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REVIEW ARTICLE

Strength, challenges and potential solutions for the advancement of the research ecosystem in AYUSH: Insights derived from the COVID-19 pandemic

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Abstract

The Ministry of Ayush (MoA), either independently or in collaboration, has diligently endeavoured to ascertain the significance of India's Ayush system in mitigating and managing COVID-19 pandemics since its inception. Despite the various constraints posed by limited resources and other impediments, a substantial amount of research has been undertaken in the Ayush arena, as evidenced by the considerable number of clinical trials registered in the Clinical Trial Registry of India (CTRI) and further on the several medical databases. To summarise the clinical trials of Ayush interventions against COVID-19, a living systematic review and meta-analysis were conducted at ITRA, Jamnagar in collaboration with South-East Asia Regional Office of World Health Organisation (WHO SEARO), New Delhi. During the course of this process, several research gaps and challenges have been observed. Researchers observed that many studies lacked in quality owning to design, execution or analysis level. There is a huge need for the upliftment of the research environment in the Ayush system of Medicines. This article has highlighted the gaps in the scientific literature, its impact on evidence quality and the feasible and practical solutions to rectify those. Continuous capacity-building to human resources, incorporation of a whole system approach in research design without breaking integrity and validity and adherence to standard international guidelines in protocol designing and reporting are a few of the propositions for future endeavours. The analysis of these issues is crucial for the prospective development of research in the field of traditional medicine.

Keywords

Ayush; COVID-19; research; SARS Co-V 2; traditional medicine

Introduction

Coronavirus disease 2019 (COVID-19), the highly contagious infectious disease caused by SARS-CoV-2, has had a catastrophic effect on the world's demographics resulting in more than five million deaths worldwide (1), emerging as the most consequential global health crisis. In the Indian subcontinent, a total of 10915905 cases and 155169 deaths were reported from March 24, 2020, to February 14, 2021 (first wave) and 13766623 cases and 114550 deaths were reported from February 15, 2021, to May 15, 2021 (second wave) (2).

Coronavirus belongs to a large family of non-segmented positive-sense single-stranded RNA viruses with a broad distribution across humans, other mammals and birds. It causes respiratory, enteric, hepatic and neurologic infections (3). SARS-CoV-2 primarily spreads by droplets and is postulated to have higher transmissibility as compared to seasonal influenza. A major concern arises due to its likely spread via even asymptomatic or minimally symptomatic individuals who may not seek any clinical evaluation (4).

The first case of COVID-19 was detected in Yan'an city of China in December 2019 and it was eventually declared a pandemic on March 11, 2020 (5, 6). Since the onset of the COVID-19 pandemic, public health specialists around the world have been concerned about its transmissibility, re-infection rates, sickness severity and viable treatment choices. The development of vaccines was the prime target in health research as treatment options were not showing promising results. In India, indigenous vaccines named Covaxin (fully developed in India), Covishield, Sputnik and NVX-Co2373 (manufactured in India) were developed later as the vaccine development process was tedious and time-consuming. Though there were no major evident side effects observed, side effects like myalgia, fever, general discomfort, headache, edema and pruritus were a few of the undesirable effects which were common with these vaccines (7).

As no plausible treatment was available for COVID-19, people turned to traditional systems of medicine for its prevention and treatment. The quest for a potential remedy engaged researchers from traditional medicine facilities around the world, including India. In the Indian subcontinent, Ayurveda, Yoga, Naturopathy, Unani, Siddha, Sowa-Rigpa and Homeopathy (Ayush) are six alternative and complementary therapies that have been popular in the community and are regulated by the Ministry of Ayush (MoA) (8).

The Ministry of Ayush took a proactive, graded, whole-of-government, whole-of-society approach centered on a comprehensive strategy to prevent infections, save lives and mitigate the impact of the pandemic. A series of actions were taken to tackle the grave situation, such as guiding the general population through advisories on self-care (9), guiding Ayush health professionals by developing clinical care guidelines and national protocol and arranging awareness programs, etc (10). To evaluate the acceptance, perception and utilization of Ayush advisories and measures for the prevention of COVID-19, a mobile application “Ayush Sanjeevani” was launched where the data of around 1.35 crore respondents were recorded (11).

