

INPLASY

A Methodological Project (SMART-P) for TranSpparency and Methodological Characteristics of Randomized Controlled Trials of Phytotherapy Interventions

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ADMINISTRATIVE INFORMATION

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Review Stage at time of this submission - Data extraction.

Conflicts of interest - None declared.

INPLASY registration number: INPLASY202370021

Amendments - This protocol was registered with the International Platform of Registered Systematic Review and Meta-Analysis Protocols (INPLASY) on 07 July 2023 and was last updated on 07 July 2023.

INTRODUCTION

Review question / Objective To investigate the transparency and methodological characteristics of randomized controlled trials (RCTs) of phytotherapy interventions.

Rationale In recent years, poor transparency and methodology about RCTs have attracted much attention among stakeholders, but the RCTs of phytotherapy interventions have not yet been fully evaluated thus far.

Condition being studied RCTs of phytotherapy interventions. Five meta-research studies will be conducted to investigate reporting completeness, risk of bias, statistical fragility, likelihood ratio, rustworthiness, reporting of sociodemographic characteristics, and disparities of gender and geographical location of the first authors and corresponding authors.

METHODS

Search strategy #1 "Phytomedicine"[Journal] OR "Phytother Res"[Journal]
#2 "Clinical Trials as Topic"[Mesh] OR "Clinical Trial" [Publication Type] OR "Controlled Clinical Trial" [Publication Type] OR "Clinical Trial, Phase II" [Publication Type] OR "Clinical Trial, Phase III" [Publication Type] OR "Clinical Trial, Phase IV" [Publication Type] OR "Randomized Controlled Trial" [Publication Type] OR trial [Title/Abstract] OR random* [Title/Abstract]
#3 #1 AND #2.

Participant or population Human objects.

Intervention Phytotherapy interventions.

Comparator No limit.

Study designs to be included Double-arm, parallel, superiority RCTs with an allocation ratio of 1:1, regardless of blinding.

Eligibility criteria Time of publication: only RCTs published in 2018 and after were included as we want to provide the up-to-date evidence regarding this field; source of publication: Phytomedicine and Phytotherapy Research.

Information sources Relevant RCTs published in Phytomedicine and Phytotherapy Research were systematically searched via PubMed database. PubMed database.

Main outcome(s) The transparency and methodological characteristics of randomized controlled trials (RCTs) of phytotherapy interventions.

Additional outcome(s) None.

Data management Data extraction will be achieved independently by two researchers, then the results will be cross-checked, and any disagreement will be resolved through a discussion.

Quality assessment / Risk of bias analysis Several tools will be used, such as CONSORT 2010, Cochrane tool 1.0, TIDieR, TRACT.

Strategy of data synthesis Qualitative description and quantitative analysis will be used. R, Stata, and Excel 2019 will be used to analyze data and draw charts.

Subgroup analysis None.

Sensitivity analysis None.

Language restriction English.

Country(ies) involved China.

Other relevant information None.

Keywords phytomedicine, phytotherapy, transparency, risk of bias, protocol.

Dissemination plans The results of five studies will be submitted for publication in peer-reviewed journals.

Contributions of each author

Author 1 - Cuncun Lu - Conceptualized the study and drafted the manuscript.
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Author 2 - Zhifei Wang - Provided the funding.

Author 3 - Wenru Shang - Provided the funding and selected the studies.

Author 4 - Ziyi Wang - Selected the studies.