

# **National Clinical Management Protocol based on Ayurveda and Yoga for management of Covid-19**

## **Frequently Asked Questions**

### **1. Are there any traditional medicines or therapies that can prevent or cure COVID-19?**

**Ans:** There are some traditional medicine remedies from Ayush systems which provide relief and alleviate some of the symptoms of COVID-19. Ayush systems follow a holistic approach towards disease management and maintaining health of a healthy person. It provides detailed advocacy and interventions for disease prevention. There are various interventions in Ayush systems which are presently being used in prophylactic approaches as well as in the management of COVID 19, and are providing good results. Further these are seen to be beneficial in symptomatic management in COVID 19.

The ongoing AYUSH-CSIR COLLABORATIVE STUDIES (a joint initiative among the Ministry of AYUSH, Ministry of Health and Family Welfare and Ministry of Science & Technology, with technical assistance from ICMR) includes four clinical studies on use of AYUSH medicines for COVID 19, both in a prophylactic role and as an add-on intervention to conventional treatment. The Ministry has also initiated 68 studies at 112 locations undertaken through National institutes, Research Councils, Universities, State Governments and other collaborating hospitals (which includes AYUSH-CSIR studies also).

However, it is underlined that the interventions and measures proposed in the Clinical management protocol are not for cure, but for the management of asymptomatic and mild cases of COVID 19 and for prophylactic care. One should not get a false feeling of safety from adopting these measures. It is also underlined that for prevention of COVID 19, the mainstay approach remains adherence to the general guidelines as released by Government, including maintaining appropriate

physical distance, wearing a mask, maintaining hand-hygiene and avoiding unnecessary crowding at any place, and these should be followed strictly.

## **2. What is immunity in Ayurveda?**

**Ans:** In Ayurveda, immunity is referred to as *vyadhikshamatva*. Ayurveda has a comprehensive approach of immunity encompassing two-fold management, respectively of health and disease. *Vyadhikshamatva* is the resistance of the body to fight a disease by either of the following two ways:

- a. *Vyadhi-Bala-Virodhitvam* – The resisting power of the body to restrain or withstand the strength or severity or progression of a disease, or
- b. *Vyadhi-Utpada-Pratibandhakatvam* – The resisting power of the body to prevent the manifestation of a disease.

Significantly, various modifiable factors have been enlisted in Ayurveda that influence the host defense responses (*Bala/Vyadhikshamatva*). These factors include a healthy diet (*Pathyaahara*), condition of biological humors (*dosha*) and the state of physical and mental health (*Sareera*). The previous Covid 19 related advisories issued by the Ministry of AYUSH are based on this host defense mechanism or salutogenesis and also on various empirical evidences available from peer reviewed and indexed publications.

## **3. What is the importance of Rasayana in strengthening the host defense?**

**Ans:** “Rasayana” in Ayurveda is a comprehensive term which refers to a group of herbs, formulations and therapies for enhancing body resistance by attaining optimal level of *Rasadi Dhatu*. This is attained through specific medicinal herbs, formulations and some specific codes of conduct. Rasayana promotes strength, vitality, longevity, memory, intelligence, perseverance of youthfulness and the maintenance of optimum strength of the body and senses. There is a substantial body of scientific information on the said herbs and their phytoconstituents in public domain regarding the various activities viz; immunomodulation, antioxidant activities, neurodegenerative disorders, rejuvenators and nutritional supplements.

#### **4. Who has prepared the National Clinical Management Protocol based on Ayurveda and Yoga for management of Covid-19?**

**Ans:** The Ministry of AYUSH has set up an Interdisciplinary Committee for Integration of Ayurveda and Yoga Interventions in the 'National Clinical Management Protocol: COVID-19'. The said Committee is chaired by Dr V M Katoch, former Director General ICMR and includes a group of experts.

The Committee, after a thorough consultative process, formulated its Report & Recommendations (which is available at <http://ayush.gov.in>) based on acceptable experimental and clinical published data indicating potential benefits and safety at the same time and trends from ongoing studies in COVID-19. The report was presented before the National Task Force on COVID 19 and the Joint Monitoring Group, both constituted by the Ministry of Health and Family Welfare.

