सत्यमेव जयते
Government of India

Research and Development Initiatives of Ministry of Ayush for COVID-19

Ministry of Ayush
Government of India

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Ministry of Ayush, Government of India

मंत्री
आयुष मंत्रालय
एवं पत्तन, पोत परिवहन और जलमार्ग मंत्रालय
भारत सरकार

सत्यमेव जयते

Minister of Ayush
and
Ports, Shipping & Waterways
Government of India

सर्बानंद सोणोवाल
SARBANANDA SONOWAL

Azadi Ka Amrit Mahotsav

MESSAGE

It gives me immense pleasure to note that Ministry of Ayush has taken several steps and measures to combat COVID-19 through evidence based preventive and management approaches.

Under the able guidance of interdisciplinary Research and Development Task Force for COVID-19, this Ministry has successfully conducted and executed 139 studies focusing on quality assurance, preclinical safety & efficacy and clinical interventions at 159 centers across the country. The centers comprised of Research Councils and National Institutes of Ayurveda, Tertiary healthcare centers and academic institutes like AIIMS, Government designated Covid-19 treatment centers & Government Medical and Ayurveda colleges along with active collaborations with CSIR, ICMR and DBT.

Through these studies, tangible evidences on prophylactic potential and management of Ayush interventions in mild to moderate cases of COVID-19 have been generated. The research outcomes were further thoroughly validated and recommended for inclusion by an interdisciplinary Committee for integration of Ayush and Yoga Interventions in National Clinical management protocol of COVID-19. Drugs like *Guduchi(Tinospora cordifolia)*, *Ashwagandha (Withania somnifera)* and Ayush Raksha Kit have been recommended for prevention whereas Ayush-64 for management of mild to moderate and asymptomatic cases of COVID-19.

Further, this Ministry has also taken several steps for dissemination of merits of Ayurveda, Yoga and other Ayush systems among all stakeholders viz. clinicians, general public for uniform and rational use of Ayush interventions by issuing guidelines. The research outcomes are being published in reputed journals from time to time for wider dissemination in the benefit of stakeholders.

National Clinical management protocol based on Ayurveda and Yoga for management of COVID-19 issued by the Ministry of Ayush is an official document and guiding principle.

I congratulate the efforts put in by Secretary, Ministry of Ayush and his team for their efforts on sustainable evidence based management of COVID -19 through Ayush interventions.

(Sarbanand Sonowal)

New Delhi
December २४, 2021

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डॉ. मुंजपरा महेन्द्रभाई
Dr. Munjpara Mahendrabhai
(M.D. Medicine)

सत्यमेव जयते

एक कदम स्वच्छता की ओर

राज्य मंत्री
महिला एवं बाल विकास और आयुष
भारत सरकार
Minister of State for
Women & Child Development and AYUSH
Government of India

Message

I am happy to learn that the Ministry of Ayush, Govt. of India has been putting constant efforts for tackling COVID-19 pandemic and containing the spread through multiple approaches and diverse efforts. The core initiatives comprise issuing the guidelines and public health advisories for sensitizing the masses focusing on prevention and immune boosting, mobilization of human resources through capacity building Ayush manpower, research and development initiatives for promotion of evidence-based Ayurveda, Yoga and other Ayush practices.

Further, the research outcomes have been effectively translate into clinical practices by issuing National Clinical Management Protocol for Covid-19 management through Ayurveda and Yoga besides issuing guidelines for management of home isolated mild to moderate COVID-19 patients through Ayurveda, Yoga, Unani, Siddha and Homoeopathy. Through national campaigns the Ayurveda intervention Ayush-64 and Siddha intervention Kabasura Kudineer have been provided for management of asymptomatic mild to moderate COVID-19 patients in home isolation. The outcomes are highly encouraging and significant in early recovery and preventing further clinical progression.

It is worth to mention the commendable initiatives of this Ministry in sensitizing the public and stakeholders for promotion and utilization of Ayush interventions through awareness programmes. Also, the Ministry of Ayush has extended support to the Ayush industries through mobilizing the resources and raw material to meet the requirements and also issued advisories for ethical promotion of Ayush drugs.

I appreciate the efforts put forth by Secretary (Ayush) and his team for optimal utilization of potential of Ayush in combating COVID -19 pandemic.

(Dr. Munjpara Mahendrabhai)

Place – New Delhi

Date - 29.12.2021

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सत्यमेव जयते

वैद्य राजेश कोटेचा
Vaidya Rajesh Kotecha

सचिव
भारत सरकार
आयुष मंत्रालय
आयुष भवन, 'बी' ब्लॉक, जी.पी.ओ. कॉम्प्लेक्स,
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Prologue

Since the onset of COVID-19, Ministry of Ayush (MoA) issued various guidelines for prophylactic and symptomatic management of COVID-19 and advisories to improve immunity and simple home remedies easily accessible to the public, aligning with the Government's pandemic response. The Ministry had actively mobilized work force and resources for appropriate utilization of available facilities to actively contain the pandemic.

Ministry of Ayush constituted an Inter-Disciplinary Ayush R&D Task Force consisting of eminent scientists from premier organizations and research institutions to spearhead research on COVID-19. Taking forward the recommendations of the Interdisciplinary Task Force, 139 clinical research studies and basic experimental studies were initiated through Research Councils and National Institutes under the Ministry, and collaborative studies with tertiary care hospital such as AIIMS, University hospitals and reputed organizations such as DBT, THSTI, ICMR and CSIR. This includes 22 experimental studies, 44 prophylactic, 44 therapeutic (standalone and add-on treatment), 15 observational studies, 10 survey studies, two pharmacopeia standard development and two systematic reviews. The prophylactic interventional studies conducted in high-risk population either residing in containment zones or frontline workers have shown promising outcomes in reducing the disease incidence. Robust clinical trials conducted on therapeutic interventions demonstrated early clinical recovery and reduction in the duration of hospital stay, prevention in further progress to severe stage and complications and improvement in quality of life.

Ministry of Ayush further set up an Inter-Disciplinary Technical Review Committee (ITRC) for recommendation of various therapeutic claims for Ayurveda and proprietary interventions for the prevention and management of COVID-19.

The Dossier titled "***Research and Development Initiatives of Ministry of Ayush during COVID-19 Pandemic***" effectively compiles the initiatives taken up by the Minsitry to mount a scientific response in line with the contemporary health care system during health crisis that heightened in the context of the pandemic emergency. This also addresses how a collective action was facilitated in the backdrop of the COVID-19 in deploying prophylactic care through deployment of Ayush workforce and infrastructure, promoting disease awareness, reducing disease burden of hospitalization and enabling early clinical recovery in disease.

I hope this concise document will provide a glimpse of R&D initiatives of Ministry of Ayush in the mitigation of COVID-19

(Rajesh Kotecha)

New Delhi
29th December, 2021

Index

आयुष मंत्रालय द्वारा कोविड-19 महामारी में किए गए वैज्ञानिक अनुसंधान कार्यों का संक्षिप्त विवरण

- आयुष मंत्रालय, भारत सरकार ने कोविड-19 महामारी के शुरुआती काल से ही सक्रिय होकर जनमानस में जागृति लाने हेतु तथा कोविड-19 से बचाव तथा उपचार हेतु आयुष औषधियों की वैज्ञानिक परिमाणों पर कारगरता सिद्ध करने के भरसक प्रयत्न किए हैं ।
- मार्च 2020 से अब तक मंत्रालय ने रोग प्रतिरोधक क्षमता को बढ़ाने के लिए जनसाधारण हेतु **विभिन्न दिशा-निर्देश और सुलभ घरेलू उपचार** की सलाह समय-समय पर जारी की है। **सामान्य रूप से रोग प्रतिरोधक क्षमता को बढ़ाने** के साथ-साथ, इन दिशा-निर्देशों में विशेषत: **श्वसन संस्थान संबंधी उपायों** पर विशेष बल दिया गया है। इन दिशानिर्देशों को आयुष मंत्रालय की वेबसाइट एवं विभिन्न सोशल मीडिया प्लेटफॉर्म और प्रिंट मीडिया के माध्यम से जन-साधारण के बीच प्रसारित किया गया है।
- कोविड-19 संकट के दौरान रोगप्रतिरोधक क्षमता बढ़ाने के आयुर्वेदिक, योग एवं अन्य आयुष पद्धतियों के उपाय, कोविड-19 के उपचार के लिए आयुर्वेद और योग पर आधारित कोविड-19 उपचार हेतु राष्ट्रीय चिकित्सीय प्रबंध (प्रोटोकॉल), आयुष डॉक्टरों के लिए टेलीमेडीसीन की मार्गदर्शिका तथा कोविड-19 के उपचारों में एकरूपता लाने हेतु आयुष पद्धति से कोविड-19 का उपचार करने हेतु मार्गदर्शिका भी आयुष मंत्रालय की वैबसाइट पर उपलब्ध है।
- आयुष औषधियों तथा सेवाओं के कोविड-19 के परिपेक्ष्य में भ्रामक विज्ञापनों तथा जानकारी के प्रसार को नियंत्रित करने हेतु भी दिशानिर्देश जारी किया गया है।
- कोविड-19 की दूसरी लहर के चलते, मंत्रालय ने घर पर ही देख-रेख के योग्य (home isolation) कोविड-19 रोगियों के उपचार हेतु दिशा निर्देश जारी किए। साथ ही **NIMHANS तथा SVYASA के साथ मिलकर**, कोरोना मरीजों का **मनो-सामाजिक स्वास्थ्य पुनः स्थापित करने हेतु एक संलेख भी प्रकाशित** किया है।
- मंत्रालय द्वारा **बच्चों की देखभाल एवं कोविड-19 के चिकित्सा उपायों के संबंध में भी दिशा निर्देश** जारी किए गए हैं |
- देश के आठ लाख से अधिक की जानकारी COVID Warrior पोर्टल पर उपलब्ध है। जिनमें लगभग 83,000 से अधिक आयुष चिकित्सकों तथा पैरा-मेडिकल स्टाफ ने iGOT प्लेटफॉर्म के माध्यम से प्रशिक्षण भी प्राप्त किया है। साथ ही आयुष एवं स्वास्थ्य मंत्रालय ने संयुक्त रूप से 33,000 आयुष को

प्रशिक्षण दिया। इन सभी मास्टर ट्रेनर ने अपने राज्यों/संकायों में आयुष स्टाफ को भी प्रशिक्षण दिया। विभिन्न राज्यों द्वारा भी लगभग 1.06 लाख आयुष स्टाफ प्रशिक्षित किये गए। उपलब्ध जानकारी के अनुसार, करीब 28,473 आयुष स्टाफ द्वारा कोविड संबंधी चिकित्सीय सेवाओं में योगदान दिया।

- **आयुष कोविड-19 काउन्सेलिंग हेल्पलाइन नंबर 14443** भी जारी किया गया है जिस पर आयुष चिकित्सकों तथा विशेषज्ञों की टीम **सुबह 6 से रात 12 बजे तक कोविड-19 मरीजों को फोन पर स्वास्थ्य संबंधी सुझाव देते हैं**।
- आयुष उपचार से ठीक हुए रोगियों की केस स्टडी को आलेखित करने एवं उजागर करने हेतु **आयुष क्लिनिकल केस रीपोसीटरी** की सुविधा भी मंत्रालय द्वारा उपलब्ध कराई गयी है। इसमें आलेखित साक्ष्यों को अग्रिम अनुसंधान अध्ययन के लिए भी लिया जा सकेगा।
- आयुष मंत्रालय ने गत वर्ष जन-साधारण द्वारा आयुष दिशानिर्देशों को उपयोग करने तथा कोविड-19 की रोकथाम में इसके प्रभाव पर डेटा एकत्रित करने के लिए **'आयुष संजीवनी'** नामक एक मोबाइल एप्लीकेशन जारी किया था। इस एप्लीकेशन के माध्यम से **तीन महीने की अवधि में करीब 1.35 करोड़ से ज्यादा प्रविष्टियाँ** संकलित की गई। इस अध्ययन में यह पाया गया कि 85.1% लोगों द्वारा कोविड-19 की रोकथाम के लिए आयुष उपायों का उपयोग किया गया, जिनमें से 89.8% लोगों ने आयुष दिशा-निर्देशों से लाभान्वित होने की सहमति व्यक्त की।
- इसी तरह **80 हजार दिल्ली पुलिसकर्मियों** में कोविड-19 से बचाव हेतु आयुर्वेदिक औषिधियों पर किए गए अध्ययन में आशाजनक परिणाम मिले।
- आयुष मंत्रालय ने एक **Inter-disciplinary AYUSH R&D Task Force** का गठन किया है। इस टास्कफोर्स में देश के प्रमुख संस्थान जैसे **ICMR, AIIMS, DBT, CSIR एवं आयुष संस्थानों के वैज्ञानिक सम्मिलित हैं**। इस टास्क फोर्स ने कोविड-19 में prophylactic and add-on intervention studies से संबंधित clinical research हेतु protocols को तैयार किया।
- **आयुष-सी.एस.आई.आर. (Ayush–CSIR) सहयोग** के माध्यम से कोविड-19 में 04 आयुर्वेदिक औषधियों पर अनुसंधान अध्ययन किए गए। इनमें अश्वगंधा को रोगनिरोधी के रूप में तथा यष्टिमधु, गुडूची + पिप्पली एवं आयुष-64 का आधुनिक चिकित्सा औषधियों के साथ कोविड-19 चिकित्सा हेतु अध्ययन किया गया।
- Inter-disciplinary AYUSH R&D Task Force की अनुशंसा के आधार पर मंत्रालय के अंतर्गत आने वाले अनुसंधान परिषदों और राष्ट्रीय संस्थानों द्वारा अन्तःवर्ती (intra mural) एवं सहयोगात्मक