The MoA also promoted Ayush research studies on COVID-19 and consulted various organizations based on their expertise. For instance, the Public Health Foundation of India (PHFI) was involved in human resource training and data interpretation. In addition, data from the research studies were submitted to the Data and Safety Monitoring Board (DSMB) regularly to maintain transparency and to monitor the progress of projects, the Project Monitoring Unit (PMU) of the task force was utilized. Due to such united and collaborative efforts, 229 AYUSH clinical trials (Ayurveda-131, Yoga and Naturopathy-33, Unani-06, Siddha-16, Homeopathy-24, neutraceuticals-15, other combinations-02) were registered in the Clinical Trial Registry of India (CTRI) until January 2022. These clinical trials evaluated many interventions for therapeutic or prophylactic aspects. Formulations such as AYUSH 64 (12), *Chyawanprasha* (13), *Guduchi* (*Tinospora cordifolia* (Thunb.) Miers.) (14), *Ashwagandha* (*Withania somnifera* Dunal) (15), *Arsenicum Album* (16), *Kabasura Kudineer* (17) *and Nilavembu Kudineer* (18) were majorly advocated and utilized.

To summarize and critically evaluate available clinical trials carried out on Ayush interventions and to assess the efficacy and safety of Ayush intervention in preventing and managing COVID-19, a Southeast Asian Regional Office of World Health Organisation (WHO-SEARO) sponsored project on living systematic review and meta-analysis was conducted in Institute of Teaching and Research in Ayurveda, Jamnagar, Gujarat. Multiple medical databases with appropriate search strategies were searched for COVID-19 clinical trials. The qualitative analysis of the trials was done based on the Cochrane guidelines. The findings of this systematic review and meta-analysis have been published in peer-reviewed journals (19, 20). Among other objectives of this project, one was to highlight the research gaps, challenges, likely solutions and future scope of Traditional Medicines (TM) in India.

During the review process, it was observed that the quality of the Ayush research lagged in key areas viz. research designs and quality publications. Further, there were unexplored areas of COVID-19 that should have been addressed. This article is an attempt to propose viable potential solutions to those flaws in order to guarantee a qualitative upgrade for any future research endeavours. Researchers in traditional medicine may benefit from having access to trustworthy and decisive suggestions and guidance provided by it. Further, it will ensure the rational and cautious usage of resources in the upcoming TM research projects.

Efforts of the MoA during the pandemic

The Ayush sector has taken an unprecedented course of action during the COVID-19 pandemic. It established a multidisciplinary ‘Ayush R&D Task Force’ and working groups comprised of scientists, pulmonologists, epidemiologists, pharmacologists and others to plan, execute and publish clinical and experimental research on Ayush interventions. A total of 139 clinical research studies and basic experimental studies were initiated at approximately 159 centers by Research Councils and National Institutes under the Ministry using the intramural and collaborative research model, based on the recommendations of the Interdisciplinary Task Force (21).

Further, the Ministry of Ayush collaborated with a number of research organizations to advance evidence-based and multidisciplinary research on Ayush systems such as the Department of Biotechnology (DBT), the

Council of Scientific and Industrial Research (CSIR) and the Indian Council of Medical Research (ICMR), as well as the All-India Institute of Medical Sciences (AIIMS). The primary interventions chosen for extensive experimental and clinical trials included *Ashwagandha*, *Yashtimadhu* (*Glycyrrhiza glabra* Linn.), *Guduchi*, *Pippali* (*Piper longum* Linn.) and AYUSH 64 (22).

To ensure rapid dissemination of the research findings, reports and research articles were initially submitted to Pre-Print repositories such as medRxiv, OFS, SSRN and others before being published in peer-reviewed journals. Studies published have been linked to the Ayush Research Portal under the title 'National Repository on AYUSH COVID-19 clinical and other R&D initiatives', which has been developed to disseminate information about AYUSH R&D initiatives, COVID-19-related AYUSH clinical trials and scientific publications. To date, a total of 145 clinical trials, 35 pre-clinical trials and 115 drug research have been linked to this repository (23).