On consideration of this report, the National Task Force on Covid 19 management suggested preparing a National Clinical Management Protocol based on Ayurveda and Yoga for management of Covid-19 for inclusion as a dedicated chapter in National Protocol for Management of COVID 19.

The Ministry of AYUSH referred these recommendations to the Chairman of its National Task Force (i.e., the UGC Vice Chairman) with a request to vet the recommendations by initiating consensus from experts from the concerned premier institutions. These institutions included the All India Institute of Ayurveda (AIIA), Delhi, Institute of Training and Research in Ayurveda (ITRA), Jamnagar, National Institute of Ayurveda (NIA), Jaipur, Central Council for Research in Ayurveda (CCRAS), Central Council for Research in Yoga and Naturopathy (CCRYN) Morarji Desai National Institute of Yoga (MDNIY) and other National Research Organizations. Finally, the National Clinical Management Protocol based on Ayurveda & Yoga for management of Covid-19 was prepared with cumulative inputs from all the above mentioned exercises and after due consideration by the best experts of all the concerned disciplines.

The report and recommendations have detailed scientific rationale with references of clinical studies, safety studies and in-silico studies based on which repurposing of the interventions for COVID 19 is proposed. This report is available in public domain at <https://www.ayush.gov.in/>. The said National Ayush protocol has been prepared in line with the protocol and rationale used by protocol of the conventional system of medicine.

**5. Is there any scientific rationale behind selection of drugs figuring in the Protocol?**

These drugs were selected after due consideration of relevant factors like published scientific evidence, literary research supported by scientific relevance, the rationale in support of repurposing of these medicines in COVID 19 and the outcomes and trends of completed and ongoing studies taken up by the Ministry of AYUSH across India.

**6. Are the recommended medicines safe?**

**Ans:** The herbs selected are some of the most commonly used and prescribed ones in India. There has been a substantial number of clinical studies on each of these without any Serious Adverse Event (SAE) and these are also being prescribed in about 25000 Govt. Ayurveda PHCs and by a large number of Ayurveda practitioners in routine clinical practices for a vast range of clinical conditions and as health tonics (Rasayana). The scientific information available in public domain was also screened to substantiate their safety in preclinical and clinical studies. Furthermore, the trends coming out of the research studies in COVID 19 as stand-alone and add-on interventions of these Ayush medicines were found to be absolutely safe and no herb-drug interaction was noted in these studies on a large number of participants.

**7. Is there any research work done in AYUSH for COVID 19?**

**Ans:** The Ministry of AYUSH has set up an Interdisciplinary Ayush R & D task force to formulate and plan research studies (clinical, preclinical, observational etc) for COVID-19. The inputs from the Taskforce which had prepared generic protocols (available in public domain at <http://ayush.gov.in>) led to many studies being initiated by Research Councils & National Institutes under ministry of AYUSH, Universities, State Governments and Covid hospitals. The above-mentioned agencies initiated various studies across the country in collaboration and consultation with reputed scientific organizations like Council of Scientific and Industrial Research (CSIR), Indian Council of Medical Research (ICMR), Public Health Foundation of India (PHFI), Department of Science and Technology (DST), Department of Biotechnology (DBT), including clinical, observational, in-silico and preclinical studies. The total number of such studies initiated by the Ministry presently stands at 68, spread over 112 locations, and being undertaken by premier institutions like National institutes, Research Councils, Universities, State Governments and other collaborating hospitals (this includes the AYUSH-CSIR studies also). Many of these are completed and data analysis has been undertaken, whereas the others are in the final stage of completion.

#### **8. How has the Ministry ensured the quality of the Research work?**

**Ans:** To ensure the scientific robustness of the interventions, the Ministry has constituted an Interdisciplinary Ayush Research and Development Task Force (<https://www.icssr.org/sites/default/files/Notification%20on%20task%20force002.pdf>) on 2nd April 2020 chaired by Prof. Bhushan Patwardhan (Vice Chairman, University Grants Commission) and comprising of senior scientists and experts from reputed institutions of Ayurveda and conventional system of medicine like ICMR, AIIMS, Amrita school of Ayurveda, AVP Research Foundation, CSIR, All India Institute of Ayurveda (AIIA) and AYUSH Research Councils. The Committee called for research proposals and inputs from all stakeholders across India. This was followed by a series of consultative processes and thorough examination of inputs. The Committee then proposed certain interventions for research studies and also prepared comprehensive research protocols for undertaking research studies on COVID 19 through AYUSH interventions. In this sequence, the Ministry of AYUSH in