(collaborative) अनुसन्धान के माध्यम से **लगभग 159 केन्द्रों पर 139 चिकित्सीय (clinical) अनुसन्धानात्मक अध्ययन एवं प्रायोगिक (experimental/ preclinical) अध्ययन किए गए**।

- इनमें से 44 रोगनिरोधी (prophylactic) अध्ययन, 44 उपचारात्मक (treatment) अध्ययन, 15 अवलोकनात्मक (observational) अध्ययन, 10 सर्वेक्षण (survey) अध्ययन, 02 systematic review और 22 प्रायोगिक (experimental) अध्ययन शामिल हैं। इनमें 70 आयुर्वेदिक अध्ययनों के अतिरिक्त 29 होम्योपैथिक, 13 सिद्ध, 08 यूनानी एवं 19 योग के अध्ययन शामिल हैं। ये अध्ययन देश के प्रमुख संस्थानों जैसे **अखिल भारतीय आयुर्विज्ञान संस्थान, नई दिल्ली; अखिल भारतीय आयुर्विज्ञान संस्थान, जोधपुर; अखिल भारतीय आयुर्विज्ञान संस्थान, झज्जर; किंग जॉर्ज मेडिकल विश्वविद्यालय, लखनऊ; आयुर्विज्ञान संस्थान, बनारस हिंदू विश्वविद्यालय, वाराणसी; राजकीय चिकित्सा महाविद्यालय, नागपुर; दत्ता मेघे आयुर्विज्ञान संस्थान, वर्धा; के.ई.एम. अस्पताल, पुणे; THSTI, फ़रीदाबाद, जैव-तकनीकी विभाग (DBT), भारत सरकार** इत्यादि में किए गए हैं ।
- गुडूचीघन वटी, सुदर्शन घन वटी, अश्वगंधा टैबलेट, च्यवनप्राश, आयुरक्षा किट (च्यवनप्राश, आयुष काढ़ा, गुडूची घन वटी, अणुतेल), कबासुर कुडिनीर, आर्सेनिकम एल्बम आदि औषधियों का कोविड-19 रोगनिरोधी चिकित्सा हेतु अध्ययन किया गया है। ये अध्ययन containment zones में रहनेवाले लोगों तथा कोविड अस्पतालों में कार्यरत स्वास्थ्य कर्मियों पर किए गए। इन अध्ययनों में उपरोक्त औषधियों के उपयोग से कोविड-19 cases की संख्या में कमी तथा सामान्य रोगप्रतिरोधक क्षमता में सुधार पाया गया।
- साथ ही आयुष-64, गुडूची घन वटी, गुडूची + पिप्पली योग, अश्वगंधा + शुंठी योग, कबासुर कुडिनीर आदि औषधियों का कोविड-19 के लक्षणरहित एवं अल्प से मध्यम लक्षणों वाले रोगियों में standalone एवं add-on चिकित्सा के रूप में अध्ययन किया गया। इनमें आयुष उपचार लेने वाले रोगियों में शीघ्र स्वास्थ्य लाभ, अस्पताल में रहने का समय कम होना, RT-PCR नेगेटिव होने वाले रोगियों की संख्या अधिक होना, व्याधि की तीव्रता न बढ़ना एवं जीवन गुणवत्ता में सुधार, ये लाभ पाये गए हैं। इन अध्ययनों से प्राप्त साक्ष्यों ने बड़े पैमाने पर आयुर्वेद की रोगनिरोधक और उपचार क्षमता प्रदर्शित की है।
- आई.सी.एम.आर.-राष्ट्रीय पोषण संस्थान, हैदराबाद एवं भारतीय तकनीकी संस्थान, वाराणसी के सहयोग से क्रमशः आयुष-64 तथा आयुष काढ़ा की in-silico studies भी की गई। इन अध्ययनों द्वारा, इन दोनो औषधियों में SARS-CoV-2 के मुख्य protease तथा RNA dependent RNA

polymerase को रोकने की क्षमता पायी गयी है। साथ ही, आई.सी.एम.आर.-राष्ट्रीय पोषण संस्थान, हैदराबाद में आयुष काढ़ा की रोगप्रतिरोधक क्षमता एवं सुरक्षा/विषाक्तता अध्ययन हेतु pre-clinical study भी की गयी।

- आयुष-सीएसआईआर द्वारा किए गए अध्ययन तथा उपरोक्त वर्णित अध्ययनों में AYUSH-64 एवं कबासुर कुडिनीर के सफल परिणामों को देखते हुए डॉ वी एम कटोच, पूर्व महानिदेशक ICMR, डॉ अरविन्द चोपड़ा, वरिष्ट चिकित्सक एवं आयुष-सीएसआईआर अध्ययनों के chief clinical coordinator, डॉ भूषण पटवर्धन, National Research Professor-Ayush व पूर्व उपाध्यक्ष, UGC तथा आयुष व CSIR के वरिष्ठ वैज्ञानिकों द्वारा इन औषधियों के COVID-19 के उपचार में कारगर होने के संबंध में मीडिया को अवगत कराया गया।
- कोविड-19 की दूसरी लहर के दौरान अस्पताल आधारित स्वास्थ्य सेवाओं पर भार कम करने के लिए, आयुष मंत्रालय-CSIR के सहयोग से किए गए अध्ययन एवं मंत्रालय अंतर्गत आने वाले अनुसंधान परिषदों और राष्ट्रीय संस्थानों के माध्यम से किए गए शोध अध्ययनों से प्राप्त प्रमाणों को देखते हुए **कोविड-19 के लक्षणरहित एवं अल्प से मध्यम लक्षण वाले रोगियों की चिकित्सा हेतु आयुष-64 और कबासुर कुडिनीर के वितरण का राष्ट्रव्यापी अभियान शुरू किया**। इस अभियान में **लगभग 96000 कोविड रोगियों** का आयुष-64 और कबासुर कुडिनीर की प्रभावशीलता से संबंधित डेटा का प्रलेखीकरण किया गया।
- **अखिल भारतीय आयुर्वेद संस्थान, नई दिल्ली** ने **लंदन स्कूल ऑफ हाइजीन एंड ट्रोपिकल मेडिसिन, लंदन** के सहयोग से **United Kingdom** के 3 शहरों में post-COVID लक्षणयुक्त रोगियों में अश्वगंधा की उपयोगिता का अध्ययन करने हेतु एक अनुसंधान प्रारम्भ किया है |
- मंत्रालय ने हाल ही में कोविड-19 तथा इसके लंबे समय तक रहने वाले दुष्प्रभाव के संदर्भ में स्वास्थ्य को बढ़ावा देने हेतु सामान्य लोगों के लिए विस्तृत दिशानिर्देश जारी किए हैं।
- आयुष मंत्रालय के अंतर्गत सीसीआरएएस द्वारा रोगप्रतिरोधक क्षमता बढ़ाने में कोविड वेक्सीन के साथ अश्वगंधा की उपयोगिता एवं सुरक्षितता का अध्ययन भी प्रारम्भ किया गया है | यह अध्ययन देश के सात शहरों (दिल्ली, मुंबई, पुणे, नागपुर, जयपुर, बेलगाम एवं हासन) में किया जा रहा है।
- कोविड-19 के समय में विशेष रूप से रोगप्रतिरोधक क्षमता वर्धक एवं स्वास्थ्यवर्धक उत्पादों की मांग बढ़ने से आयुष फार्मास्युटिकल क्षेत्र में भी उल्लेखनीय वृद्धि देखी गई है।

Ministry of Ayush initiatives in mitigation of COVID-19

The Ministry of Ayush (MoA) issued various guidelines and advisories to improve immunity and advised simple home remedies easily accessible to the general public.[1] It also recommended a set of self-care guidelines duly vetted by eminent Ayurveda experts for preventive health measures, with special emphasis on respiratory health and improving general immunity.[2]

The guidelines for registered practitioners of respective Ayush systems were issued by the MoA to have a considerable degree of uniformity in the management of the disease.[3] Considering the urgent need for delivering healthcare services to the public during lockdown period, the MoA also published "Telemedicine Practice Guidelines" for Ayush practitioners.[4,5] The MoA also issued an order to prevent dissemination of misleading information about Ayush interventions and advertising claims for COVID-19.[6] During the resurgence of COVID-19 and based on the experiences of the first wave, MoA has also released Guidelines for Ayush Practitioners for COVID-19 Patients in Home Isolation, Home care guidelines for children and Advisory for Ayush Practitioners about prophylactic care in children during the COVID-19 Pandemic and Information for Ayurveda Practitioners for prophylactic and symptomatic management of suspected and diagnosed cases of Mucormycosis.[7]

Further, Ayush Preventive Measures for self-care during COVID-19 Pandemic has also been revised as per the need of the current scenario.[8] The MoA has also issued advisory for Ayush practitioners on ethical practices during COVID-19 pandemic.[9] The MoA in collaboration with NIMHANS and SVYASA also released protocol for psychosocial rehabilitation of COVID-19 Patients.[10]

The MoA also issued directives to all State/UT licensing authorities and drug controllers of AYUSH to expedite the process of approval/license/license renewal for manufacturing of ASU products improving immunity and sanitizers.

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[1]PIB 2020. Advisory for Corona Virus. https://pib.gov.in/PressReleasePage.aspx?PRID=1600895, Accessed January 7, 2021 and Ministry of AYUSH,Govt. of India 2020. D.O. No. S.16030/18/2019-NAM dated 6th March 2020

[2]Ministry of AYUSH, Govt. of India 2020. Ayurveda''s immunity boosting measures for self care during COVID 19 crisis. https://www.ayush.gov.in/docs/123.pdf

[3] Ministry of AYUSH, Govt. of India 2020.Guidelines for AYUSH Practitioners for COVID 19. https://www.ayush.gov.in/ayush-guidelines.html

[4] Ministry of AYUSH, Govt. of India 2020. Telemedicine Practice Guidelines for Ayurveda, Siddha and Unani Practitioners. https://www.ayush.gov.in/docs/CCIM_Telemedicine_Guidelines.pdf

[5] Ministry of AYUSH, Govt. of India 2020. Telemedicine Practice Guidelines for Homeopathic Practitioners. https://www.ayush.gov.in/docs/126.pdfAccessed 7th January 2021

[6]Ministry of AYUSH, Govt. of India 2020. Order Z.25023/09/2018-2020-DCC (AYUSH) dated 1st April 2020

[7]Ministry of AYUSH, Govt. of India 2021. Guidelines for Ayurveda Practitioners for COVID-19 Patients in Home Isolation; Guidelines for Homoeopathy Practitioners for Prophylaxis and Symptomatic Management of COVID-19 Patientsin Home Isolation; Guidelines for Unani Practitioners for COVID-19 Patients in Home Isolation; Guidelines for Siddha Practitioners for COVID-19 Patients in Home Isolation; Home care guidelines for children and Advisory for AYUSH Practitioners about prophylactic care in Children during the COVID-19 Pandemic; Information for Ayurveda Practitioners for prophylactic and symptomatic management of suspected and diagnosed cases of Mucormycosis

[8]Ayurveda Preventive Measures for self-care during COVID-19 Pandemic; Siddha's Preventive Measures for self-careduring COVID-19 Pandemic; Unani medicine based Preventive Measures for self-care during COVID-19 Pandemic [9]Advisory for Ayush practitioners on ethical practices during COVID-19 pandemic

[10] PIB 2021. Yoga and Naturopathy to aid the Psychosocial Rehabilitation of Covid-19 Patients

The Ministry also issued an order to prevent the dissemination of misleading information about Ayush services by stopping publicity and advertisement of Ayush-related claims for COVID-19 on April 1, 2020. The Ministry has recently issued Ayush recommendations for the public on holistic health and well-being "Preventive measures and care during COVID-19 & long COVID-19".[11]

Mobilization of Human Resource

As part of the efforts to achieve maximum stakeholder mobilization, the Ministry immediately acted as follows:

Communicated to the Heads of all Ayurveda, Siddha, Unani, and Homoeopathy institutes for the appropriate utilization of available infrastructure facilities such as, hospital (IPD and OPD), pathology laboratory, ICU, along with medical and paramedical staff to combat the COVID-19 pandemic. Various Ayush hospitals were designated as quarantine centres, isolation centres, and COVID-care centres by respective State Governments.