The Ayush researchers have generated multiple high-quality research as an outcome of diligent work and diverse initiatives. The approach was meticulous, coordinated, well-planned and significantly more professional than before, which was encouraging to its collaborators.

Common issues and challenges

During the qualitative analysis of the research trials during the living SRMA, it was observed that some issues were uniformly found in almost all the studies. As a consequence of these issues, the credibility of the results was compromised. These issues are mentioned in the following section with an explanation of their concealed repercussions on the final results.

Research design

Though there are plenty of studies (229 studies till January 2022) registered in the clinical trial registry of India with clinical trials on formulations or single drugs of Ayush for the prevention or management aspect of various stages i.e., asymptomatic, mild, moderate and severe stages of COVID-19 patients, many of these studies were not rigorously and methodologically designed especially as per PICO (Population, Intervention, Control and Outcome) framework, which is the prerequisite and base of any clinical trial.

Few research studies on Ayush failed to identify the primary outcome of interest among all outcomes or the primary outcome was not stated explicitly. For instance, considering the severity of the disease, mortality has been considered the most important patient-centric clinical outcome of COVID-19 (24) and this outcome was measured in one of the seventeen included articles (therapeutic interventions) in the SRMA. Defining a reliable and measurable outcome is crucial when designing clinical trials. The outcome should be selected considering the patient's needs and value and has to be evaluated over a clinically relevant time. If there are multiple outcomes of interest, such outcomes must be converted into a composite outcome to evaluate the net benefits.

A scarce number (two out of 26 RCTs included in the SRMA) of Ayush clinical trials met the gold standard of clinical trial design. Clinical researchers regard the double-blind, randomized controlled trial (RCT) as the gold standard in effective research (25). Additionally, even in blinded RCTs, the study failed to address/report on other critical components recommended by the CONSORT (The Consolidated Standards of Reporting Trials) guidelines for RCT reporting, such as allocation concealment, level of blinding and so on, which negatively impacts the internal validity of the study. CONSORT guidelines advocate an objective scientific process that, when properly conducted, produces knowledge free of bias for evaluating the effectiveness of a novel intervention or treatment.

Most of the studies (15 out of 17 included therapeutic RCTs in the SRMA) were carried out with a small sample size (< 100 participants), that was decided randomly according to the researchers' comfort, time available and resources. A study on a small sample is appealing for obvious reasons, but it is a waste of time and money because the results are inevitably ambiguous. It may result in a null trial due to inadequate participants studied or as a result of sparse data bias. A smaller sample size will produce results that may not adequately influence to recognition of a difference between groups and it may turn out to be falsely negative, resulting in a type II error.

Quality in publication

Ayush-related trials on COVID-19 were primarily published in good reputed peer-reviewed journals; however, some reports were published in sub-optimal journals that were not within the UGC-CARE list (recommended journal list by the University Grants Commission (UGC) of India). Publication in the UGC-CARE journal is the bare minimum standard for the publication. Further, the publication of the article in the sub-standard journal also impacts the reach of the information to the larger group of researchers.

Research on severe COVID-19

Most clinical trials (~35%) on effectiveness in the conventional system focused on the severe to critical stage of COVID-19 (26), as severe to the critical stage of COVID-19 was the most concerning aspect compared to mild to moderate conditions. There was a single published article on the effect of Homeopathy interventions, as an add-on to standard care for moderate and severe COVID-19 cases (27). It may be due to insufficient hospital infrastructure to meet emergencies or scarce resources to manage the advanced stage of COVID-19. However, trials involving such populations were required in the Ayush systems.

Research on vulnerable population

There was no evidence on the effect of integrated to standard care or standalone Ayush drugs on COVID-19-infected vulnerable populations such as children, pregnant and lactating women, old age, HIV, cancer patients, etc. Pregnant and lactating women, patients with high-risk comorbidity, had an increased risk for severe disease from SARS-CoV-2 infection. Most studies excluded such vulnerable people indicating no evidence of the efficacy of Ayush

drugs on vulnerable people. Nonetheless, it requires special ethical consideration. In such a case, a multispecialty team-based approach was required to use an integrated treatment approach. Particular precautions and concerns were required based on the balanced benefit and harm ratio while recommending integrated therapeutic agents for COVID-19 under this group.