a joint initiative with Ministry of Health and Family Welfare and Ministry of Science & Technology took up four clinical studies on AYUSH medicines for COVID 19 used as prophylactic and as add-on intervention. These came to be called the AYUSH-CSIR collaborative studies, and were taken up under technical assistance from ICMR. These studies are currently in progress with a robust clinical protocol that was prepared by AYUSH Task Force with substantial contributions from eminent rheumatologist, clinician and researcher Dr Arvind Chopra, Center for Rheumatic Diseases (CRD) Pune.

The Ministry also monitored all the studies being undertaken by National institutes and Research Councils and other collaborating hospitals and institutes through a Project Monitoring Unit.

A Central Ethics Committee was also constituted with members from reputed institutes like AIIMS and all studies are put before the committee thereafter to ensure safety and robustness of the studies at each study site. All inputs and suggestions by ethical committees are properly addressed before initiation of the study.

To ensure Data Safety and safety of participants and proper conduct of studies, Data Safety and Monitoring Board (DSMB) was also constituted which was chaired by Dr Nandini Kumar, Former Deputy Director General Sr. Grade (ICMR) and Vice President, Forum for Ethics Review Committees in India.

## **9. What is the basis of recommending Guduchi in the protocol?**

**Ans:** Guduchi is one of the most commonly used herbs in Ayurveda. It has been studied and found effective in viral fevers, as anti-inflammatory, antipyretic and immuno-modulatory interventions. There are three in-silico studies, which show its high binding efficacy against SARS-CoV-2 targets involved in attachment and replication of the virus, as compared to Favipiravir, Lopinavir/Ritonavir and Remdesivir. About 7 studies are also being done under the Ministry of AYUSH on

Guduchi as Prophylactic care on about 1.33 Lakh population and with very good results in preventing COVID 19 and in management of asymptomatic COVID 19 without any side effect. Further detailed rationale of its inclusion has been provided in the Interdisciplinary Committee for integration of Ayurveda and Yoga Interventions in the 'National Clinical Management Protocol: COVID-19' which is made available in public domain on the Ministry of AYUSH website.

**10. What is the basis of recommending Ashwagandha in the protocol?**

**Ans:** Ashwagandha (*Withania somnifera*) (WS) is one of the most extensively experimented Ayurveda medicinal plants and has been used in Ayurveda practice since centuries. Ashwagandha has been selected owing to its properties like immune-modulatory, anti stress and antiviral efficacy. In-silico studies have shown its high binding affinity to ACE2–RBD interface which may stop SARS COV 2 entry into cells. The WS root extract has shown positive results against protracted social isolation induced stress and anxiety which makes it a good medicine for prophylactic use. Further, the medicine also has very good pulmonary protective function and hence is beneficial in post Covid care. There are substantial number of studies on Ashwagandha published in reputed peer reviewed journals to establish its efficacy, safety and protective action.

**11. What is the basis of recommending the combination of Guduchi and Pippali in the protocol?**

**Ans:** Ayurveda describes the decoction of Guduchi and Pippali for management of a disease (*Vata Kaphaja Sannipatik Jvara*) that has manifestations akin to COVID-19. These two herbs are very common in clinical practice of Ayurveda and being used for various respiratory diseases. There has been extensive studies on both the herbs and their phytoconstituents to establish their safety, immuno-modulatory, antipyretic, antiviral and anti inflammatory properties. In-silico studies on Piper longum (Pippli) and *Tinospora cordifolia* (Guduchi) have shown high affinity to potential targets of SARS-COV 2 (COVID 19 causing virus). Further, the outcomes of

clinical studies and interim trends of ongoing clinical studies have also substantiated their role in management of COVID 19.

