INPLASY PROTOCOL

To cite: Zhao et al. A COSMIN systematic review of patient-reported outcome measures for fatigue among patients living with hemodialysis. Inplasy protocol 202340002. doi: 10.37766/inplasy2023.4.0002

Received: 03 April 2023

Published: 03 April 2023

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Review Stage at time of this submission: **Piloting of the study selection process.**

Conflicts of interest:
None declared.

A COSMIN systematic review of patient-reported outcome measures for fatigue among patients living with hemodialysis

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Review question / Objective: **The primary goal of this review was to provide a comprehensive overview of patient-reported outcome measures targeted at fatigue among patients with hemodialysis, and to critically appraise and summarize the quality of their measurement properties. The secondary goal of this review was to provide evidence-based recommendations for PROMs selection in fatigue of hemodialysis research and clinical practice. The construct: fatigue; The population: patients with hemodialysis; The type of instrument: patient-reported outcome measures; The measurement properties: all.**
Condition being studied: **Fatigue is reported as the most common symptom of patients with hemodialysis, which has negative effects on individual`s health-related quality of life. Although researchers at home and abroad have explored the assessment tool of fatigue in multi-dimension, there is no gold-standard measure for fatigue in hemodialysis.**

INPLASY registration number: This protocol was registered with the International Platform of Registered Systematic Review and Meta-Analysis Protocols (INPLASY) on 03 April 2023 and was last updated on 05 April 2023 (registration number INPLASY202340002).

INTRODUCTION

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The population: patients with hemodialysis; The type of instrument: patient-reported outcome measures; The measurement properties: all.

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METHODS

Search strategy:

#1 construct

((((("fatigue"[MeSH Terms]) OR (fatigue [Title/Abstract])) OR (chronic fatigue syndrome [Title/Abstract])) OR (physical fatigue [Title/Abstract] OR mental fatigue [Title/Abstract] OR muscle fatigue [Title/Abstract])) OR ("tired"[Title/Abstract])

#2 population

(((hemodialysis[MeSH Terms]) OR (dialysis[MeSH Terms])) OR (hemodialysis[Title/Abstract])) OR (haemodialysis[Title/Abstract])

#3 type of instrument

(scale*[Text Word]) OR measure*[Text Word]) OR score*[Text Word]) OR PROM[Text Word]) OR patient reported outcome measure*[Text Word]) OR instrument*[Text Word]) OR index*[Text Word]) OR questionnaire*[Text Word]) OR survey*[Text Word]) OR assessment*[Text Word]) OR profile*[Text Word]) OR apprais*[Text Word]) OR status[Text Word]

#4 sensitive search filter developed by Terwee et.al

(instrumentation[sh] OR methods[sh] OR Validation Studies[pt] OR Comparative Study[pt] OR "psychometrics" [MeSH] OR psychometr*[tiab] OR clinimetr*[tw] OR clinometr*[tw] OR "outcome assessment, health care''[MeSH] OR outcome assessment[tiab] OR outcome measure*[tw] OR ''observer variation''[MeSH] OR observer variation[tiab] OR ''Health Status Indicators"[Mesh] OR "reproducibility of results"[MeSH] OR reproducib*[tiab] OR ''discriminant analysis''[MeSH] OR reliab*[tiab] OR unreliab*[tiab] OR valid*[tiab] OR coefficient[tiab] OR homogeneity[tiab] OR homogeneous[tiab] OR ''internal consistency''[tiab] OR (cronbach*[tiab] AND (alpha[tiab] OR alphas[tiab])) OR (item[tiab] AND (correlation*[tiab] OR selection*[tiab] OR reduction*[tiab])) OR agreement[tiab] OR precision[tiab] OR imprecision[tiab] OR "precise values"[tiab] OR test– retest[tiab] OR (test[tiab] AND retest[tiab]) OR (reliab*[tiab] AND (test[tiab] OR retest[tiab])) OR stability[tiab] OR interrater[tiab] OR inter-rater[tiab] OR intrarater[tiab] OR intra-rater[tiab] OR intertester[tiab] OR inter-tester[tiab] OR intratester[tiab] OR intra-tester[tiab] OR interobserver[tiab] OR inter-observer[tiab] OR intraobserver[tiab] OR intraobserver[tiab] OR intertechnician[tiab] OR inter-technician[tiab] OR intratechnician[tiab] OR intra-technician[tiab] OR interexaminer[tiab] OR inter-examiner[tiab] OR intraexaminer[tiab] OR intra-examiner[tiab] OR interassay[tiab] OR inter-assay[tiab] OR intraassay[tiab] OR intra-assay[tiab] OR interindividual[tiab] OR inter-individual[tiab] OR intraindividual[tiab] OR intra-individual[tiab] OR interparticipant [tiab] OR inter-participant[tiab] OR intraparticipant[tiab] OR intra-participant[tiab] OR kappa[tiab] OR kappa's[tiab] OR kappas[tiab] OR repeatab*[tiab] OR ((replicab*[tiab] OR repeated[tiab]) AND (measure[tiab] OR measures[tiab] OR findings[tiab] OR result[tiab] OR results[tiab] OR test[tiab] OR tests[tiab])) OR generaliza*[tiab] OR generalisa*[tiab] OR concordance[tiab] OR (intraclass[tiab] AND correlation*[tiab]) OR discriminative[tiab] OR ''known group"[tiab] OR factor analysis[tiab] OR factor analyses[tiab] OR dimension*[tiab] OR subscale*[tiab] OR (multitrait[tiab] AND scaling[tiab] AND (analysis[tiab] OR analyses[tiab])) OR item discriminant[tiab] OR interscale correlation*[tiab] OR error[tiab] OR errors[tiab] OR "individual variability"[tiab] OR (variability[tiab] AND (analysis[tiab] OR values[tiab])) OR (uncertainty[tiab] AND (measurement[tiab] OR measuring[tiab])) OR "standard error of measurement"[tiab] OR sensitiv*[tiab] OR responsive*[tiab] OR ((minimal[tiab] OR