Research on the standalone effect of the intervention

In the beginning, the integration of the Ayush system of drugs and standard care was the right approach in COVID-19 trials, considering it as a pilot study and due to uncertainty of the results. As most of the trials were conducted on Ayush interventions as an adjunct to standard care, the individual efficacy of Ayush drugs was not established. However, once the effectiveness of Ayush intervention was recognized, selected potent interventions should have been further evaluated as standalone versus standard care. Nevertheless, this would require careful evaluation and decision considering many factors.

Research on drugs-herbs or herbs-herbs interactions

The primary objective of all Ayush trials was to evaluate the efficacy of interventions used in COVID-19 patients in clinical settings. Therefore, the interaction of herb-based intervention with conventional medicines was not vigorously evaluated. Though the herb-based Ayush interventions are relatively safer, yet, interaction with other conventional care cannot be ruled out while using in an integrated manner. In vivo studies on rat models of Traditional Chinese Medicine drug-herb interaction suggested potential drug-interaction risks in COVID-19 treatment (28). Such experimental study should have been carried out in the case of Ayush interventions for drug-herb interactions.

Long-term safety and efficacy

Pharmacovigilance activity in Ayush hospitals needs to be strengthened. In most of the trials on COVID-19, herb-based Ayush medicines were found to be safe. However, the trial duration was relatively short, so long-term safety and efficacy could not be established. It is generally difficult to run clinical projects for a long time due to limited resources. So observational studies could be conducted to detect the long-term effect of treatment in routine care in hospital settings to observe the patients prospectively for pre-defined safety outcomes. Alternatively, hospital clinical records should be evaluated through a retrospective study. In the case of patent drugs, post-marketing surveillance may help identify long-term safety.

Solutions and recommendations

The research team suggests solutions and recommendations to fill the gaps and overcome the above-mentioned challenges. Some solutions and recommendations address the limitations identified in the present review and some are general solutions that cover a broader scope of improvement in Ayush systems. These possible way forwards are mentioned below:

Continuous capacity-building in research methodology

As research is a grey area of Ayush, researchers have to be trained frequently to be well-equipped with statistical tools, techniques and equipment advancements. During the COVID-19 pandemic, efforts in human resource development through capacity-building programs were undertaken by the Ministry of Ayush. Eminent experts were invited from other recognized institutions of basic sciences and public health research and have significantly contributed to the skill development and capacity-building programs to train the Ayush academicians and researchers of several research councils and national institutions. The outcome of these meticulously coordinated endeavours was highly promising. It is imperative to adhere to these practices as part of a regular routine in order to cultivate a highly skilled and proficient resource team.

Improvement in quality of research

Creating research questions is one of the most challenging parts a researcher faces when embarking on a study. A good research project begins with formulating an appropriate research question and writing a good protocol. PICO (population, intervention, control and outcomes) and FINER are guiding principles for formulating an effective research question (29). Ayush clinical trials registered in CTRI have adequately specified the population, intervention and control, but not the expected measurable outcome. The outcome must be chosen in light of numerous stakeholder perspectives, the available funding and the study's scope. It will help with the data collection for the study groups, ensuring that the analysis is thorough and the study is of high quality.

Sample size calculation is a critical aspect of any clinical study involving samples (30). It is generally complex and requires expert assistance. Online software tools like GLIMMPSE (https://samplesizeshop.org/glimmpse-power-software/), CLINCALC (https://clincalc.com/stats/samplesize.aspx), are available for the sample size calculation, which may be considered if found suitable. It is better to involve a statistician while fixing the sample size, data analysis and interpretation. A well-designed clinical trial should be accompanied by appropriate statistical analysis for the fair finding of the trial.

