INPLASY PROTOCOL

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Conflicts of interest:
None declared.

Effects of pulmonary rehabilitation on patients with sarcoidosis: a systematic review and meta-analysis of randomised controlled trials

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Review question / Objective: **Is pulmonary rehabilitation an effective intervention in patients with sarcoidosis?**
Condition being studied: **Sarcoidosis.**
Eligibility criteria: **We will include studies published until March 2022. The population studied must be adults (>18y) with diagnosis of sarcoidosis that performed a structured program of pulmonary rehabilitation. We will include only outpatients. They must be patients with stable disease and without exacerbation for at least one month.**

INPLASY registration number: This protocol was registered with the International Platform of Registered Systematic Review and Meta-Analysis Protocols (INPLASY) on 11 March 2022 and was last updated on 11 March 2022 (registration number INPLASY202230046).

INTRODUCTION

Review question / Objective: **Is pulmonary rehabilitation an effective intervention in patients with sarcoidosis?**

Condition being studied: **Sarcoidosis.**

METHODS

Participant or population: **Patients with medical diagnosis of sarcoidosis.**

Intervention: **Pulmonary rehabilitation.**

Comparator: No intervention or lifestyle intervention.

Study designs to be included: We will include randomised controlled trials (RCTs).

Eligibility criteria: We will include studies published until March 2022. The population studied must be adults (>18y) with diagnosis of sarcoidosis that performed a structured program of pulmonary rehabilitation. We will include only outpatients. They must be patients with stable disease and without exacerbation for at least one month.

Information sources: We will review the PubMed/MEDLINE, Cochrane Library (CENTRAL), CINAHL, Web of Science, SCOPUS, and EMBASE databases.

Main outcome(s): 1. Exercise capacity: defined as peak oxygen consumption (VO2peak) in a cardiopulmonary exercise test (CPET) or distance walked in the six-minute walk test (6MWT). 2. Quality of life: measured through a standardized questionnaire (e.g. Saint George´s respiratory questionnaire, SGRQ) 3. Adverse events - Continuous data will be presented as the mean difference with standard deviations, or median and interquartile range. In addition, dichotomous categorical data will be reported in the overall mean proportion (%) of the population.

Additional outcome(s): 1. Fatigue, measured through a standardized questionnaire (e.g. Fatigue assessment scale, FAS) 2. Maximum workload (Wmax) 3. Oxygen pulse saturation (O2pulse) 4. Minute ventilation (VE) 5. Ventilatory equivalent (VE/VCO2) 6. Oxygen saturation, baseline and final of 6MWT 7. Dyspnea, baseline and final of 6MWT 8. Diffusing capacity (DLCO) 9. Forced Vital Capacity (FVC) 10. Forced expiratory volume in the first second (FEV1).

Quality assessment / Risk of bias analysis: The methodological quality assessment framework for CTs developed by the Cochrane Collaboration´s tool for assessing the risk of bias in randomised trials (Higgins and Green 2009) will be used to assess the risk of bias with regards to sequence generation, allocation concealment, blinding (participants, study personnel and outcome assessors), incomplete outcome data, selective outcome reporting, and others potential bias not covered by the framework. To minimise the bias, the studies will be graded independently by two reviewers (RTC-LSN). The scoring will be compared and discrepancies will be sorted by a third reviewer (EGS).

Strategy of data synthesis: Studies will be selected for inclusion using the predefined and explicit eligibility criteria. The full literature search results will be screened independently by two reviewers (XAR-EC) to identify all citations that may meet the inclusion criteria. The full manuscripts of all selected citations will then be retrieved and assessed by two reviewers (XAR-EC) against the inclusion criteria. Any disagreements over study inclusion will be resolved by consensus or, if necessary, by arbitration by a third reviewer (RTC). Study characteristics (design, country), baseline patient characteristics (age, demographic and anthropometric characteristics), outcomes (VO2peak, distance walked, quality of life, adverse events, fatigue, maximal workload, oxygen pulse, VE/VCO2, and pulmonary function), will then be extracted from the studies selected for inclusion by two reviewers (XAR-RTC) using a pre-designed and piloted data extraction form to avoid any errors.
Any disagreements between the reviewers will be resolved by consensus or, if necessary, through arbitration by a third reviewer (EGS). Authors may be contacted to request the provision of missing data on a case-by-case basis, considering the importance and relevance of the data which is missing.

Subgroup analysis: By the severity of sarcoidosis. By training type (continuous vs interval training).

Sensitivity analysis: We will perform sensitivity analysis based on sample size,

heterogeneity, methodological quality, and statistical model. We will exclude studies with low quality, and ensure the stability of analysis results.

Language: English.

Country(ies) involved: Spain.

Keywords: sarcoidosis; pulmonary rehabilitation; exercise; physical training; exercise capacity.

Dissemination plans: We will send to peer-review journal (Q1 or Q2 in respiratory medicine category).

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