minimally[tiab] OR clinical[tiab] OR clinically[tiab]) AND (important[tiab] OR significant[tiab] OR detectable[tiab]) AND (change[tiab] OR difference[tiab])) OR (small*[tiab] AND (real[tiab] OR detectable[tiab]) AND (change[tiab] OR difference[tiab])) OR meaningful change [tiab] OR "ceiling effect"[tiab] OR "floor effect''[tiab] OR ''Item response model"[tiab] OR IRT[tiab] OR Rasch[tiab] OR "Differential item functioning"[tiab] OR DIF[tiab] OR ''computer adaptive testing"[tiab] OR "item bank"[tiab] OR "cross-cultural equivalence"[tiab])
#5 #1 AND #2 AND #3 AND #4

Participant or population: Patients undergoing hemodialysis (≥18 years of age).

Intervention: None.

Comparator: None.

Study designs to be included: Any original cross-sectional study or longitudinal study.

Eligibility criteria: Inclusion criteria: (1) the PROMs should aim to measure fatigue;(2) the study sample is patients with hemodialysis or ESRD;(3) the aim of the study should be evaluation of on or more measurement properties (including development, translation, or validation the measurement properties using their raw data) ;(4) published in English or Chinese;(5) Full-text available.Exclusion criteria: Studies that only use a measure to investigate levels of fatigue in a country or region, or as an outcome (e.g., in randomized controlled trails), or in a validation study of another instrument, will not be included.

Information sources: To identify relevant studies, PubMed, Embase, PhycINFO, CHNAHL, ProQuest, CNKI, CBM and WANFANG will be systematically searched. The timeframe was defined as inception to 1st of March 2023. The search was restricted to English and/or Chinese articles. The reference list of all included sources of evidence will be screened for additional studies. Any study that reports on the development and/or validation of fatigue measurements in hemodialysis will be included.

Main outcome(s): First, we will evaluate the methodological quality of each included study using the COSMIN risk of bias checklist and the result will be presented. Second, we will identify one or more psychometric properties following COSMIN guideline recommendation of measures in a review and summarize the evidence and grade the quality of the evidence for each property by using the GRADE approach. Third, we will provide evidenced-based recommendations of selection of PROMs in fatigue for hemodialysis research and clinical practice.

Data management: Two authors will extract data from included studies using Microsoft Excel. A standardized extraction table will be designed including the details of studies (first author, published year, country or region, measure name), study characteristics (study sample, setting), and scale characteristics (PROMs, constructs, target population, mode of administration, recall period, response options, range of scores, original language, available translations).

Quality assessment / Risk of bias analysis: The Consensus-based Standards for the Selection of Health Measurement Instruments (COSMIN) checklist was applied to assess methodological quality of each study. The COSMIN risk of bias checklist has 10 domains and 116 items. It is used to assess methodological quality in terms of PROM development, content validity, structural validity, internal consistency, cross-cultural validity/ measurement invariance, reliability, measurement error, criterion validity, hypotheses testing for construct validity and responsiveness. Each item has five options, namely 'very good', 'adequate', 'doubtful', 'inadequate' and 'not applicable'. The 'worst score counts' principle is used to determine the overall quality of relative domains.

Strategy of data synthesis: All references identified through databases were imported into Endnote reference manager. Firstly, two researchers independently screen titles and abstracts, and following screening full-texts in case the abstract was not sufficient to make decision. Full-texts reviewed and the data were extracted into a COSMIN data extraction table (Terwee et al. 2012). Secondly, two researchers will independently summaries the quality of psychometric properties for each PROM according to the COSMIN criteria, and a third researcher (ZD) will be invited to discuss any inconsistency and disagreement. The COSMIN criteria rates the psychometric properties of PROMs, including structural validity, internal consistency, cross-cultural validity/ measurement invariance, reliability, measurement error, criterion validity, hypotheses testing for construct validity and responsiveness, as sufficient (+), insufficient (–) or indeterminate (?). We will first rate each single study on psychometric properties. Then we will synthesis the results and come to an overall conclusion on the quality of the PROM's psychometric properties as a whole according to the specific situation. If the ratings for each measure are consistent, the results from different studies on one psychometric property will be qualitatively summarized or pooled through meta-analysis and finally be rated as '+' or '–'. A meta analysis will be conducted according to the availability of quantitative data of psychometric properties. Finally, Two researchers will independently grade the quality of evidence, that is, the confidence that the pooled or summarized result is trustworthy, according to the modified Grading of Recommendations, Assessment, Development and Evaluation system. A third researcher will be invited to discuss any inconsistency and disagreement. Using four factors to determine the quality of evidence (risk of bias, inconsistency, indirectness and imprecision), each psychometric property of PROM is graded as high, moderate, low or very low evidence.

Subgroup analysis: None.

Sensitivity analysis: None.

Language restriction: English or Chinese.

Country(ies) involved: China.

Keywords: Hemodialysis: patients reported outcome; measurement; fatigue.

Contributions of each author:

Author 1 - Dan ZHAO - Drafted the manuscript, work out the research strategy, completed the COSMIN checklist and the GRADE evaluation system, and contributed to the development of conceptualization.
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