The Hon'ble Prime Minister addressed the stakeholders of the Ayush sector on March 28, 2020 to provide their services whenever needed by the State Governments. More than eight lakh Ayush doctors, paramedic staff, and students offered their services for the clinical management, surveillance, and management of COVID isolation centres and quarantine wards by enlisting themselves on COVID warrior portal. Details of trained Ayush personnel were made available at State/District administration and they have been utilized in the fight against COVID-19 as and when required. Training on "COVID-19 Preparedness, Response and Containment" was provided to the Ayush stakeholders to develop master trainers across the states.

Ministry of Ayush and Ministry of Health and Family Welfare (MoHFW) have jointly provided training to 33,000 Ayush master trainers. Total 83,000 Ayush personnel had obtained training at Integrated Government Online Training (iGOT) portal on continual basis. Further, different states have also provided training to about 1.06 lakhs Ayush personnel. As per available information, around 28,473 Ayush staff was deployed for COVID-19 related healthcare services.

During the recent crisis of manpower and infrastructure in the second wave of COVID-19 pandemic, Ministry of Ayush has communicated to all States/UTs and released advisory for augmentation of Ayush human resource in the management of COVID-19 at appropriate levels under the supervision of medical expert/specialist and in managing e-sanjeevani portal for tele-consultation and counseling.

[11] Ministry of Ayush, Govt. of India 2021. Ayush recommendations for the public on holistic health and well-being. https://www.ayush.gov.in/docs/AyushRecommendations4_LongCovid.pdf

The States/UTs were also suggested to use Ayush infrastructure (50000+ beds, hospitals of 750+ AYUSH colleges, 86 clinical facilities of National Institutes and Research Councils under the MoA) by converting them into COVID Care Centres/hospitals (along with Ayush doctors, nurse and other staff).

The Ministry interacted with Principal Secretaries Ayush/Directors of Ayush from all States and UTs to expedite the utilization of Ayush human resource and infrastructure in the mitigation of COVID-19; and also extended support through the budget in the National Ayush Mission for procuring *AYUSH-64* and *Ayuraksha Kit* to further strengthen the fight against COVID-19.

Dissemination of MoA Initiatives on COVID-19 among masses

The Ministry has launched a campaign "AYUSH for Immunity" to bring behavioral changes in the general public towards promotion of immunity through Ayush interventions wherein more than fifty thousand people participated.[12] The Ministry has also published a campaign bulletin on "AYUSH for Immunity". Webinars were also organized to sensitize the Ayush practitioners.

The Ministry has also set-up an Ayush COVID-19 Dashboard to furnish the guidelines related to AYUSH measures for improving immunity, official communications, research undertaken on COVID-19, measures for prophylaxis and management.[13]

The National Repository on Ayush COVID-19 clinical and other R&D initiatives was developed to disseminate information related to Ayush R&D initiatives, COVID-19 related AYUSH clinical trials and scientific publications and is available on the AYUSH Research Portal of the MoA.[14]

[12]Ministry of AYUSH, Govt. of India 2020. AYUSH For Immunity https://www.mygov.in/campaigns/ayush/?utm_source=mygov_campaign

[13]AYUSH COVID-19 Dashboard https://health.ncog.gov.in/ayush-covid-dashboard/

[14]Ministry of AYUSH, Govt. of India 2020. National Repository on AYUSH COVID-19 Clinical and Other R&D Initiatives at AYUSH Research Portal. http://ayushportal.nic.in/Covid.aspx

R&D initiatives on COVID-19 undertaken by the Ministry of Ayush

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 collaborated with several research organizations to encourage, promote and advance evidence-based research on Ayush systems. These multi-pronged initiatives aimed at creating public awareness regarding measures to improve immunity and mitigate the impact of the pandemic.

Glimpses of R&D initiatives on COVID-19

The MoA constituted an inter-disciplinary Ayush R&D Task Force consisting of scientists, pulmonologists, epidemiologists, pharmacologists etc., from premier organizations and research institutions and seven working groups to deal with various aspects of clinical and experimental research.[15] The Task Force formulated guidelines for Ayush clinical and observational studies in COVID-19 covering various aspects of trial protocols.[16] The Task Force has also taken up proposals received from screening committees of Research Councils under the Ministry and proactively explored possibilities for research based on available leads. The Ministry of Ayush issued a gazette notification to facilitate research on COVID-19 through Ayush systems across the country.[17] The ambit of this notification includes prophylactic measures and interventions for the quarantine, asymptomatic and symptomatic cases of COVID-19, with a view to generate scientific evidence. Taking forward the recommendations of the Interdisciplinary Task Force, 139 clinical research studies and basic experimental studies were initiated at approximately 159 centers by Research Councils and National Institutes under the Ministry through the Intra-mural and collaborative research mode.

So far, 139 clinical, pre-clinical and epidemiological studies viz. Ayurveda (70 studies), Homeopathy (29 studies), Siddha (13 studies), Unani (08 studies) and Yoga & Naturopathy (19 studies) were undertaken by the Research Councils and National Institutes under the Ministry. The collaborative institutes for these studies include AIIMS New Delhi, AIIMS New Jodhpur, King George Medical University Lucknow, Institute of Medical Sciences BHU, Govt. Medical College Nagpur, DMIMS Wardha, KEM Hospital Pune, National Institute of Pharmaceutical Education and Research Kolkata, Institute of Genomics and Integrative Biology New Delhi, Indian Institute of Integrative Medicine Jammu, Employee State Insurance Scheme hospitals, Department of Biotechnology, Government of India

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[15]Ministry of AYUSH, Govt. of India 2020. Notification no. A.17020/1/202-E.I dated 2nd April 2020. https://icssr.org/sites/default/files/Notification%20on%20task%20force002.pdf

[16]Ministry of AYUSH, Govt. of India 2020. Guidelines for Clinical Trials on AYUSH interventions for COVID-19 https://www.ayush.gov.in/docs/clinical-protocol-guideline.pdf

[17]Ministry of AYUSH, Govt. of India 2020. Gazette Notification CG-DL-E-21042020-219088; dated 21st April 2020

institutes such as Regional Centre of Biotechnology and Translational Health Science and Technology Institute (THSTI) etc. It includes 22 experimental studies, 44 prophylactic, 44 therapeutic (standalone and add-on treatment), 15 observational studies, 10 survey studies, two pharmacopeia standard development and two systematic reviews (Figure 1). The clinical studies were monitored and reviewed by Data and Safety Monitoring Board (DSMB) for monitoring of clinical trials and population based prophylactic studies of AYUSH interventions related to COVID-19. The Ministry has also constituted a Project Management Unit to coordinate these studies and providing technical assistance throughout all phases of the studies conducted at different centers.

The prophylactic interventional studies were conducted in high-risk population either residing in containment zones or frontline workers through AYUSH Research Councils and National Institutes (Figure 2). These studies have shown very promising outcomes in reducing the incidence of COVID-19 among Ayush prophylactic care users. Well-designed clinical studies on Ayush interventions as stand-alone or adjunct to standard of care in asymptomatic and mild to moderate COVID-19 patients adopting integrated protocols were conducted (Figure 3). The core outcomes of these studies demonstrated early clinical recovery and achieving early negative RT-PCR results, reduction in the duration of hospital stay, prevention in further progress to severe stage and complications, and improvement in quality of life.

The Ministry has recently funded a novel research study to explore the safety, immunogenicity and protection of Ashwagandha administration with COVID-19 vaccine (COVISHIELD™). The objective of this study is to investigate the immunomodulatory effects of Ashwagandha in vaccinated individuals and to assess the effect of Ashwagandha on the sustenance of the vaccine response. The outcomes of this study will hold importance as sustenance of immune response to the vaccine will have implications for long term prevention against COVID-19 including breakthrough infection. This study has been conducted at seven study sites (Delhi, Mumbai, Pune, Nagpur, Jaipur, Belgaum and Hassan).

