INPLASY PROTOCOL

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Conflicts of interest:
The authors declare no conflict of interest.

Interventions for promoting physical activity in patients with end stage renal disease receiving hemodialysis

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ABSTRACT

Objective: **To evaluate the effectiveness of interventions to promote physical activity in patients with end stage renal disease receiving hemodialysis.**

Methods: **We will searched the English databases the Cochrane Central Register of Controlled Trials (CENTRAL), Embase, PubMed, Web of Science and the Chinese databases CNKI, WanFang, cqvip to identify relevant studies using the following as MeSH search terms and keywords: "exercise[Mesh]", "exercise therapy[Mesh]", "renal replacement therapy[Mesh]", "kidney failure, chronic[Mesh]", "end-stage kidney", "hemodialysis" etc. To comfirm any articles missed by the initial search, we also evaluated the reference lists of previously reported systematic review. We limited our searches to studies published in English and Chinese involving stable adult human participants receiving hemodialysis. Reference sections of the retrieved articles were hand-searched for citations missed by the electronic searches.**

INPLASY registration number: This protocol was registered with the International Platform of Registered Systematic Review and Meta-Analysis Protocols (INPLASY) on 29 March 2020 and was last updated on 29 March 2020 (registration number INPLASY202030013.

INTRODUCTION

Objectives / Review question: **To evaluate the effectiveness of interventions to promote physical activity in patients with end stage renal disease receiving hemodialysis.**

METHODS

Participant or population: We will include adults (18 years of age and over) with a diagnosis of patients with end stage renal disease receiving hemodialysis according to established criteria, regardless of disease severity. We will include studies that incorporate a mix of diagnostic groups only if we can obtain data on any of the review outcomes separately for end stage renal disease receiving hemodialysis.

Intervention: We will include trials that objectively assess physical activity as an outcome. These trials may compare any intervention designed to increase physical activity with no/sham intervention, or may compare a targeted physical activity intervention in addition to another standard intervention common to both groups. Interventions may include, but are not limited to, exercise training, education programmes, activity counselling and self-management strategies. Thesemay be supervised or unsupervised interventions.

Comparator: (1)One or more interventions to increase physical activity vs no intervention/sham intervention/stretch exercise; (2)One or more interventions to increase physical activity in addition to a standard intervention common to both groups.

Study designs to be included: All randomised controlled trials of interventions designed to promote participation in physical activity for end stage renal disease receiving hemodia.

Eligibility criteria: The eligibility criteria were the following: (1)patients with end stage renal disease receiving hemodialysis, (2)randomized controlled studies that included aerobic, resistance, or combined exercise with a pre–post intervention, (3)studies that evaluated the effects of exercise on at least one of the outcomes in this systematic review.

Information sources: We will identify trials from the Cochrane Central Register of Controlled Trials (CENTRAL), Pubmed, Embase, Web of Science, and the Chinese databases CNKI, WanFang, cqvip. We will check reference lists of all primary studies and review articles for additional references. We will search relevant manufacturers' websites for trial information.

Main outcome(s): Studies must include variable(s) that reflect participation in physical activity, as measured objectively using a pedometer, accelerometer or activity monitor. Outcomes of interest include, but are not limited to step count, activity counts, energy expenditure and physical activity time (different intensities, range of thresholds used). Primary time points will be at baseline (prior to commencement) and at the time of intervention completion; we will use change in physical activity from baseline for analysis where possible. Additionally, we will categorise any follow-up measurements reported following intervention completion as either short-term (within one month), mediumterm (between one to six months) or long-term (longer than 6 months).

Additional outcome(s): (1)Health-related quality of life (measured using either a generic or disease specific tool) (2)Exercise capacity: measured using an exercise test e.g. cardiopulmonary exercise test, 6-minute walk test (3)Adverse events (e.g. musculoskeletal injury) (4)Adherence to intervention.

Quality assessment / Risk of bias analysis: Two review authors will independently assess risk of bias for each included RCT using the criteria outlined in the Cochrane Handbook for Systematic Reviews of Interventions.We will resolve disagreements by discussion or by involving another review author. We will assess risk of bias according to the following domains: (1) Random sequence generation; (2) Allocation concealment; (3) Blinding of participants and personnel; (4) Blinding of outcome assessment; (5) Incomplete outcome data; (6) Selective outcome reporting; (7) Other bias. We will grade each potential source of bias as

either high, low or unclear and will provide an extract from the study report together with a justification for our judgement. We will resolve discrepancies by consensus. We will summarise the "Risk of bias" judgements across different studies for each of the domains listed and summarise results in a "Risk of bias" table. We will consider blinding separately for different key outcomes when necessary. When considering treatment effects, we will take into account risk of bias for studies that contribute to this outcome.

Strategy of data synthesis: We will perform a pooled quantitative synthesis where the trials are clinically homogeneous. We will pool data using a randomeffects model to incorporate between study heterogeneity into the meta-analysis. Where the trials are clinically heterogeneous we will performa narrative synthesis.

Subgroup analysis: We plan to perform the following subgroup analyses: (1) Duration of intervention (< 6 months versus > 6 months); (2) Supervision of intervention (yes or no); (3)age of participants (< 18 years old versus 18~60 years old versus > 60 years old). We will use physical activity as the outcome for subgroup analyses. We will use the formal test for subgroup interactions in Review Manager 5.

Sensibility analysis: We plan to examine the effects of methodological quality on the pooled estimate by removing studies that are at high or unclear risk of bias for the domains of blinding and incomplete outcome data. Additionally,we plan to examine the effects ofmeasurement device on the pooled estimate by removing studies that use pedometers.

Language: English and Chinese.

Countries involved: China.

Keywords: physica activity; hemodialysis; end stage renal disease.

Contributions of each author:
Author 1 - Data collection and analysis.
Author 2 - Design this meta protocol.
Author 3 - Revise for this protocol.