic evaluation studies, letters to the editor, commentaries, editorials, conference abstracts that do not describe clinical outcomes and reviews that do not report on outcomes or contain original research.

Information sources: The following eight databases will be searched for relevant studies: Web of Science, PubMed, Embase.com, Cochrane Library, CINAHL, Wanfang database, CNKI, and Chinese BioMedical Database. ClinicalTrials.gov, International Standard Randomized Controlled Trial Number Register, Chinese Clinical Trial Registry, the World Health Organization's International Clinical Trials Registry Platform, PROSPERO and INPLASY will also be searched for relevant, ongoing trials. Relevant key search terms will include "neurogenic bladder", "neurogenic urinary bladder", "neurogenic dysfunction of the urinary bladder", "urinary bladder neurogenic dysfunction", "neuropathic bladder", "bladder neurogenesis", "neurogenic lower urinary tract dysfunction", "neurogenic overactive bladder", "neurogenic detrusor overactivity" and "overactive bladder syndrome".

Main outcome(s): Any.

Quality assessment / Risk of bias analysis: As the purpose of this review is to identify reported outcomes and not to determine the effectiveness of management strategies, no assessment of the study's methodological quality will be performed. Similarly, as the aim of this scoping review is to identify all reported outcomes in order to generate a long list of outcomes to inform the development of the COS, and there is no validated tool to assess the quality of outcome reporting, it was decided a priori that the quality of outcome reporting of included studies would not be assessed.

Strategy of data synthesis: We will enter the data into Microsoft Excel in order to aid tabulation and analysis.

Subgroup analysis: Not Applicable.

Sensitivity analysis: Not Applicable.

Language: The language is limited to English and Chinese.

Country(ies) involved: China.

Keywords: Neurogenic bladder; Core outcome set; Outcome measurement instruments.

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