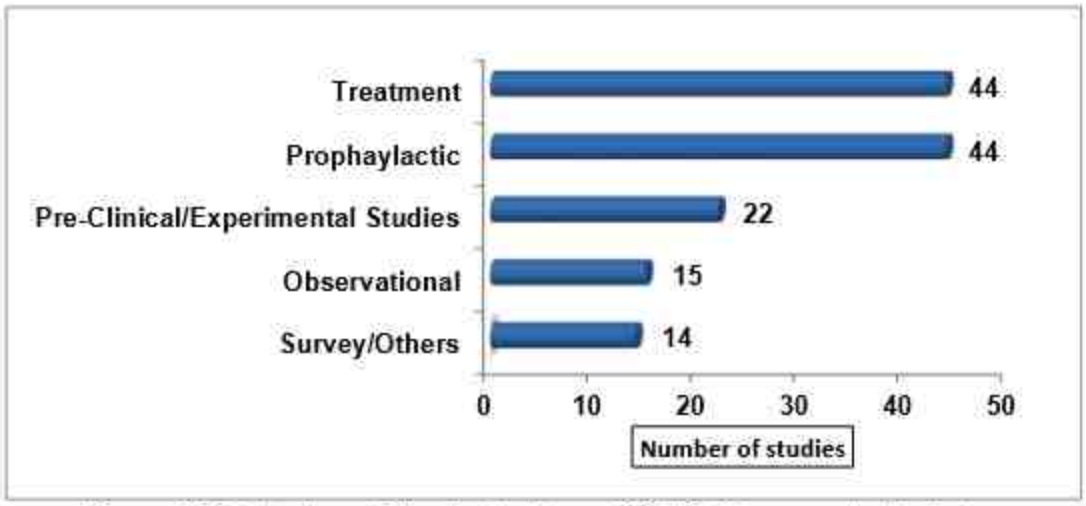


Figure 1: Distribution of Ayush studies on COVID-19 as per study design

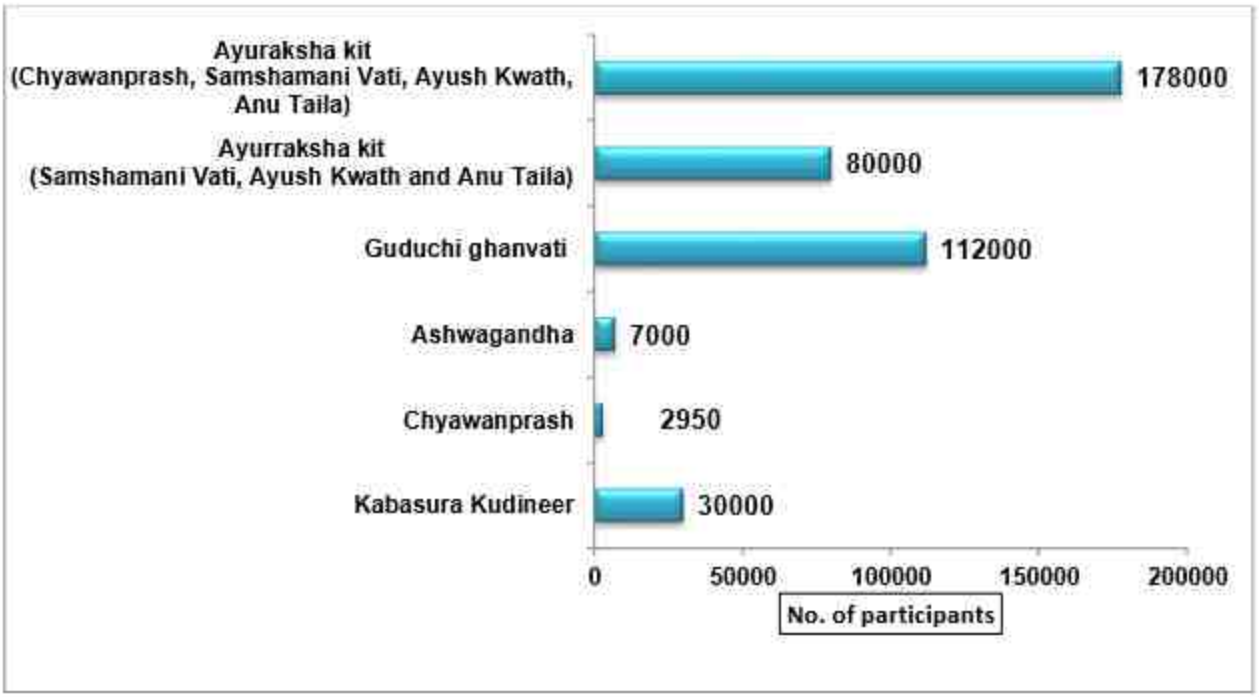


Figure 2: Clinical studies on Ayush Interventions for prophylaxis of COVID-19

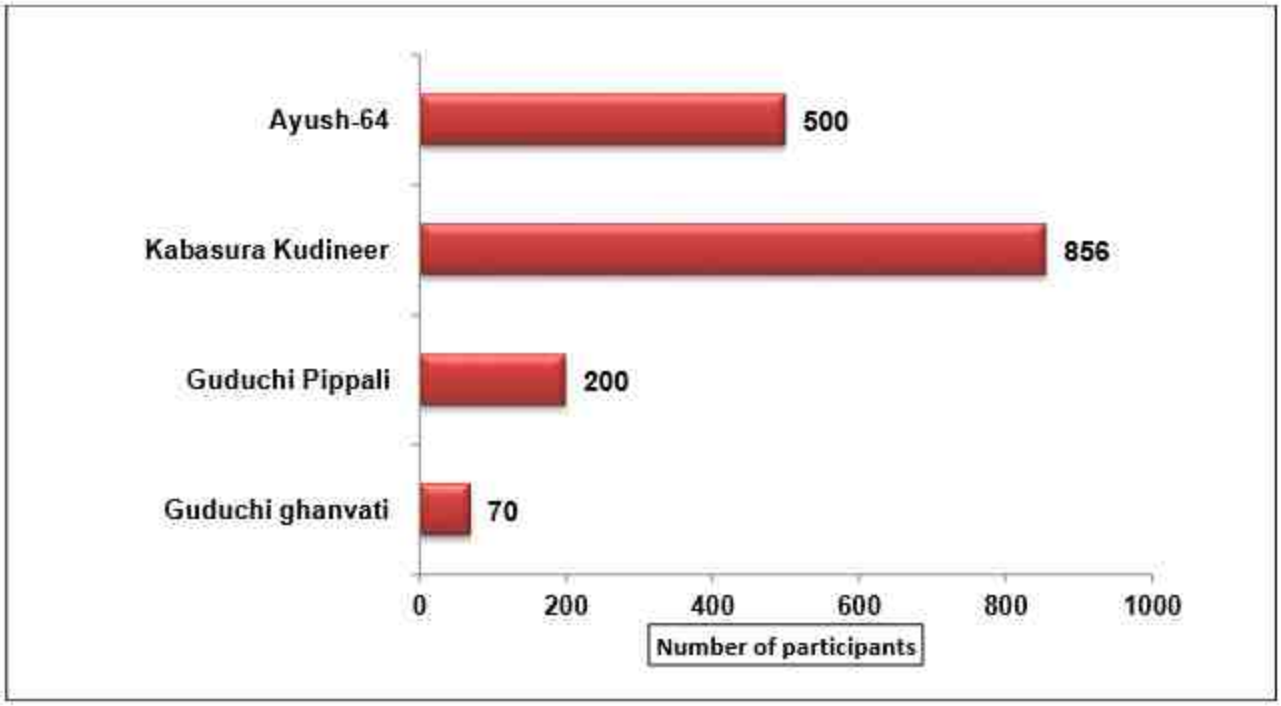


Figure 3: Clinical studies on Ayush Interventions for management of COVID-19

AYUSH-CSIR Collaborative Studies on Ayurvedic Interventions

Developing inter-ministerial linkages, the Ministry in collaboration with Council of Scientific& Industrial Research (CSIR), Government of India has undertaken clinical studies on four different Ayurveda interventions, namely *Ashwagandha* for prophylaxis and *Yashtimadhu, Guduchi-Pippali* and*AYUSH-64* (a poly herbal formulation) as adjunct to standard of care for COVID-19 management. These studies are periodically reviewed by an independent Monitoring Committee. Also, all the trial related activities of these studies have been audited by an independent clinical trial auditor. Among these, a multicenter study on *AYUSH-64* has been completed. Study participants treated with *AYUSH-64* recovered early compared to standard of care group. Significant beneficial effects of *AYUSH-64* on general health, fatigue, anxiety, stress, appetite, general happiness and sleep were also observed. No study drug related SAE reported and *AYUSH-64* was well tolerated (clinically and as per lab parameters). The other three studies are also completed and final report is being prepared.

Other Research Studies on Ayurvedic Interventions

The Ayurvedic interventions viz., *Guduchighan Vati, Sudarshanghan Vati, Ashwagandha tablet, Chyavanprash, Neem capsules* and *Ayurveda Raksha* Kit (containing *Chyavanprash, AYUSH Kwatha, Guduchighan Vati, Anu Taila*) for prophylaxis have been provided to population residing in containment zones and high risk healthcare workers and individuals across the country. Ayurvedic interventions viz.*AYUSH-64, Guduchighanvati, Guduchi-Pippali, Yashtimadhu* and *Ashwagandha-Shunthi* have been evaluated in asymptomatic and mild to moderate COVID-19 patients as standalone or add-on intervention with standard care. Further, in-silico studies on *AYUSH-64* and *AYUSH Kwatha* have been undertaken in collaboration with National Institute of Nutrition Hyderabad (ICMR) and Indian Institute of Technology Varanasi respectively to evaluate their ingredients for inhibitory action against SARS-CoV-2 Main Protease and RNA dependent RNA polymerase. Also, a pre-clinical study has been conducted at National Institute of Nutrition Hyderabad (ICMR) to evaluate the immunomodulatory potential and safety/ toxicity of *Ayush Kwatha* formulation.

Research Studies on Homeopathy Interventions

The homeopathic medicines extensively studied against COVID-19 are *Arsenicum album 30 C* for prophylactic purpose and *Eupatorium perfoliatum 30C, Camphora, Bryonia alba, Arsenicum iodatum 30C Phosphorous 200C & Gelsemium Semp 30C* in asymptomatic and mild symptomatic cases of COVID-19 as add-on intervention. Prophylactic efficacy of *Arsenicum album 30 C* has been evaluated in containment zones of prime cities in India such as Delhi, Chennai, Mumbai, Kolkata, Hyderabad, Surat, slums of Dharawi, Mumbai and prison complexes in Delhi.

The outcome from the overall population studied reveal statistically significant results in reducing the incidence of COVID- 19 compared to the non-intervention cohorts in all the studies. Further, studies on Homeopathic medicines as add-on to standard care have been conducted to assess its therapeutic efficacy in asymptomatic and mild COVID-19 patients. The results of these studies reveal trend of early recovery and lesser mortality rate compared to the control group. For understanding the mechanistic pathways of *Cinchona officinalis* (3C, 6C &12C), a homeopathic drug, as an anti-viral drug against SARS CoV-2, an in-vitro study is being conducted by National Institute of Homeopathy.

Research Studies on Unani Interventions

Population based prophylactic studies have been conducted in Lucknow, Srinagar, Mumbai, Aligarh, New Delhi and Bengaluru among high and moderate risk population through Unani Interventions. Lower incidence of COVID-19 has been observed during the study period in the intervention group. Further, two studies have been undertaken to assess the role of Unani therapeutic regimen as add on to the standard of care, in preventing the progression of the severity of the disease in mild to moderate COVID-19 cases. The early clinical recovery has been observed in the Unani intervention group as compared to the control group. Unani medicines have been well tolerated in all these studies. In-silico screening of four Unani formulations viz. *Triyaq-e-Wabai, Triyaq-e-Arba, Arq- e-Ajeeb* and *Unani Joshanda* revealed their potential as binding energy against SARS-CoV-2 protein i.e. Spike glycoprotein and Main Protease (M^{pro}). The pharmacopoeial standards of *Ayush Joshanda* and *Unani Joshanda* has also been developed followed by preparation of monographs.

Research Studies on Siddha Interventions

Siddha intervention *Kabasura Kudineer* (KSK) has been most extensively studied for its prophylactic and therapeutic efficacy in COVID-19 in different medical institutes at Chennai, Coimbatore, Delhi and Noida. Prophylactic studies on *Kabasura kudineer* showed that it effectively offers protection to high-risk population exposed to COVID-19 in containment zones. KSK when given as add-on to standard of care to the asymptomatic COVID-19 cases, shows significant reduction in the viral load for the 3 genes- ORF gene, E gene and S gene, in terms of ct value on the 10^{th} day in the study group compared to the control group. Similarly, three RCT on Siddha formulations as add-onto standard care showed accelerated recovery and lesser mortality rate in the trial group compared to the standard care.

Research Studies on Yoga

Effect of Yoga was studied for its effect on stress, symptom severity, and heart rate variability in COVID-19patients undergoing conventional treatment and it showed significant reduction in anxiety

(Hamilton Rating scale) and clinical symptoms, significant improvement in heart rate variability and increased relaxation response.

Yoga also improved sleep latency, increase in REM and deep sleep and decrease in number of wakefullness episodes in COVID-19 patients undergoing conventional treatment. The effect of yoga practices (Yogic breathing 1:1, 1:2, *Anulom-vilom Pranayama, Shashankasana*, Chair breathing) was also studied on oxygen saturation levels and relaxation response in COVID-19 positive patients on oxygen supplementation. The interim trends from this ongoing study showed that, SPO_2 levels increased immediately following 27 rounds of yogic practices. Further, a randomized controlled pilot study to assess the effect of *Pranayama* on incidence of COVID-19 and mental status of healthcare personnel exposed to COVID-19 patients revealed that *Pranayama* for 28 days significantly decreased the COVID-19 positivity rate among exposed healthcare professionals working at five different COVID-19 centers in Delhi compared to the control group.

National Repository on Ayush COVID-19 Clinical and Other R&D Initiatives

The National Repository on Ayush has been developed to provide information related to Ayush R&D initiatives, COVID-19-related Ayush clinical trials sponsored/collaborated by the Ministry of Ayush and others agencies, and COVID-19 related scientific publications and Ayush guidelines. This repository is available on the Ayush Research Portal of the Ministry.

Ayush Sanjivani Mobile Application based Population Study

Subsequent to the issuance of AYUSH advisory and guidelines on COVID-19, the Ministry of Ayush developed and launched Ayush Sanjivani mobile application to generate data on acceptance, usage of AYUSH advocacies among the population and its impact in prevention of COVID-19. A cross-sectional analysis was done to evaluate the pattern and extent of utilization of Ayush-based measures, benefits obtained, association between the use of Ayush-based measures and incidence of COVID-19, symptomatic status, and duration of use of Ayush measures. More than 1.35 crore cumulative data of Ayush beneficiaries have been collected through this application. Further, 7,23,459 individual responses by general public and 74,568 individual responses submitted by Ayush physicians of their self-use has also been captured through this application during this study.