Project and data monitoring

Close supervision of an investigator ensures that all research activities are implemented according to the approved study protocol and as per good clinical practice norms. Continuous monitoring helps to avoid research fraud, decrease the chances of unethical behaviour, identify protocol deviations at an early stage and assure the appropriate and effective dissemination of outcomes of the research. To avoid data quality concerns, it is necessary to provide real-time research data entry and submission to independent data monitoring and safety committees. To support observational research, a centralized database should be built. Ayush Hospital Management Information System (A-HMIS) is a good initiative taken by MoA that may cater to the information-related needs of patients, clinicians, hospitals, policymakers and researchers.

Adherence to international standards and guidelines

The safety, effectiveness and quality control of herbal medications and conventional procedure-based therapies

have become crucial issues for both health authorities and the general public as a result of the enormous growth in the use of traditional medicine around the world. Without the establishment of worldwide standards and suitable procedures for evaluating traditional medicines in parallel, diverse traditional medical practices have emerged in various cultures and regions based on the individual researcher's ease. Eventually, it cost the reliability and reproducibility of the work. The current levels of adherence to reporting guidelines are suboptimal. The researcher should check the equator network (31) to check the reporting guidelines suitability to their study type. Following reporting guidelines need to be considered and adhered to while reporting research in Ayush (Table 1).

Table 1. List of reporting guidelines with the study type

S.N.	Study type	Guidelines
1	Systematic review	PRISMA (32)
		PRISMA-P (33) (for protocol)
2	Randomized clinical trial	CONSORT (34)
		SPIRIT (35) (for protocol)
3	Observational studies	STROBE (36)
4	Diagnostic/Prognostic studies	STARD (37)
		TRIPOD (38) (for protocol)
5	Case Reports	CARE (39)
6	Animal pre-clinical studies	ARRIVE (40)

Whole system approach

Experts repetitively indorse that complementary and alternative medicine's conjectures are fundamentally different from contemporary medicines and demand modified methods of analysis. TM has a holistic and individualized treatment approach. Hence, it is difficult to produce evidence for the effect of treatment in Ayush that meets the standards of RCTs; the initial difficulties lie in their practice presuppositions and complex interventions performed. It involves multiple components, channels and targets while exhibiting effects on the body (41). It is challenging to establish it by using current medicine's study approach of "single component and single target". As a result, several times, promising interventions have been found to exhibit null effects when investigated through conventional RCT design.

Moreover, the RCT design cannot be ignored as it aims to eliminate the likely biases involved in the clinical trial and determine the intervention's actual effect. Thus, clinical research on drug efficacy in Ayush systems of medicine requires both factors; conserving personalized medicine phenomena and eliminating possible biases. It may be achieved in Ayush systems by incorporating the black-box approach while designing RCT. In the black-box approach, the investigator/treating physician will be free to select interventions from pre-defined sets of treatment modalities/plans considering traditional concepts and methods for diagnostics and therapeutics. However, each component of the decision and set of actions must be predefined at the protocol level to avoid possible bias. Such a set of actions must be aligned with traditional practice. There is still the possibility of a double-blind trial in such designs if the outcome assessor is different from the physician and caregiver. One successful effort has been made for rheumatoid arthritis and published in 'Annals of the Rheumatic Diseases' (42). Unfortunately, such attempts have not been replicated, though one decade has passed. Researchers should come forward to design such trials for different disease conditions to assess the efficacy and applicability of traditional concepts in routine practice. Institutions with enough resources and skilled researchers should initiate such clinical research incorporating the black-box design.

Biological pathway: Network pharmacology

The biochemical mechanisms of Ayush medicines on the human body remain largely unexplored. Drugs that have unknown biological pathways are poorly recognized and accepted in clinical practice in contemporary science. Traditional medicines containing multi-component molecules may produce multi-target activities that are difficult to recognize by the present pharmacological one-target, one-drug approach. A new approach is required to understand the multi-component traditional medicines effects. Network pharmacology is a novel approach in system biology that is both sophisticated and promising for understanding the complex bioactivities of herbs or combinational drugs in the body (43). This method has moved the paradigm from "one-target, one-drug" to "network-target, multiple-component-therapeutics". This method makes it highly effective for analyzing drug combinations, mainly Traditional Medicine (TM) preparations. Indian Traditional Medicines sector should use this emerging pharmacology technique to construct interactive networks of traditional medicines to know their rationale, mechanisms and scientific basis.

