



Government of India

**Prophylaxis and Management of
COVID-19 through AYUSH interventions
Best practices and evidence-based
approach**



**Ministry of Ayush
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Best practices and evidence based approach

Prologue: The Ministry of Ayush (MoA), Government of India has undertaken several R&D initiatives to harness the potential of Ayush systems to contain the impact of the COVID-19 pandemic. The MoA has collaborated with several research organizations to encourage and promote advance evidence-based research on Ayush systems.

The MoA constituted an Inter-disciplinary Ayush R&D Task Force consisting of scientists, and medical professionals from premier institutions to deal with various aspects of clinical and experimental research on COVID-19. The Task Force formulated guidelines for Ayush clinical and observational studies on COVID-19 covering various aspects of clinical trial protocols. Overall, 139 clinical, pre-clinical and epidemiological studies were undertaken by the Research Councils and National Institutes under the Ministry. The collaborative institutes for these studies include AIIMS New Delhi, AIIMS Jodhpur, AIIMS Jhajjar, King George Medical University Lucknow, Institute of Medical Sciences BHU, Govt. Medical College Nagpur, etc. It includes 44 prophylactic, 44 standalone and add-on treatment, 15 observational and 10 survey studies as well as 22 experimental studies, two pharmacopoeial standards development and two systematic reviews.

Developing inter-ministerial linkages, the Ministry of Ayush in collaboration with Council of Scientific & Industrial Research (CSIR) Government of India has also undertaken clinical studies on four different Ayurveda interventions for COVID-19 prophylaxis and management. Further, preclinical and pharmacokinetics evaluation of selected Ayush Herbal extracts/formulations for mitigating COVID-19 and associated pathologies have been undertaken in collaboration with Department of Biotechnology (DBT), Govt. of India at Translational Health Science and Technology Institute (THSTI), Faridabad, India. Further, in-silico studies on AYUSH-64 and AYUSH Kwatha have been undertaken in collaboration with National Institute of Nutrition (NIN), Hyderabad (ICMR)

and Indian Institute of Technology (IIT), Varanasi respectively to evaluate their ingredients for inhibitory action against SARS-CoV-2 virus. A pre-clinical study was also conducted at National Institute of Nutrition Hyderabad (ICMR) to evaluate the immune-modulatory potential and safety/toxicity of *AYUSH Kwatha* formulation.

Based on the potential leads emerged out of various studies, the Ministry has undertaken nation-wide community-based studies through its Research Councils and National institutes for mass distribution of *AYUSH-64* and *Kabasura Kudineer* to asymptomatic, mild to moderate COVID-19 patients in home isolation during the second outbreak of COVID-19 in India.

Evidence based Ayush approaches and interventions for prophylaxis and management of COVID-19

Ayush interventions for management of COVID-19: The well-designed clinical studies on Ayush interventions as standalone or adjunct to standard of care in asymptomatic and mild to moderate COVID-19 patients were conducted adopting integrated protocols. Ayush interventions viz. *AYUSH-64*, *Guduchighan vati*, *Guduchi-Pippali*, *Yashtimadhu*, *Ashwagandha-Shunthi*, *Kabasura Kudineer*, *Nilavembu Kudineer*, *Eupatorium perfoliatum* 30C, *Camphora*, *Bryonia alba*, *Arsenicum iodatum* 30C etc. have been evaluated as standalone and add-on intervention with standard care.

AYUSH-64: The seven clinical studies on AYUSH-64 in COVID-19 were conducted involving 500 participants. The outcomes of these studies demonstrated early clinical recovery and reduced duration of hospital stay without any progression of the disease to severe or critical stage of COVID-19. In addition, there was improvement in Quality of life (QoL) parameters. AYUSH-64 was found to be well tolerated and safe. A community-based interventional study on AYUSH-64 was conducted across the country in 64642 asymptomatic, mild, and moderate COVID-19 patients in home isolation. The findings of this study highlight that a significant proportion of the study participants benefitted considerably in terms of better clinical recovery, improved general well-being and reduced need of hospitalization. Further, in-silico study on AYUSH-64 done in collaboration with National Institute of Nutrition Hyderabad (ICMR) showed that about 35 out of 36 of its Phyto-constituents have high binding affinity against COVID 19 virus. Safety Toxicity studies have also been done to ascertain its safety and it has been in use since 1980 for the treatment of malaria and flu like illness without any adverse effect reported.

