INPLASY PROTOCOL

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Conflicts of interest:
All authors declare that they have no conflict of interest.

The impact of exercise intervention for patients undergoing hemodialysis on fatigue and quality of life: a protocol for systematic review and meta-analysis

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Review question / Objective: **P: diagnosed as end-stage renal disease and undergoing hemodialysis therapy; I: intervention had to consist in regular aerobic, resistance, or combined exercise training; C: control groups were described as “usual care”, “no exercise”, “sham exercise”, “attention control”, or “placebo”; O: outcomes representing fatigue were taken into account; quality of life was assessed as a secondary outcome; S: only randomized controlled trials were included.**
Condition being studied: **This systematic review was conducted following the Preferred Reporting Items for Systematic Reviews and Meta-analyses statement. Four English electronic databases: CENTRAL, PubMed, EMBASE, Web of Science and four Chinese databases, namely China National Knowledge Infrastructure (CNKI), Wanfang, Chinese Biomedical Literature Database (CBM) and Chinese Science and Technology Journal Database (VIP) were systematically searched from inception to June 2020, using the following terms: "Fatigue"[Mesh], "Kidney Failure, Chronic"[Mesh], "Renal Replacement Therapy"[Mesh], hemodialysis, "end-stage kidney", ESRD et al.**

INPLASY registration number: This protocol was registered with the International Platform of Registered Systematic Review and Meta-Analysis Protocols (INPLASY) on 17 May 2020 and was last

INTRODUCTION

Review question / Objective: **P: diagnosed as end-stage renal disease and undergoing hemodialysis therapy; I: intervention had to consist in regular aerobic, resistance, or combined exercise training; C: control groups were described as “usual care”, “no exercise”, “sham exercise”, “attention control”, or “placebo”; O: outcomes representing fatigue were taken into account; quality of life was assessed as a secondary outcome; S: only randomized controlled trials were included.**

Rationale: **Fatigue are suggested to promote the development of risk factors for cardiovascular disease progression,**

and might have a direct effect on physical activity and quality of life in patients during hemodialysis. Therefore, proper management of fatigue in patients during hemodialysis may yield favourable outcomes.

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METHODS

Search strategy: Search strategy in Pubmed: ((((((((((((dialysis[Title/Abstract]) OR hemodialysis[Title/Abstract]) OR haemodialysis[Title/Abstract]) OR hemodiafiltration[Title/Abstract]) OR haemodiafiltration[Title/Abstract]) OR "end-stage kidney"[Title/Abstract]) OR "end-stage renal"[Title/Abstract]) OR "endstage kidney"[Title/Abstract]) OR "endstage renal"[Title/Abstract]) OR ESKD[Title/Abstract]) OR ESKF[Title/Abstract]) OR ESRD[Title/Abstract]) OR ESRF[Title/Abstract])) OR (("Renal Replacement Therapy"[Mesh]) OR "Kidney Failure, Chronic"[Mesh]) AND (((((exhaustion[Title/Abstract]) OR ((weary[Title/Abstract]) OR weariness[Title/Abstract])) OR ((tired[Title/Abstract]) OR tiredness[Title/Abstract])) OR lassitude[Title/Abstract]) OR fatigue[Title/Abstract]) OR "Fatigue"[Mesh].

Participant or population: Adult participants (age over 18 years old) with a clinical diagnosis of end-stage renal disease undergoing hemodialysis (≥3 months).

Intervention: Intervention had to consist in regular aerobic, resistance, or combined exercise training.

Comparator: Control groups were described as "usual care", "no exercise", "sham exercise", "attention control", or "placebo".

Study designs to be included: Only randomized controlled trials were included.

Eligibility criteria: (1) Adult participants (≥18 years old) with a clinical diagnosis of end-stage renal disease undergoing hemodialysis (≥3 months; (2) Intervention had to consist in regular aerobic, resistance, or combined exercise training; (3) Control groups were described as "usual care", "no exercise", "sham exercise", "attention control", or "placebo"; (4) Outcomes representing fatigue were taken into account. (5) Only randomized controlled trials were included.

Information sources: We will search Pubmed, Cochrane Central Register of Controlled Trials (CENTRAL), Web of Science, Embase as well as four Chinese databases, namely China National Knowledge Infrastructure (CNKI), Wanfang, Chinese Biomedical Literature Database (CBM) and Chinese Science and Technology Journal Database (VIP). All the English and Chinese literature published from inception to May 31, 2020 will be retrieved. In addition, we will also undertake a targeted gray literature search on Clinical Trials.gov and the Chinese Clinical Trial Registry to gain unpublished or in-progress trials or completed but prepared for publication. Meanwhile, the reference list of previous clinical studies and reviews will be searched as supplementary sources.

Main outcome(s): Fatigue assessed by subjective or objective methods.

Additional outcome(s): Quality of life was assessed as a secondary outcome.

Quality assessment / Risk of bias analysis: The following items will be independently assessed by two authors using the risk of bias assessment tool. (1) Was there adequate sequence generation (selection bias)? (2) Was allocation adequately concealed (selection bias)? (3) Was knowledge of the allocated interventions adequately prevented during the study? (4) Participants and personnel (performance bias) (5) Outcome assessors (detection bias) (6) Were incomplete outcome data adequately addressed (attrition bias)? (7) Are reports of the study free of suggestion of selective outcome reporting (reporting bias)? (8) Was the study apparently free of other problems that could put it at a risk of bias?

Strategy of data synthesis: Data will be pooled using the random-effects model but the fixed effect model will also be used to ensure robustness of the model chosen and susceptibility to outliers.

Subgroup analysis: Based on available data, we will perform the following subgroup analyses: (1) Age: ≥ 18 years and < 60 years versus ≥ 60 years (2) Gender: female versus male (3) Dialysis vintage: < 3 years versus ≥ 3 years.

Sensibility analysis: We will perform sensitivity analyses in order to explore the influence of the following factors on effect size: (1) Repeating the analysis taking account of risk of bias (allocation concealment) (2) Repeating the analysis excluding any very long or large studies to establish how much they dominate the results.

Language: English.

Country(ies) involved: China.

Keywords: hemodialysis; exercise; fatigue; systematic review.

Contributions of each author:
Author 1 - Fan Zhang - Author 1 developed statistical analysis, designed and drafted the manuscript.
Author 2 - Liuyan Huang - The author provided study selection.
Author 3 - Hui Wang - The author provided study selection.
Author 4 - Yan Bai - The author contributed to the risk of bias assessment strategy.
Author 5 - Xing Zhao - The author contributed to the risk of bias assessment strategy.
Author 6 - Huachun Zhang - The author provided disagreement resolution.