Quality control in medicinal products

The quality control of TM is directly related to the safety and effectiveness of TM. Ayush has set up a quality control of TM focusing on macro-microscopic identification, physicochemical analysis and chromatographic fingerprinting. Recently, it has shifted to marker analysis (44). However, the research pattern of the quality control of Ayush medicines is still relying on the analysis method research. These standards are comparatively low in comparison to international standards.

Further, there are some challenges in quality control systems due to many intrinsic and extrinsic factors influencing raw material quality. Thus, the scientific and reliable quality assurance system complying with the characteristics of traditional medicines is yet to be fully constructed. Quality assurance systems should include a robust mechanism for compliance and assurance of Good Cultivation and Collection Procedures (45) and Good Manufacturing Procedure guidelines (46) uniformly across the country in the herbal sector rather than only focusing on the testing report of the finished product. More emphasis should be given to developing biomarkers for herbs rather than chemical markers in quality control research.

A systematic approach to clinical care guideline development

Currently, many clinical trials have been carried out on many disease conditions using Ayush interventions, some of which are published in peer-reviewed journals. However, the findings of such trials are not being recognized by guideline developers, stakeholders and panellists and therefore, are poorly reflected in the National Guidelines and Protocols. Opinions and literature-based guidelines and recommendations in clinical care should be replaced by evidence-based recommendations through a scientific and systematic approach to providing recommendations. Contemporary practices lead to poor utilization of research findings at the policy level and create 'research waste'. The evidence scrutiny should be more objective and uniform. The GRADE approach (Grading of Recommendations Assessment, Development and Evaluation) (47) is the most rational way for generating recommendations at large. This approach encompasses many other factors while making judgments about the strength of a recommendation, such as the balance between benefits and harms, the quality of the evidence, the translation of the evidence into specific circumstances and the certainty of the baseline risk and costs (resource utilization) (48).

Upgradation of Ayush peer-review journal

At present, many peer-reviewed journals are efficiently publishing articles related to Ayush regularly to disseminate the research findings and updates in the field of Ayush, such as The Journal of Ayurveda and Integrative Medicine (J-AIM), Indian Journal of Research in Homoeopathy, AYU, etc. However, among all Ayush-related journals only two journals, The Journal of Ayurveda and Integrative Medicine (J-AIM) and the Indian Journal of Research in Homoeopathy, are indexed with the Scopus database. The Ayush sector must put more effort into publishing research work in internationally recognized journals to reach out to a diverse section of scholars. The Ministry of Ayush may motivate and support the institutions that are running journals to publish quality papers only and guide them for indexing in the globally recognized database (WoS and Scopus).

Involvement of the private sector

Most of the funds for research in traditional medicines are being granted by the government. Unlike modern medicine, private industry-led research has not thrived in the Ayush sector. Further, many clinical trials have been done in traditional medicines as part of postgraduate and doctorate research and it is the leading research source for Ayush systems. During the pandemic, some pharma industries came forward and engaged in clinical research, which is an encouraging sign for future perspectives and should continue further. Government encouragement of evidence -based medicines may compel the private sector to conduct research and clinical trials.

Conclusion

While Ayurveda holds significant promise in the field of healthcare management, the available scientific knowledge is currently heterogeneous and lacks a comprehensive framework for assessment and utilization. The initiatives undertaken by the MoA during the pandemic, along with the subsequent scientific advancements observed, provide compelling evidence of the capabilities and potential of the organization. Implementing a few improvements to the policy and research framework will further enhance the effectiveness of the system and optimize resource allocation.

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Authors' contributions

MG carried out conceptualization, investigation and writing of the original draft. KP participated in formal analysis, investigation and writing of the original draft. RK carried out investigation and writing of the original draft. AT participated in funding acquisition, project administration, resources and writing, reviewing and editing. KS carried out conceptualization, project administration and writing, reviewing and editing.

Compliance with ethical standards

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