The findings of this study highlighted that a good proportion of the representative population has utilized Ayush measures across different regions of the country, during the COVID-19 pandemic and have considerable benefits in terms of general well-being and reduced incidence of COVID-19.[18]

Ayush-DBT Collaborative Pre-clinical Studies

Pre-clinical and pharmacokinetics evaluation of select Ayush herbal extracts/formulations for mitigating SARS-CoV-2 and associated pathologies have been undertaken through Department of Biotechnology, Govt. of India- Ayush Network Research Projects. These studies have been undertaken at Translational Health Science and Technology Institute Faridabad, India. The objective of these studies is to assess their in-vitro and in-vivo anti-viral activity against SARS-Cov-2 and immune-modulatory potential and also to generate pharmacokinetic data on seemingly potent candidates. The preclinical studies include nine priority interventions of oral use viz. *Ashwagandha, Guduchi, Guduchi+Pippali, Yashtimadhu, AYUSH-64, Swertia chirata, Picrorrhiza kurroa, Alstonia scholaris, Ceasalpinia bonduc* and four intranasal administrations (*Anu Taila, Shadbindu Taila,* Sesamum oil, Cow *Ghee*). *Anu taila* showed better result in combating the effect of SAR-CoV2 infection as seen by low viral load in lungs in the Golden Syrian hamsters challenged with SARS-CoV-2.

WHO-Ayush R&D Initiatives

The Ministry of Ayush and World Health Organization has entered into the Technical service agreement to undertake a project "Assessment of integration of Ayush into the Public Health System for combating COVID-19". The study is being executed in collaboration with Public Health Foundation of India (PHFI) at select 10 states across the country to understand the level of integration of Ayush system of medicine within the national healthcare systems for combating COVID-19 as well as to understand community needs/ demand, current utilization, behavior and perception related to use of Ayush system in the prevention of COVID-19.

AIIA-LSHTM Collaboration

All India Institute of Ayurveda (AIIA) with collaboration of London School of Hygiene and Tropical Medicine (LSHTM) is initiating a randomized double-blind placebo-controlled trial on Ashwagandha to study its efficacy in promoting recovery in long-term symptoms following a recent COVID-19 illness. The trial has been conducted in 3 cities in the UK viz., Leicester, Birmingham, and London (Southall and Wembley).

[18] Srikanth N, Rana R, Singhal R, Jameela S, Singh R, Khanduri S, Tripathi A, Goel S, Chhatre L, Chandra A, Rao BCS, Dhiman KS. Mobile App–Reported Use of Traditional Medicine for Maintenance of Health in India During the COVID-19 Pandemic: Cross-sectional Questionnaire Study. JMIRx Med 2021; 2(2):e25703

Other R&D support

The Ministry of Ayush also developed an online mechanism for crowd sourcing of scientific evidence-based solutions from the Ayush systems to address the pandemic.[19] The Ministry also modified the existing extramural research scheme to support short-term research projects for evaluating the impact of Ayush interventions in the prophylaxis and management of COVID-19.

The Ministry set-up an Interdisciplinary Technical Review Committee (ITRC) for COVID-19 for the examination of the applications/claims on patent and proprietary ASU&H medicines/classical ASU&H medicines with new indication or re-purposing of licensed patent and proprietary, ASU&H medicines for COVID-19. The committee reviewed 43 applications in the light of quality standards, preclinical safety requirements of the drug(s), and clinical efficacy with appropriate rationale.

The Ministry also constituted a core group of experts to identify and propose formulations for prophylaxis, management of COVID-19, and post-COVID care. The interventions shortlisted for drug development and commercialization are based on the core principles of Ayush systems, and have substantial experimental and clinical leads on the efficacy and safety from the COVID-19 studies undertaken by the Ministry.

National Clinical Management Protocol based on Ayurveda and Yoga for management of COVID-19

The Ministry has set-up an Interdisciplinary Committee for Integration of Ayurveda and Yoga Interventions in the 'National Clinical Management Protocol: COVID-19" to crystallize the outcomes and interim trends of COVID-19 studies undertaken by different institutes under the Ministry. The Committee has formulated its First Report & Recommendations based on the interim trends of ongoing and completed Ayush studies on COVID-19 and experimental and clinical published data indicating potential benefits and safety of Ayush interventions.[20] Based on NITI Aayog and ICMR recommendations on the committee report, the Ministry of Ayush has issued the National Clinical Management Protocol based on Ayurveda & Yoga for management of COVID -19 on 6th October, 2020 enabling uniform clinical management.[21]

This protocol is for the management of asymptomatic and mild COVID-19 cases. The Ayurveda

[19]Ministry of AYUSH, Govt. of India 2020. OM No.Z-28015/48/2020-HPC (EMR) AYUSH https://main.ayush.gov.in/sites/default/files/proposals_1.pdf

[20]Ministry of AYUSH, Govt. of India 2020. OM no. A. 17020/1/2020-E.I dated 16th July 2020. https://www.ayush.gov.in/docs/Report%20and%20Recommendations%20of%20Interdisciplinary%20Committee.pdf

[21]PIB 2020. "National Clinical Management Protocol based on Ayurveda and Yoga for the management of Covid-19" released jointly by Health and AYUSH Ministers. https://pib.gov.in/PressReleaseIframePage.aspx?PRID=1662012 [21]Ministry of AYUSH, Govt. of India 2020. National Clinical Management Protocol based on Ayurveda and Yoga for themanagement of Covid-19. https://main.ayush.gov.in/event/national-clinical-management-protocol-based-ayurveda-and- yoga-management-covid-19

protocol includes general and dietary measures and specific treatment guidelines as per the clinical condition of the patient.[21] It incorporates guidelines for prophylaxis, management of asymptomatic and mild COVID-19 cases and post-COVID management. The Yoga protocol is for the primary prevention from COVID-19 and post-COVID care by improving the respiratory and cardiac efficiency, reducing stress and anxiety and enhancing immunity.

Scientific Publication of outcomes of COVID related Research Studies

The Ministry constituted an advisory panel on July 29, 2020 to provide their inputs and suggestions for the finalization of manuscripts related to the outcomes of the research studies on COVID-19 for publication in scientific journals of high repute. The details of manuscripts published and available as preprint are available from Page 53 onwards of this document.

Translation of Research Outcomes to the masses

Based on the empirical evidence, *AYUSH-64*, a polyherbal formulation developed by Central Council for Research in Ayurvedic Sciences, Ministry of Ayush was repurposed for COVID-19 and extensive studies viz. in-silico, in-vitro and clinical studies were conducted to evaluate its therapeutic potential. The *in-silico* molecular docking study conducted at ICMR-National Institute of Nutrition, Hyderabad showed that among 36 compounds, 35 exhibited good binding energies than the published positive co-crystal compound of N3 peptide. In-vitro antiviral screening assay of AYUSH-64 under Ministry of Ayush–Department of Biotechnology (DBT) collaborative study at Translational Health Science and Technology Institute (THSTI) also demonstrated reduction of viral load of SARS CoV-2. The seven clinical studies on *AYUSH-64* conducted at nine reputed medical institutions showed its efficacy in the treatment of asymptomatic & mild cases as standalone and for the management of mild and moderate COVID-19 as an adjunct to standard care. It was observed that *AYUSH-64* as adjunct treatment to Standard Care resulted in significant improvement in clinical recovery and duration of hospital stay without any progression of the disease to severe or critical stage. Also, there was improvement in Quality of life (QoL) parameters. *AYUSH-64* was found to be well tolerated and safe.

Kabasura Kudineer, a Siddha multi-ingredient formulation was also evaluated for its therapeutic efficacy in COVID-19 through molecular docking, pre-clinical and clinical studies. The nine phyto- constituents in this formulation showed highest binding affinity with SARS-CoV-2spike protein in the molecular docking studies. This formulation also demonstrated in-vitro immune- modulatory and thrombolytic activity. *Kabasura Kudineer* (KSK) also showed inhibition of virus replication similar to standard drug Remdesivir in the in-vitro study.

Kabasura kudineer as prophylaxis provided effective protection to high-risk population exposed to COVID-19 in containment zones. Further, KSK when given as add-on to standard of care in asymptomatic and mild COVID-19 patients showed accelerated recovery, significant reduction in the viral load and lesser mortality rate compared to the standard care. Hence, with its preclinical and clinical evidences, *Kabasura Kudineer* shows promising effect in mitigation of COVID -19 pandemic.

The tangible evidence generated through robust studies conducted by AYUSH-CSIR collaboration and Research Councils/National Institutes under the Ministry of Ayush, led to positioning of *AYUSH- 64*/*Kabasura Kudineer* as potential adjuncts to standard care in COVID management. To reduce the burden on the hospital-based health care delivery system during the current outbreak of COVID-19 second wave in India, the Ministry of Ayush has conducted a community-based study 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. The data related to the effectiveness of *AYUSH-64* and *Kabasura Kudineer* is also documented. The study has been completed. Overall, 96139 participants enrolled for the study (Figure 4).

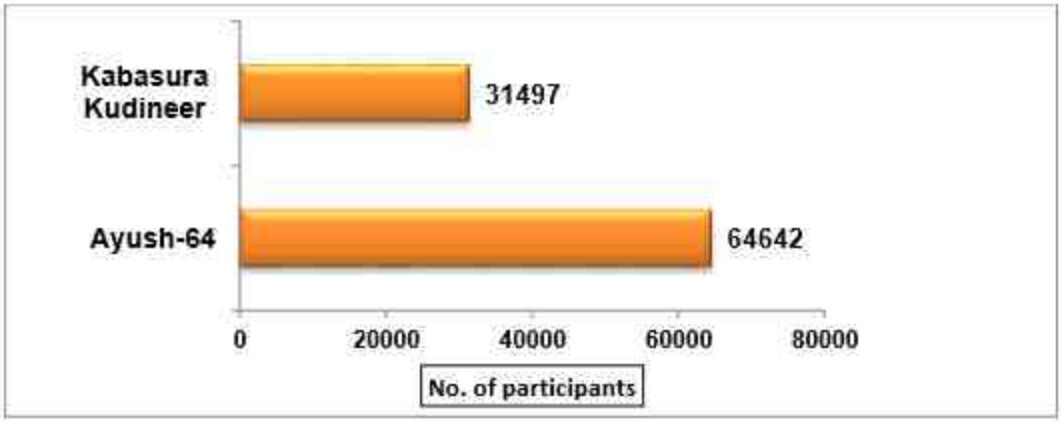


Figure 4: Community-based study on Ayush Interventions for management of COVID-19

AYUSH for addressing global challenge

The contribution of the Ayush systems in maintaining health and improving immunity during the COVID-19 pandemic is well accepted. Proactive initiatives, inter-departmental/inter-ministerial successful co-ordination and conduct of integrative researches, active participation of the private and public stakeholders in effective implementation of initiatives, and widespread acceptance of Ayush measures by general public largely helped in combating this crisis. The Ministry of AYUSH is committed for evidence-based integration of Ayush systems and modern medicine to address the public health challenge. The carnage evoked by this pandemic has not only demonstrated the role of AYUSH in managing the disease but also instilled the need to focus on wellness and preventive care wherein AYUSH systems can contribute significantly.