Guduchighan vati: two clinical studies were conducted involving 70 asymptomatic, mild to moderate cases of COVID-19 and an early clinical recovery was observed. No adverse events were observed in

both the studies. 93.3% participants turned RT-PCR negative for COVID-19 in the Ayurveda intervention group as compared to 66.6% participants in the standard care group by 10th day. All the symptomatic participants clinically recovered by 5th day in the Ayurveda intervention group.

Guduchi-Pippali: Two clinical research studies among 200 participants were done in which Guduchi-Pippali has been used as intervention and early clinical recovery was observed in the Ayurveda add-on intervention group (two days earlier as compared to the standard group). No worsening of disease and drug-herb interaction was observed clinically.

Kabasura Kudineer: Seven clinical research studies on 856 participants were conducted. Total 31497 people were benefitted in the Nation-wide Kabasura Kudineer distribution campaign. The clinical trials on Kabasura Kudineer as add-on to standard of care showed early clinical recovery, significant reduction in the viral load and lesser mortality rate in the Kabasura Kudineer group. Another community-based interventional study on Kabasura Kudineer in asymptomatic, mild, and moderate COVID-19 patients in home isolation showed early clinical recovery. Significant improvement was also observed in the score of well-being parameters such as appetite, sleep, physical and mental health.

Ayush interventions for COVID-19 Prophylaxis: Research studies were undertaken to evaluate the prophylactic efficacy of Ayush medicines such as *Guduchi Ghan Vati (Samshamani Vati)*, *Chyawanprash*, *Ashwagandha*, *Sudarshan Ghan Vati*, *Arsenicum Album*, *Kabasura Kudineer*, *Anu Taila*, *Ayush Kwath* etc. against COVID-19. These prophylactic interventional studies were conducted in high-risk population either residing in containment zones or frontline workers. These studies have shown very promising outcomes in reducing the incidence of COVID-19 among Ayush prophylactic care users.

Ashwagandha: Ashwagandha was given as prophylactic among 7000 people in four studies and the same will also be studied in UK in collaboration with The London School of Hygiene & Tropical Medicine (LHSTM), UK in prophylactic care against COVID 19. A clinical trial comparing the efficacy/safety of Ashwagandha with Hydroxychloroquine Sulphate (HCQ) for COVID-19 Prophylaxis in high risk healthcare workers showed that Ashwagandha is non-inferior to Hydroxychloroquine in terms of prophylactic effect against COVID-19. Further, it has a superior safety profile as significantly less adverse events were reported in the Ashwagandha group compared to HCQ group.

Ayuraksha Kit: Ayuraksha Kit is a combination of four formulations viz., *Chyawanprash*, *Samshamani Vati*, *Ayush Kwath* and *Anu Taila* (for nasal instillation). A study on Ayuraksha kit was conducted by Central Council for Research in Ayurvedic Sciences (CCRAS) among 1.78 lakh participants. A study on the evaluation of the immuno-stimulatory potential of Ayuraksha Kit was done in cohort of 80,000 Delhi police personnel by All India Institute of Ayurveda (AIIA). Less incidence of COVID-19 and low Mortality rate were observed among the participants. The research findings of the community based prophylactic studies suggested the safety and prophylactic efficacy of the Ayuraksha Kit. The individual components of this kit were also found effective for their prophylactic efficacy and safety against COVID-19.

Guduchighan Vati: It was given as prophylactic intervention to approximately 1.12 lakh participants. The formulation prepared from aqueous extracts of the stem of *Tinospora cordifolia* named as *Guduchi Ghana vati* or *Samshamani Vati* has shown positive effects on the immune status and general well-being of the people as observed in clinical trials during the COVID-19 pandemic.

Chyawanprash: Total 07 prophylactic studies have been conducted among 2950 participants. The results support the prophylaxis potential of Chyawanprash as one of the preventive remedies for COVID-19. It has been found effective and safe among high-risk health care workers and apparently healthy individuals in reducing the incidence of COVID-19.

Anu Taila: *Anutaila* is a formulation prescribed for *Nasya* (instillation of drops in the nostrils) for therapeutic as well as prophylactic purposes in different doses. The prophylactic efficacy of Anutaila was studied against SARS CoV-2 virus in a pre-clinical study which revealed that intranasal instillation of Anu oil is useful in limiting both viral load and severity in COVID-19.

