INPLASY PROTOCOL

To cite: Li et al. Effect of Bifidobacterium Bifidum for Chronic Obstructive Pulmonary Disease in China: A Systematic Review and Meta-Analysis. Inplasy protocol 202260023. doi: 10.37766/inplasy2022.6.0023

Received: 06 June 2022

Published: 06 June 2022

Corresponding author:
Tong Guan

guantgzy@163.com

Author Affiliation:
The First Affiliated Hospital of Guangzhou University of Chinese Medicine.

Support: **None.**

Review Stage at time of this submission: **Completed but not published.**

Conflicts of interest:
None declared.

Effect of Bifidobacterium Bifidum for Chronic Obstructive Pulmonary Disease in China: A Systematic Review and Meta-Analysis

Li, SY[1]; Zhang, WS[2]; Guan, T[3].

Review question / Objective: **Exploring whether Bifidobacterium bifidum is effective in the treatment of patients with chronic obstructive pulmonary disease in China in the context of our national situation.**
Condition being studied: **Chronic Obstructive Pulmonary Disease is clinically characterized by dyspnoea, the mechanism of which is that it is a disease that occurs irreversibly in the small airways, imposing a huge economic burden on patients and society. According to research, the prevalence of Chronic Obstructive Pulmonary Disease in middle-aged and elderly patients in China is currently over 10% and is increasing year by year. In our cities, patient costs account for about 40% of household income, compared to about 30% in rural areas.**

INPLASY registration number: This protocol was registered with the International Platform of Registered Systematic Review and Meta-Analysis Protocols (INPLASY) on 06 June 2022 and was last updated on 06 June 2022 (registration number INPLASY202260023).

INTRODUCTION

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elderly patients in China is currently over 10% and is increasing year by year. In our cities, patient costs account for about 40% of household income, compared to about 30% in rural areas.

METHODS

Search strategy: We set up search strategies based on keywords. These include PubMed, Embase Database, The Cochrane Library, and the China National Knowledge Infrastructure, and the search period was from March 2012 to March 2022. A comprehensive collection of clinical randomized controlled trials (RCTs) related to bifidobacteria and COPD clinical medication guidance. The search was set up as a subject search, with the following terms: "chronic obstructive pulmonary disease" or "COPD", "bifidobacterium" or “probiotic*".and other combinations; references to the included literature were also searched and browsed, thus to broaden the search and minimize omissions.

Participant or population: All patients (≥18 years) with confirmed chronic obstructive pulmonary disease , no restrictions on duration, age, gender, complications, severity, and stage of patients.

Intervention: Bifidobacterium or a combination of preparations were given to all experimental groups of the study.

Comparator: All included study controls can be either placebo controls or blank controls.

Study designs to be included: Randomised controlled trials.

Eligibility criteria: 1) Subjects were all patients (≥18 years) with confirmed COPD, (No restrictions on duration, age, gender, complications, severity, and stage of patients). 2) Intervention: Bifidobacterium or a combination of preparations were given to all experimental groups of the study (no restrictions on specific drugs, dosing regimen, mode of administration, or duration of observation). 3) Comparison intervention: Controls: All included study controls can be either placebo controls or blank controls. 4) Outcomes: Primary outcomes: The incidence of diarrhea; Secondary outcomes: Percentage of gram cocci/bacteria in feces; 5) Study design: RCTs.

Information sources: We searched the four major databases of the Cochrane Library, EMBASE, PubMed, and the China National Knowledge Infrastructure for the keywords "bifidobacteria", "chronic obstructive pulmonary disease”, and” Randomised controlled trials”. The keywords were searched from March 2012 to March 2022.

Main outcome(s): The incidence of diarrhea.

Additional outcome(s): The secondary outcomes: Percentage of gram cocci/bacteria in feces.

Data management: Two reviewers (Shuyao Li and Wenshuang Zhang) independently reviewed the titles and abstracts of potentially relevant studies as well as the full text; any disagreement between the two reviewers were resolved by discussion and decision by a third reviewer (Tong Guan).

Quality assessment / Risk of bias analysis: The Cochrane Handbook for Systematic Reviews of Interventions will be used to assess the quality of reviews. Results will be independently cross-checked by two reviewers (Shuyao Li and Wenshuang Zhang). After internal discussion, any remaining discrepancies are resolved by a third reviewer (Tong Guan).

Strategy of data synthesis: RevMan version 5.3 (Cochrane Collaboration) will be used for data synthesis. For effect size estimation, RRs and 95% CIs of binarised outcomes will be used. Continuous data will be presented with the MD and 95% CI. When different scales of measurement are reported, SMD statistics will be used for the analysis of continuous data. Efforts will be made to identify sources of heterogeneity in each dimension and to

provide a narrative and qualitative summary.

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

Sensitivity analysis: RRs and 95% CIs of binarised outcomes will be used. Continuous data will be presented with the MD and 95% CI. When different scales of measurement are reported, SMD statistics will be used for the analysis of continuous data.

Language: English and Chinese.

Country(ies) involved: China.

Keywords: Chronic obstructive pulmonary disease, Probiotics, Randomized ControlledTrial.

Contributions of each author:
Author 1 - Shuyao Li.
Author 2 - Wenshuang Zhang.
Author 3 - Tong Guan.