Research studies on COVID-19 undertaken by Research Councils and National Institutes under Ministry of Ayush

- Number of COVID-19 related studies - 139

  - Prophylactic studies – 44
  - Interventional studies - 44
  - Observational studies – 15
  - Pre-clinical/experimental studies – 22 (including 13 AYUSH-DBT studies)
  - Systematic Review - 02
  - Other studies – 12 (08 Survey studies; 02 Monographs preparation)
  - Study Sites – More than 150 (including pre-clinical study centers)
  - Studies Completed – 102

- AYUSH System-wise

  - Ayurveda - 70
  - Homeopathy – 29
  - Siddha – 13
  - Unani – 08
  - Yoga & Naturopathy – 19

Initiatives taken by MoA for COVID-19 at a glance

Ministry of Ayush Initiatives For COVID-19

- Guidelines and Public Health Advisories
- Mobilization of Human Resource
- Research and Development (R&D)
- National Clinical Management Protocol
- Nation-wide campaign for AYUSH-64/ Kabasura Kudineer distribution
- Dissemination of Research Outcomes/ Publication
- Impetus to AYUSH Industry

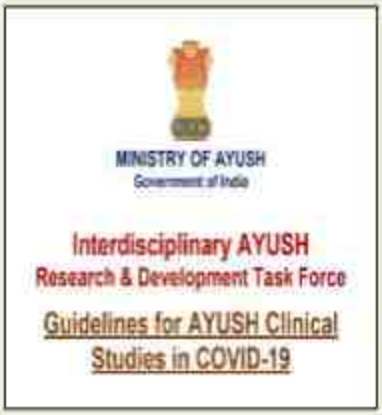
Public health advisories, guidelines and protocols issued by Ministry of Ayush

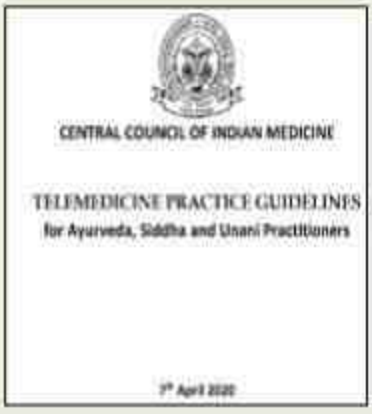
During the outbreak of COVID -19 in 2020:

- Ayurveda **Preventive Measures for self-care** during COVID-19 Pandemic
- Self-care guidelines for prevention and immunity w.s.r. to **respiratory health**
- **Telemedicine** Practice Guidelines
- Guidelines for Ayurveda Practitioners for COVID-19 Patients

During the resurgence of COVID 19 in 2021:

- Ayurveda Preventive Measures for self-care during COVID-19 Pandemic (Revised Advisory)
- Guidelines for Ayurveda Practitioners for COVID-19 Patients in **Home Isolation**
- Yoga protocol for **psychosocial rehabilitation of COVID-19 Patients** (CCRYN, NIMHANS and SVYASA)
- Advisory for Ayush practitioners on **ethical practices** during COVID-19
- Information for Homeopathy and Ayurveda Practitioners on **Mucormycosis**
- Home care guidelines and Advisory for AYUSH Practitioners about **prophylactic care in Children**
- Ayush recommendations for the public on holistic health and well-being **"Preventive measures and care during COVID-19 & long COVID-19" (recently issued)**





Press Information Bureau
Government of India
AYUSH

07 MAY 2021 8:33PM by PIB Delhi

Advisory issued for induction of trained AYUSH human resources for clinical management of COVID-19

Continuing with the efforts to augment human resources for the management of COVID-19 cases, the Ministry issued advisory to deploy the trained AYUSH human resources available with them for clinical management of COVID-19 cases.

The decision to deploy AYUSH professionals to the frontlines of the COVID-19 war is in continuation of decisions taken a few days back to boost availability of medical personnel to fight COVID-19 such as postponement of the NEET-PG Exam, giving priority to medical personnel completing 100 days of Covid duties in forthcoming regular Government recruitments and deployment of medical interns in Covid Management duties under the supervision of their faculty.

AYUSH doctors are institutionally qualified professionals, well-trained in various aspects of medical care. They have already proven their competence in various COVID-19 management roles in different institutions across the country. Some of the institutions under the Ministry of AYUSH like the All-India Institute of Ayurveda (AIIA), New Delhi which functions as a COVID -19 Care Centre, are efficiently managing Covid-19 cases at present. Further, States/UTs have trained nearly 1.06 lakh AYUSH professionals in different aspects of COVID-19 management, and 28,473 professionals have been deployed for COVID-19 activities. Training to AYUSH professionals in different aspects of COVID-19 management was also provided by the Ministry of AYUSH through the Integrated Government Online Training (iGOT) digital platform (https://igot.gov.in/), and 66045 AYUSH professionals completed the same. In addition, the Ministry of AYUSH and the Ministry of Health and Family Welfare have jointly provided training to 33,000 AYUSH master trainers. Thus, a large number of AYUSH professionals have already been prepared through various efforts to take up frontline tasks in the fight against the pandemic. Details of about 8.32 Lakhs of AYUSH manpower have been compiled through the initiatives of the Ministry of AYUSH and provided on the Covid Warriors portal (covidwarriors.gov.in).

More than eight lakh Ayush doctors, paramedic staff, and students offered their services for the clinical management, surveillance, and management of COVID isolation centres and quarantine wards by enlisting themselves as COVID warriors on the government portal. Details of trained Ayush personnel were made available at State/District administration and they have been utilized in the fight against COVID-19 as and when required.

Ministry of Ayush and Ministry of Health and Family Welfare (MoHFW) have jointly provided training to 33,000 Ayush master trainers. Total 1.06 lakh Ayush personnel had obtained training at Integrated Government Online training (iGOT) portal on continual basis. Services of about 28,473 Ayush Human resource was utilised for combating COVID-19 crisis.

Released Advisory on 7th May 2021 and offered states to use Ayush infrastructure (50000+ beds, hospitals of 750+ AYUSH colleges, 86 clinical facilities of National Institutes and Research Councils under Ministry of AYUSH) by converting them into COVID Care Centres/hospitals (along with Ayush doctors, nurse and other staff)

Along with Ayush infrastructure, Human Resource has also been appropriately utilized

Ayush facilities as COVID Care Centres with Ayush HR have been successfully implemented at various Ayush institutions

AIIA (data of June 20 to Jan 21)	Patients completed treatment: 592
	92% of people have opted for standalone Ayurveda treatment

National Institute of Ayurveda, Jaipur has been recently permitted by Govt. of Rajasthan to start 150-bed COVID Care Centre.

In Tamil Nadu, National Institute of Siddha has been converted into COVID Care Centre.

Dhanvantri Ayurvedic College Chandigarh, Chaudhary Brahm Prakash Ayurved Charak Sansthan, New Delhi, A&U Tibbia College New Delhi and Naiminath Ayurvedic College Agra have managed COVID-19 patients by effectively utilizing Ayush Human Resource at their own facilities as COVID Care Centers.

The utilization of Ayush facilities along with Ayush HR have shown excellent results and may be replicated at other CCCs also as approved and released in the Advisory dated 7th May, 2021.

➢ Ministry of Ayush has also operationalized a dedicated community support helpline i.e. toll-free number 14443, to provide AYUSH-based approaches and solutions for the challenges raised by Covid-19. The helpline is operational pan-India from 6 am to 12 midnight-all seven days of a week.

➢ The experts would not only be providing counselling and feasible remedies to the patients but would also guide them about the availability of nearby Ayush facilities.

➢ The portal has received total of 167920 calls since its inception from all across India.

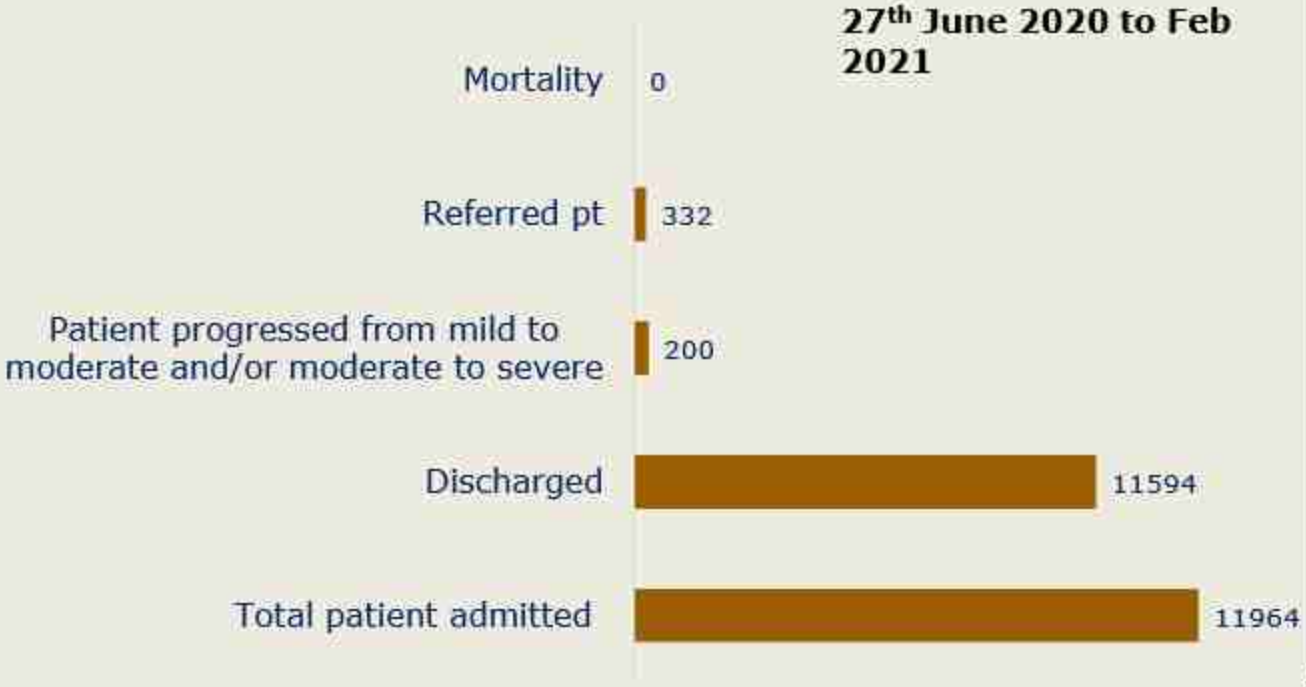
COVID-19 SUCCESS STORIES IN AYUSH

Sardar Patel COVID Care Centre (SPCCC) under Ministry of Home Affairs (managed by ITBP)

The healthcare facility follows naturopathy and Ayurveda protocols as add-on to standard care for boosting immunity of the in-patients at the center

The admitted patients are given Ayurvedic kadha in the morning followed by meals as advised by dieticians and the day ends with milk with turmeric

Status of COVID 19 cases treated at SPCCC



COVID Health Centre
All India Institute of Ayurveda

Total patients received treatment: 592

Patients completed treatment: 532

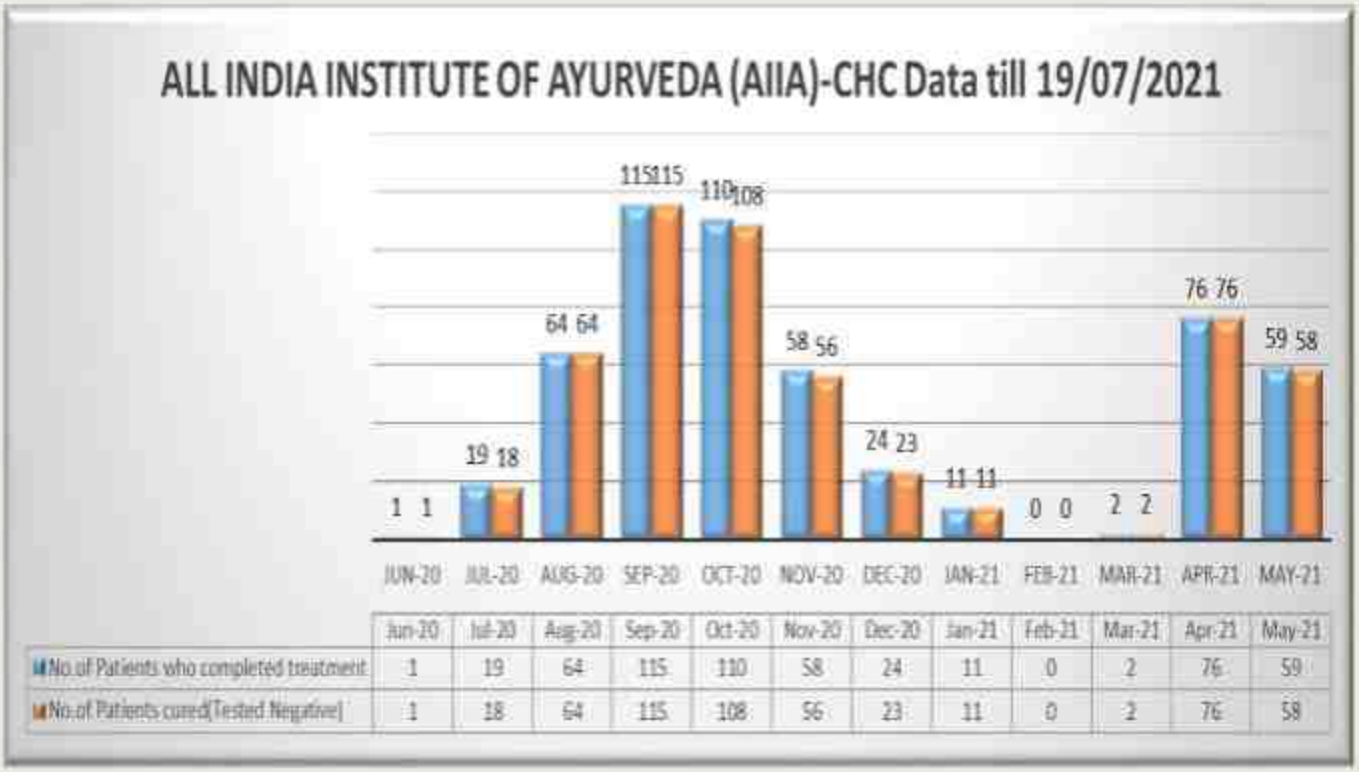
34 patients were referred

92% of people administered Ayurveda standalone treatment

Average recovery period observed: 10 days.