**12. What is the basis of recommending AYUSH 64 in the protocol?**

**Ans:** AYUSH 64 formulation was developed for Malaria after a long scientific research following the drug development process. It was developed in compliance to all regulatory requirements and quality and pharmacopoeial standards by the Central Council for Research in Ayurvedic Sciences (CCRAS) the apex body for research in Ayurveda under the Ministry of AYUSH. This drug was repurposed based on its ingredients having notable antiviral, immune-modulator and antipyretic properties. An in-silico study was done on AYUSH 64 which showed that about 35 of its phyto-constituents have high binding affinity in COVID 19 virus. The formulation has also shown very promising results in Influenza like illness. The 6 clinical studies across India on AYUSH 64 have shown very promising trends. Based on these factors and also on its clinical use & safety profile it was recommended in COVID 19 care.

**13. Why did the Committee propose only 4 drugs?**

**Ans:** This was the first report and recommendations on the Interdisciplinary Committee. The Committee thoroughly reviewed the national clinical management protocol of COVID 19 and the rationale of inclusion of interventions in the protocol. In the light of same, repurposing of existing Ayurveda interventions based on their extensive scientific evidences published in peer reviewed journals like pre clinical studies, safety and toxicity studies, clinical studies and interim trends of substantial number of studies on a large cohort, initially 4 interventions are proposed beside Yoga interventions. However, similar work on scientific assessment and evaluation of other AYUSH interventions from Siddha, Unani, Homeopathy and Sowa Rigpa are also in progress and soon may be explored for inclusion in the National clinical management protocol.

**14. How many studies are in progress, undertaken by the Ministry for COVID 19?**

**Ans:** At present about 68 clinical and observational studies are undertaken at 112 sites across India. Many of these are completed and are in publication stage and others are in the final stage of completion. Further, for better understanding of the interventions in COVID 19 disease, several preclinical studies and molecular docking studies in collaboration with reputed institutions/research organisations like DST are also in progress.

**15. Has any large-scale study been undertaken in AYUSH for prophylactic care?**

**Ans:** Prophylactic care is a major part of the AYUSH protocol, and in order to substantiate and understand its role in the management of Covid 19, several studies on a large cohort are being undertaken by the Ministry through Research Councils and National Institutes across India. Notable ones are prophylactic care through AYUSH interventions in about 20000 sample size by each Research Council and National Institute covering a large area through their peripheral institutes across India wherein AYUSH interventions are studied. Further, All India Institute of Ayurveda, Delhi has carried a promising study over a big cohort of 80000 Delhi police personnel for two months starting in May and are following up the cohort since then. The studies have shown very promising trends in reducing incidence of COVID 19 and Influenza like symptoms among participants to a significant level and also in improving Quality of Life.

**16. What is the Ayush Sanjivani app used for? What outcome does the Ministry get from this app?**

**Ans:** The Ministry of AYUSH developed a mobile application named AYUSH Sanjivani, for impact assessment of the effectiveness, acceptance and usage of the different AYUSH advisories brought out by the Ministry for prevention of COVID-19. The study received an overwhelming response. About 1.47 crore inputs

received on this platform showed the huge popularity and wide acceptance of AYUSH interventions.

**17. Is taking Ayush Kwath regularly injurious to liver?**

**Ans:** Ayush kwath is made up of a few common herbs which are used as kitchen spices viz. Dalchini, Lavang, Shunthi and Tulasi. These are regularly used by the majority of Indian households on a regular basis and are absolutely safe. There is no known study or report on it having any Adverse effect. These herbs are *ushna virya* (hot in potency) and may be used with added *munnaka* or *mishri* as per need or a person and taste. The ingredients of Ayush kwath are very good antioxidants. Antiviral and immuno modulatory properties of the ingredient like Tulasi are well documented in research studies.

**18. Are the medicines prescribed in the protocol immune-boosting?**

**Ans:** Ayurveda system of healthcare takes holistic approach towards disease management and preservation of health in which salutogenesis (maintaining optimum health and immune status) is a major aspect. The medicines selected in the Protocol have immuno modulatory effect i.e. they tend to strengthen the immunity of a person in a natural way. In present times when altered lifestyles, diet and stress are a common, maintaining a natural immune system is challenging, and this renders a person prone to infections and diseases. The immuno modulatory interventions of Ayurveda which are included under the broad term '*Rasayana*' are very helpful in preserving optimum health of a person. They also help in preventing disease and in controlling disease progression. This should not be confused with hyper immune status or aberrant activity of the immune system. (Also read answer to question 2)