AYUSH Kwath: The experimental studies conducted on the ingredients of *AyushKwath* showed their immune-modulatory, antiviral, anti-oxidant, anti-inflammatory and hepato-protective properties. The results of an in-silico study conducted at IIT, Varanasi revealed that Beta-Sitosterol, a component of AYUSH Kwath, was found to be potential inhibitor of SARS-CoV-2 virus. A pre-clinical study conducted at ICMR-National Institute of Nutrition Hyderabad to evaluate the safety/toxicity of *AYUSH Kwatha* has also established its safety.

Kabasura Kudineer: Two Prophylactic studies on 30,000 participants were done. The studies revealed that the decoction was effective and safe among high-risk health care workers and apparently healthy individuals in reducing the incidence of COVID-19 and improving the general wellbeing.

Yoga and Pranayama: A randomized controlled pilot study among 280 participants to assess the effect of *Pranayama* on incidence of COVID-19 in healthcare personnel exposed to COVID-19 patients revealed that *Pranayama* for 28 days significantly decreased the COVID-19 positivity rate among exposed healthcare professionals.

The studies on Homeopathic and Unani medicines in prophylaxis and management of asymptomatic and mild COVID-19 as add-on intervention also revealed lesser incidence of COVID-19 and trend of early recovery respectively compared to the control group.

Rationale for utilizing Ayush interventions for COVID-19 prophylaxis and management: The current understanding of COVID-19 indicates that good immune status is vital for prevention and safeguard from disease progression. Ayush interventions can certainly play a pivotal role in the modulation of immune system thereby providing prophylaxis against COVID-19 and prevention of disease progression in COVID-19 patients. Based on the study outcomes of the clinical trials undertaken during COVID-19 pandemic, these Ayush medicines are proposed for COVID-19 prophylaxis and management.

Further, the safety of these interventions is already established as these interventions are routinely used in the clinical practice since ages. Moreover, there is wide-spread acceptance regarding the effectiveness and safety of Ayush interventions in common ailments among the masses.

It is worth mentioning that above said Ayush formulations are included in the “National Clinical Management Protocol based on Ayurveda & Yoga for management of COVID -19” and Guidelines for respective Ayush Practitioners and Advisories for COVID-19 Patients in Home Isolation issued by the Ministry of Ayush.

Recommended Ayush approaches and practices for prophylaxis and management of COVID-19

S. No.	Name of medicines	Dose	Duration	Estimated Cost per pack	Estimated cost per individual (in Rs)
Interventions for COVID-19 Prophylaxis (any one of these)					
1.	Ayuraksha Kit	Chyawanprash 6 gm once a day; Ayush kwath 75 ml (3 gm power boiled in 150 ml water and reduced to 75 ml) once a day; Samshamani Vati 500 mg twice a day; Anu taila one to two drops nasal application in each nostril with fingertip once a day	30 days	Rs. 262.50/-	Rs. 262.50/-
	Samshamani vati/ Guduchi Ghan Vati	1 tablets (500 mg) twice a day	30 days	Rs. 40/-	40/-
	Ashwagandha tablet	500 mg twice a day	30 days	Rs. 92/-	92/-
Interventions for COVID-19 management					
1.	AYUSH-64	2 tablets of 500 mg twice a day in asymptomatic COVID-19	20 days	Rs 117.40/- (40 tablet pack)	234.80/-
		2 tablets of 500 mg Thrice a day in mild to moderate COVID-19	20 days		352.20/-
2.	Kabasura Kudineer	5 gm twice a day (to prepare decoction)	20 days	Rs. 106/- (100gm pack)	212/-

Epilogue: The proposed Ayush interventions are commonly used in clinical practice and are readily available. Ayush pharmaceutical industry is ready to supply these medicines at CPSU (IMPCL) rates and assured to sustain the supply chain for smooth distribution across the country. These Ayush medicines may be distributed through National Ayush Mission and National Health Mission. The States/UTs governments may promote these evidence based Ayush interventions through different agencies at state and district levels, local civic bodies, school health programs, educational institutes etc. The Ministry of Ayush proposes for optimal utilization of evidence based Ayush interventions for the prophylaxis and management of COVID-19 in the continuing state of COVID-19 pandemic.

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