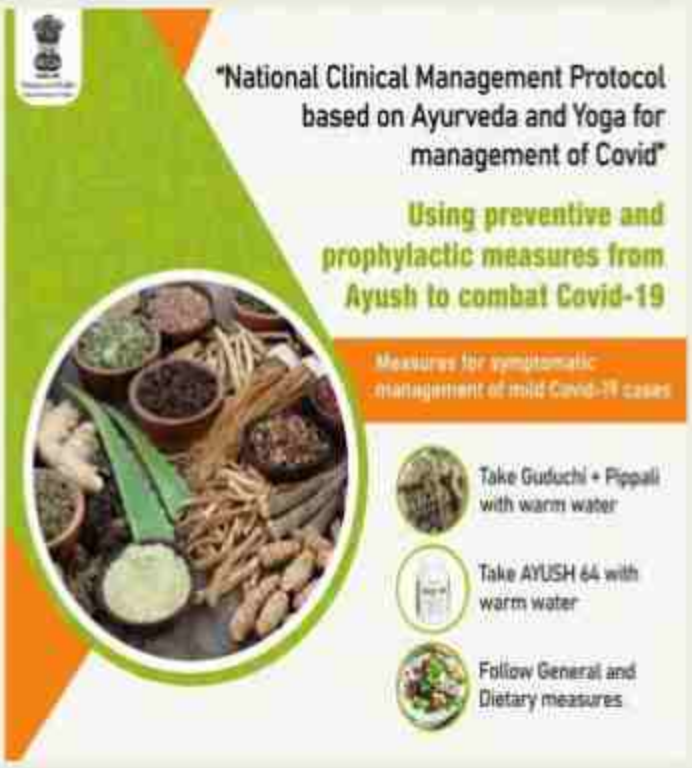
RAT/RT-PCR tested negative after treatment in 99%

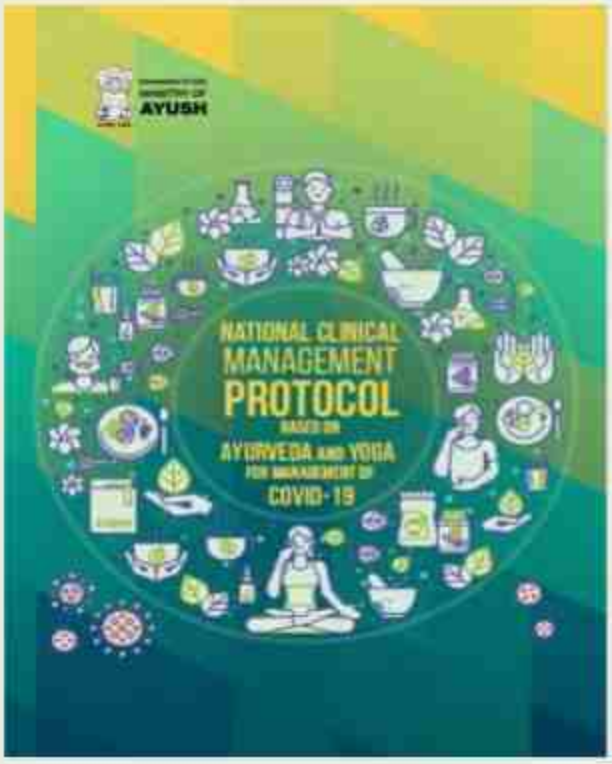
Only one mortality recorded during second wave of COVID 19



	Jun-20	Jul-20	Aug-20	Sep-20	Oct-20	Nov-20	Dec-20	Jan-21	Feb-21	Mar-21	Apr-21	May-21
No.of Patients who completed treatment	1	19	64	115	110	58	24	11	0	2	76	59
No.of Patients cured(Tested Negative)	1	18	64	115	108	56	23	11	0	2	76	58

National Clinical Management Protocol based on Ayurveda and Yoga for Management of COVID 19





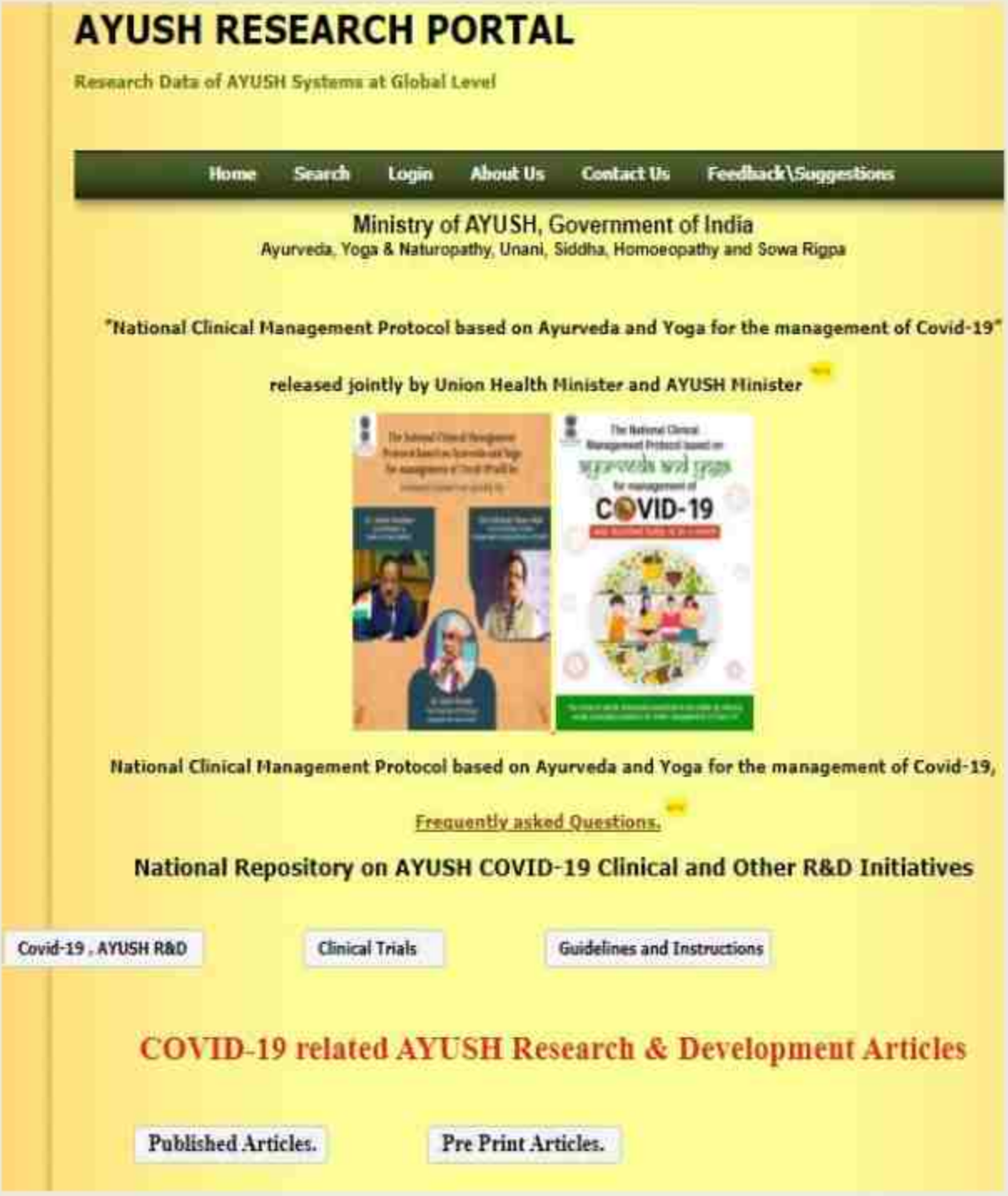
Released in October 2020 by Govt. of India

Ministry has set up a Interdisciplinary Committee, chaired by Dr V M Katoch, former Director General ICMR. They based on empirical scientific evidences proposed Ayurveda and Yoga interventions in their Report and recommendations for COVID 19

The report was presented before the National Task Force on COVID 19 and Joint Monitoring Group, MoHFW

Based on their recommendations, National Clinical Management Protocol based on Ayurveda and Yoga for Management of COVID 19 was released by GoI

National Repository on AYUSH COVID-19 Clinical and Other R&D Initiatives



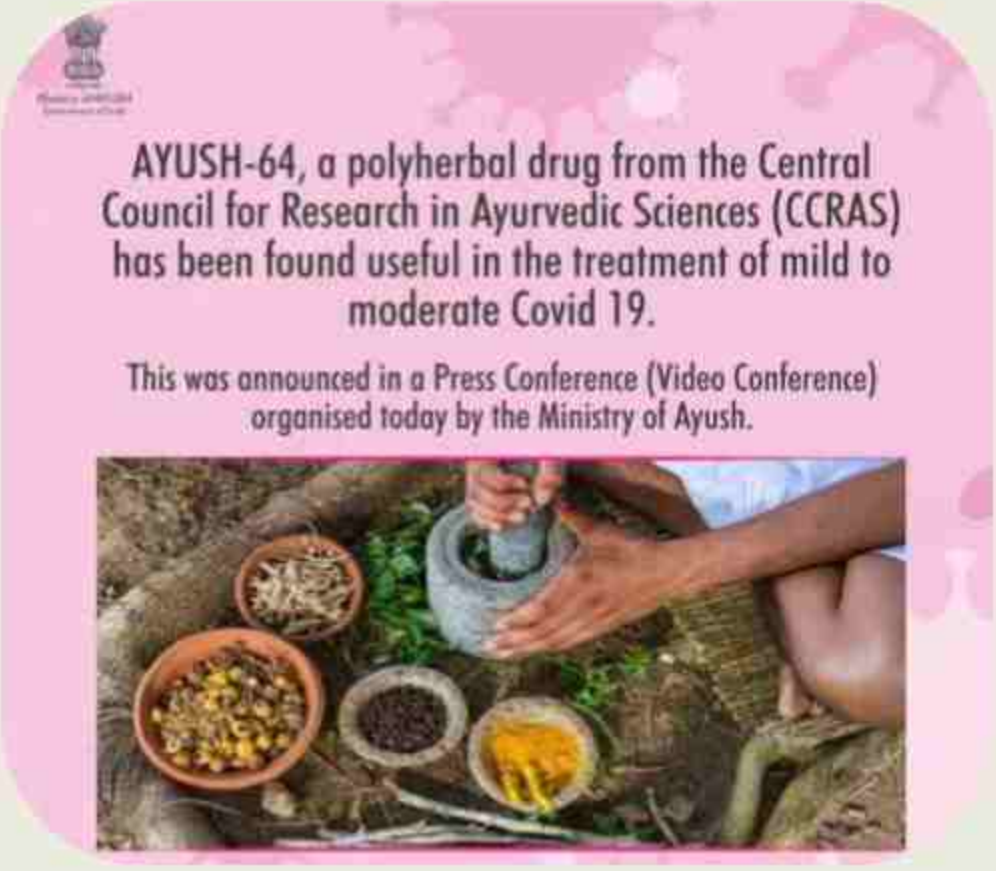
- Ayush Research Portal
  - Total number of visitors: **781421**
  - 33326 Research papers/ abstracts
- National Repository on AYUSH COVID-19 Clinical and Other R&D Initiatives: **Total 245 articles**

Public awareness campaigns/initiatives

Nation-wide campaign for distribution of AYUSH-64 and Kabasura Kudineer through 87 clinical units of Research Councils and National Institutes under the Ministry of Ayush across the country with support from Sewa Bharti, has been launched by the then Hon'ble MoS (IC), Ministry of Ayush Shri Kiren Rijiju in May 2021.

96,139 participants enrolled in this prospective community based study. Clinical recovery was observed in 89% and 88.5% participants who received Ayush 64 and Kabasura Kudineer respectively by 21st day.

95% and 78.8% participants turned RT-PCR negative by 21st day who received Ayush 64 and Kabasura Kudineer respectively.



