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# Efficacy and safety of AYUSH-64 as standalone or adjunct to standard care in COVID-19: a structured summary of protocol for a systematic review

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## Abstract

**Trial registration:** Registered with PROSPERO ([CRD42021267844](https://doi.org/10.1186/s13643-022-01983-8)) dated 14.07.2021.

**Keywords:** Ayurveda, AYUSH-64, Polyherbal, SARS-CoV-2, Pandemic

## Background

Apart from vaccines, significant efforts have been made to develop prophylactic and therapeutic interventions against COVID-19. Lack of standard therapeutic options for the management of COVID-19 contributes to seriousness of this novel disease. The current strategy for exploring therapeutic interventions to manage this pandemic is broadly based on repurposing and repositioning of existing medications and recommending them for symptomatic support. In the early stage of COVID-19, the interventions that limit the progression of the disease and facilitate early recovery may play a significant role. AYUSH-64 is a polyherbal Ayurveda formulation developed by the CCRAS, Ministry of Ayush, Government of India. It has been found effective and safe in various infective febrile conditions like malaria, microfilaremia, chikungunya, and influenza [1–5]. AYUSH-64, was repurposed for the management of asymptomatic and mild to moderate COVID-19 based on the experimental and clinical outcomes indicating its potential benefits

and safety in disease conditions like influenza-like illness. Government of India recommended the use of AYUSH-64 to manage the asymptomatic and mild COVID-19 cases on the basis of outcomes of clinical studies on AYUSH-64 in COVID-19 [6, 7]. In this context, this systematic review is planned to synthesize evidence related to the safety and efficacy of AYUSH-64 as standalone or adjunct to standard care in managing asymptomatic and mild to moderate COVID-19.

## Methods

The PRISMA-P (Preferred Reporting Items for Systematic Reviews and Meta-analyses- Protocol statement) guidelines have been followed for drafting this protocol. All Randomized Controlled trials that assess the efficacy and safety of AYUSH-64 for the management of COVID-19 as standalone or adjunct to conventional standard care will be considered for this systematic review. Comprehensive search will be done for the published studies as per the pre-designed search strategy in the electronic databases such as AYUSH Research Portal's "National Repository on AYUSH COVID-19 Clinical and Other R&D Initiatives", PubMed, Cochrane Central Register of Controlled Trials, DHARA, IndMED, COVID-19 Evidence Alerts from McMaster PLUSTM, Epistemonikos,

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TRIP database, Google Scholar, National Collaborating Centre for Methods and Tools database of COVID-19 studies, Clinical Trial Registry of India and WHO dashboard for clinical trials related to COVID-19 from inception till October 2021. Data selection and extraction for each study will be performed independently by two review authors, with disagreements resolved by discussion with third review author/consensus. Risk of bias assessment will be performed using the revised tool to assess the risk of bias in randomized trials (RoB 2). The results will be quantitatively synthesized (meta-analysis) using Review Manager 5.4. If meta-analysis will not be conducive due to substantial heterogeneity, we will summarize and explain the results of the included studies as the systematic qualitative synthesis.

## Discussion

To date, this will be the first systematic review on the Ayurveda intervention, AYUSH-64 that will synthesize the evidence on its efficacy and safety in the management of COVID-19. The pilot search undertaken before planning this systematic review resulted in 07 clinical studies on AYUSH-64 that evaluate its efficacy and safety in the management of COVID-19. These search results justify the initiation of this systematic review. This systematic review will help the policy makers for wider implementation of AYUSH-64 in the management of asymptomatic and mild to moderate COVID-19. The results of this systematic review will be published in an indexed open-access journal to ensure wider dissemination.

## Supplementary Information

The online version contains supplementary material available at <https://doi.org/10.1186/s13643-022-01983-8>.

**Additional file 1.** Full protocol of this systematic review.

**Additional file 2.** Example of search strategy (PubMed).

## Acknowledgements

The authors thank the Central Council for Research in Ayurvedic Sciences, Ministry of Ayush, Government of India, for extending their technical support to conduct the study. We acknowledge the contribution of the investigators and other research personnel who conducted the clinical trials on AYUSH-64 during the COVID-19 pandemic.

## Full protocol

The full protocol is enclosed as an additional file, accessible from the journal website (Additional file 1). This communication serves as a summary of the key elements of the full protocol.

## Authors' contributions

Review question, search strategy, and first draft of the protocol were designed by AKR, AA, KK and PM. Protocol was refined by BY and SK and approved by BC and NS. AKR, PM, AA wrote the first draft of this manuscript and further refined by BY, SK, BC, and NS. All the authors participated in the idea refining, revising the manuscript for important intellectual content, and approved the final version submitted for publication.

## Funding

This systematic review is not funded by any organization.

## Availability of data and materials

Not applicable.

## Declarations

### Ethics approval and consent to participate

Ethics approval is not required for systematic review.

### Consent for publication

Not applicable.

### Competing interests

The authors declare that they have no competing interests.

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Received: 6 December 2021 Accepted: 15 May 2022

Published online: 24 May 2022

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