INPLASY PROTOCOL

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Intradialytic training in patients with end-stage renal disease: a systematic review and meta-analysis of randomized clinical trials assessing the effects of three different training interventions

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Review question / Objective: **P: patients with end-stage renal disease (hemodialysis patients) I: intradialytic exercise (including aerobic exercise, resistance exercise, combined exercise) C: without intradialytic exercie O: VO2 peak, 6MWT, STS, TUG, SF-36, Kt/V, CRP, IL-6, Hemogloin, total cholesterol, BMI, SBP, DBP S: RCTs.**
Condition being studied: **Patients with end-stage renal disease (ESRD) usually have a series of cardiovascular risk factors. Hypertension, increased levels of inflammatory markers, dyslipidemia, and physical inactivity are highly prevalent in this setting. Hemodialysis (HD) is the primary treatment for ESRD, and optimization of adjunctive therapies may improve prognosis. Recently, structured intradialytic training (IDT) has been proposed as an effective complementary therapy for patients with ESRD by increasing dialysis.**

INPLASY registration number: This protocol was registered with the International Platform of Registered Systematic Review and Meta-Analysis Protocols (INPLASY) on 13 August 2020 and was last updated on 13 August 2020 (registration number INPLASY202080051).

INTRODUCTION

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METHODS

Search strategy: We will search, with no time restrictions, the following databases for relevant English language literature: PubMed/MEDLINE, the Cochrane Controlled Register of Trials (CENTRAL), EMBASE, Scopus, Web of Science and Google Scholar. The search string will be built as follows: (((((hemodialysis[Title/Abstract])OR(hematodialysis[Title/Abstract]))OR(haemodialysis[Title/Abstract]))OR("RenalDialysis"[Mesh]))OR(intradialytic[Title/Abstract])) AND((exercise[Title/Abstract]) OR (training[Title/Abstract])). The electronic database search will be supplemented by a manual search of the reference lists of included articles.

Participant or population: Adult (≥ 18 years old) patients with ESRD undergoing hemodialysis, regardless of sex.

Intervention: Patients receive aerobic exercise, resistance exercise, or combined exercises during hemodialysis.

Comparator: Patients receive usual care in hemodialysis without exercise.

Study designs to be included: Randomized controlled trial(RCT).

Eligibility criteria: Eligible studies were required to meet the following criteria: (1) population: adult (≥ 18 years old) patients with ESRD undergoing HD, regardless of sex; (2) intervention: IDT, defined as aerobic, resistance, or combined exercise, regardless of duration of exposure; (3) comparison group: usual care or sham exercises (e.g., stretching), regard-less of duration of exposure; (4) outcomes: Kt/V (primary outcome), BP, CRF (VO2peak or VO2max), 6-minute walk test (6MWT), hemoglobin, C-reactive protein (CRP), interleukin-6 (IL-6), and total cholesterol (TC) (secondary outcomes); (5) Design: RCTs (parallel, crossover or factorial). Crossover trials were considered in their full form if a washout period of at least 2 weeks was respected; otherwise, only the first phase of the trial was included, to avoid carryover effects. Factorial designs were eligible if there was demonstrable absence of interactions between treatments.

Information sources: We also e-mailed authors of published results to seek information about any unregistered ongoing studies, and those of registered RCTs to seek potentially relevant data for inclusion. All databases were searched using terms for IDT and specific modalities (e.g., "intradialytic exercise"), as well as for outcomes and clinical condition (e.g., "extracorporeal dialysis"), combined with MeSH terms, synonyms, truncations, and Boolean operators. For PubMed/MEDLINE, a highly sensitive filter for RCTs was also used . We further searched the reference lists of included studies for other potentially eligible reports.

Main outcome(s): VO2 peak, 6MWT, STS, TUG, Kt/V.

Additional outcome(s): SF-36, CRP, IL-6, Hemoglobin, total cholesterol, BMI, SBP, DBP.

Quality assessment / Risk of bias analysis: Two reviewers will independently assesses the quality of the selected studies according to the Cochrane Collaboration's tool for randomized controlled trials. Items will be evaluated in three categories: Low risk of bias, unclear bias and high risk of bias. The following characteristics will be evaluated: Random sequence generation (selection Bias) Allocation concealment

(selection bias) Blinding of participants and personnel (performance bias) Incomplete outcome data (attrition bias) Selective reporting (reporting bias) Other biases Results from these questions will be graphed and assessed using Review Manager 5.3.

Strategy of data synthesis: Risk ratio (RR) for both fixed and random effects models (weighting by inverse of variance) will be used. A continuity correction will also be used for cells with zero values. Between-study heterogeneity will be assessed using X2 (Cochran Q) and I2 statistics. According to the Cochrane handbook, the I2 will be considered non-important (60%). Results will be assessed using forest plots and presented as RRs for the main outcome and secondary outcomes. An influence analysis will be performed to ascertain the results of the meta-analysis by excluding each of the individual studies. Publication bias will be assessed by a funnel plot for meta-analysis and quantified by the Egger method. Statistical analysis will be conducted using stata software for Mac v15.0 (Stata Corp., College Station, Texas) [module "meta"] and R studio v1.0.136 (The R Foundation for Statistical Computing) [package "meta v4.2].

Subgroup analysis: We will consider subgroups such as jurisdiction, clinic type, and location(rural/urban).

Sensibility analysis: Between-study heterogeneity will be assessed using X2 (Cochran Q) and I2 statistics. According to the Cochrane handbook, the I2 will be considered non-important (60%). Results will be assessed using forest plots and presented as RRs for the main outcome and secondary outcomes. An influence analysis will be performed to ascertain the results of the meta-analysis by excluding each of the individual studies.

Language: No.

Country(ies) involved: China.

Keywords: Hemodialysis, End-stage renal disease, intradialytic exercise, Dialysis efficacy, Meta-analysis

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