Interdisciplinary AYUSH R & D Task Force

Chaired by Prof. Bhushan Patwardhan (Former Vice-Chairman, University Grants Commission, New Delhi)

Experts from premier institutions & research organizations such as AIIMS, ICMR & AYUSH institutions

Formulated and designed clinical research protocols for prophylactic and add-on intervention studies in COVID-19

Also, drafted the guidelines for Ayush Clinical Studies in COVID-19 covering various aspects of clinical trial protocols

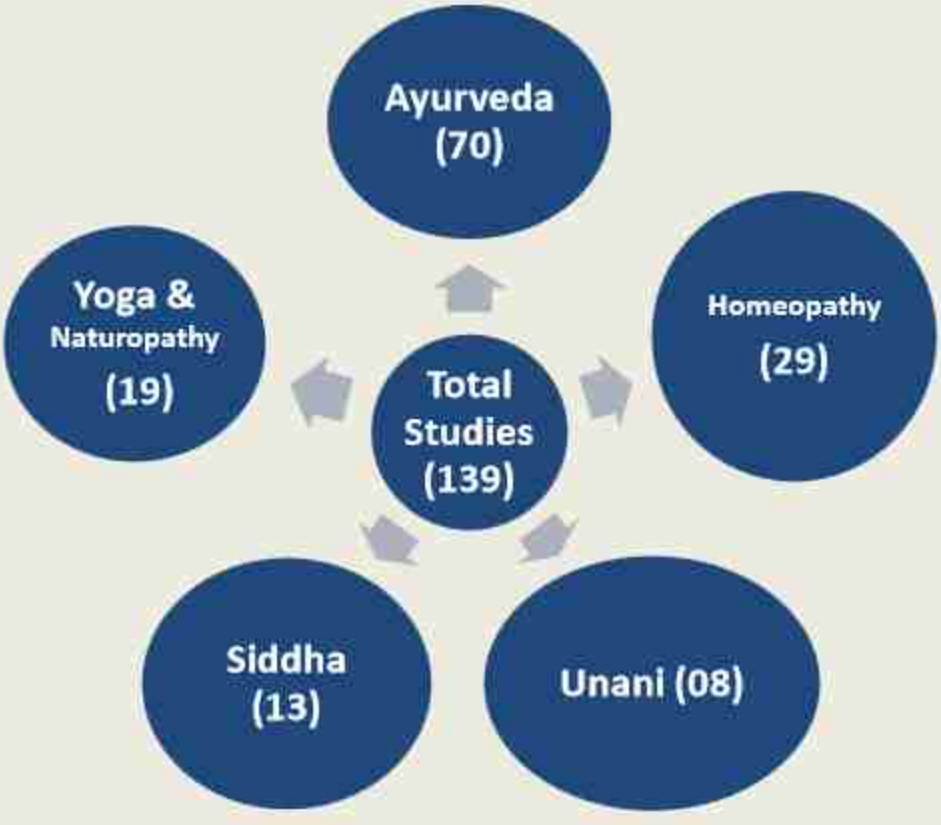
The Task Force also constituted seven working groups to deal with the different aspects of research and public health

Major collaborators

CSIR, DST, AIIMS Jodhpur, AIIMS Jhajjar, ICMR-NIN, Hyderabad; KGMU Lucknow; GMC, Nagpur; DMIMS, Wardha; Govt. of NCT of Delhi; Govt. of Telangana; Govt.

AYUSH Research Studies on COVID-19

AYUSH System-wise COVID-19 Studies



Ayush 64: Repurposed for COVID-19

Recommended in National Clinical Management protocol based on Ayurveda and Yoga

Quality Standards: Developed by CCRAS, Ministry of Ayush

Evidences on clinical and pre-clinical safety: Total 10 studies in collaboration with CSIR, DBT, ICMR and reputed hospitals

Evidences on symptom management (ILI) /Anti-viral /Immunomodulatory activity

Pre print of Ayush-CSIR collaborative study available at medRxiv preprint server

Coadministration of AYUSH 64 as an adjunct to Standard of Care in mild and moderate COVID-19: A randomised, controlled, multicentric clinical trial

Arvind Chopra[1], Girish Tillu[2], Kuldeep Chuadhary[3], Govind Reddy[4], Alok Srivastava[5], Muffazal Lakdawala[6], Dilip Gode[7], Himanshu Reddy[8], Sanjay Tamboli[9], Manjit Saluja[1], Sanjeev Sarmukkaddam[1], Manohar Gundeti[3], Ashwinikumar Raut[10], BCS Rao[11], Babita Yadav[11], Narayanam Srikanth[11], Bhushan Patwardhan[2]

Published study on Ayush 64 efficacy in Influenza Like Illness

Original Research Article

AYUSH 64, a polyherbal Ayurvedic formulation in Influenza like Illness: results of a pilot study

Manohar S. Gundeti [a], Laxman W. Bhurke [b], Pallavi S. Mundada [b], Sanjay Murudkar [c], Ashita Surve [d], Ramavatar Sharma [e], Sunita Mata [e], Rakesh Rana [f], Richa Singhal [g], Neera Vyas [h], Shruti Khanduri [i], B.S. Sharma [j], Srikanth N [j], Dhiman KS [k]

Show more

https://doi.org/10.1016/j.jaim.2020.05.010

A Randomized, Open Label, Active Control, Multi-Centre Exploratory Drug Trial to Evaluate Efficacy and Safety of AYUSH 64 as Adjunct Treatment to Standard of Care in Mild to Moderate COVID-19

- **AYUSH-CSIR collaborative study**
- **Study site: KGMU Lucknow, DMIMS Wardha and BMC COVID Centre, Mumbai**
- **Sample size:** 140

Study Outcomes:

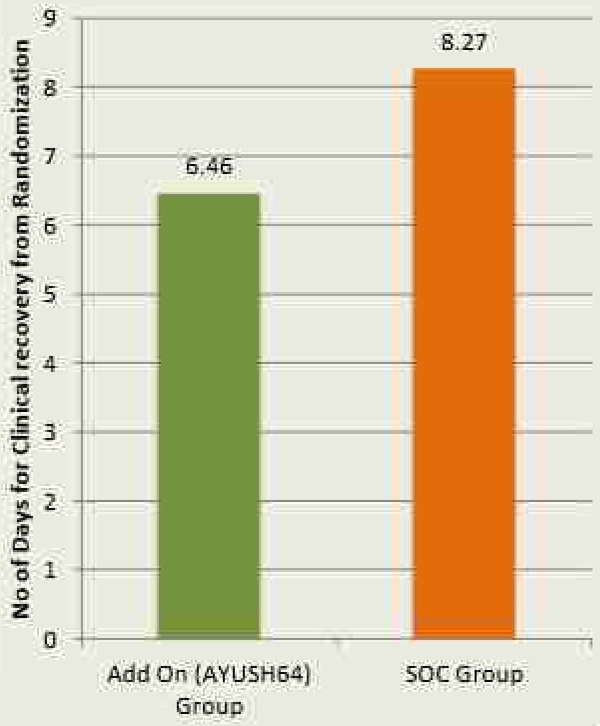
Participants treated with AYUSH-64 **recovered early** (maximum within one week) compared to standard care

Mean time to negative RT-PCR for COVID-19 was lesser in AYUSH-64 group.

No study drug related SAE reported.


Coadministration of AYUSH 64 as an adjunct to Standard of Care in mild and moderate COVID-19: A randomized, controlled, multicentric clinical trial

Pre print available at medRxiv



Evaluation of Efficacy and Safety of Ayush-64 add-on-therapy for patients with Covid-19 (Stage-I)- A Randomized controlled trial

Trial Site: Government Medical College, Nagpur

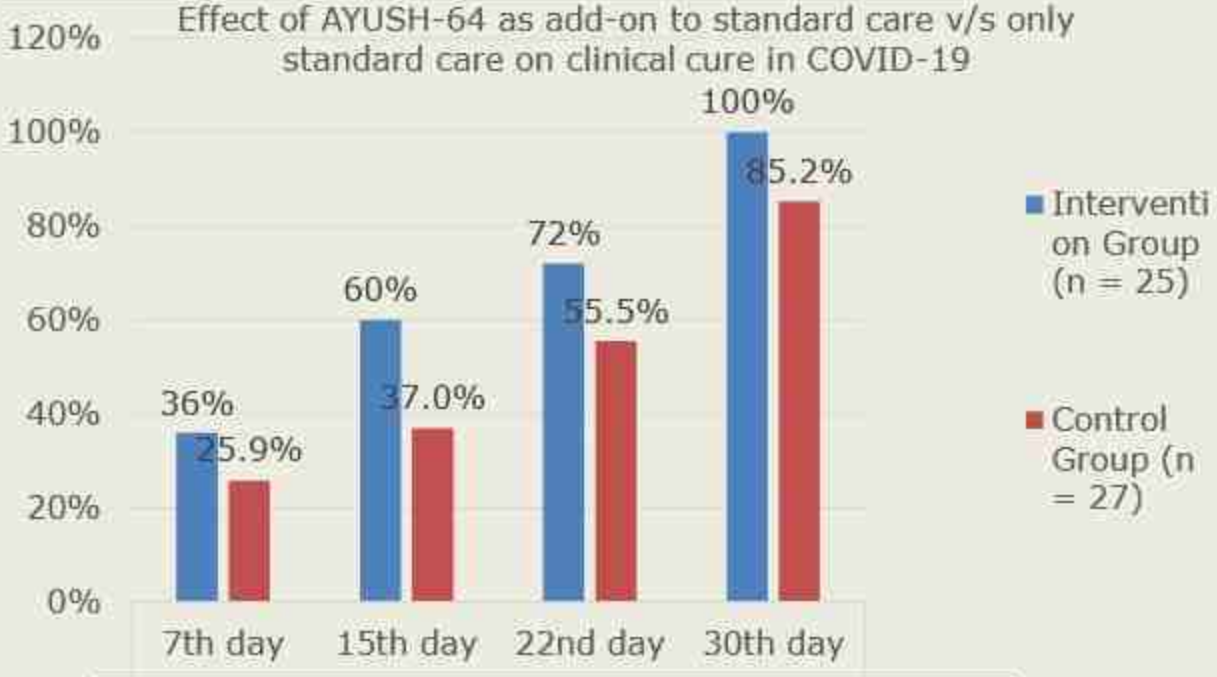
Sample Size: 60

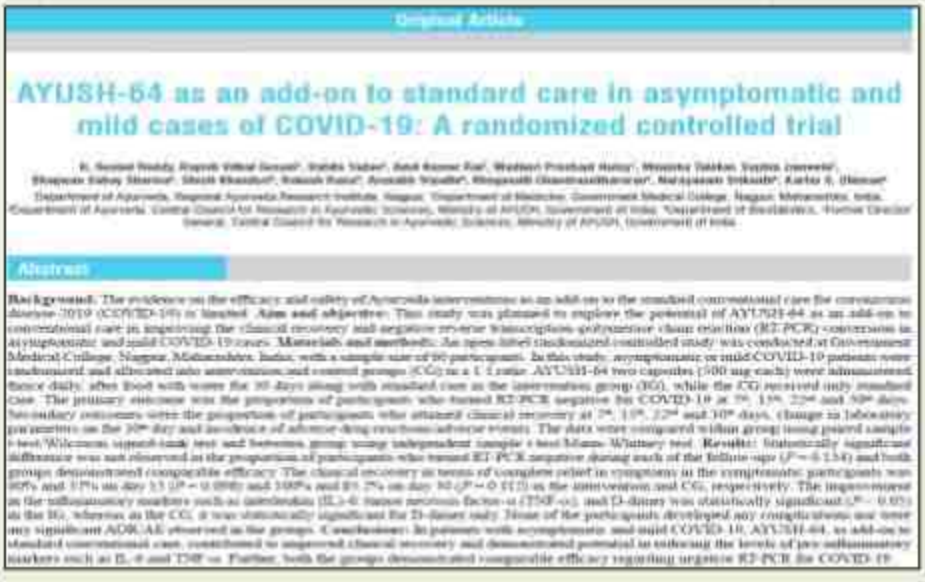
Study Outcomes

The clinical recovery rate was better at 15th day in the add-on intervention.

Complete clinical recovery in all the participants of the add-on intervention group on 30th day whereas it was 85.2% in the control group.

Statistically significant reduction in the levels of IL-6, D-dimer and TNF-α in the add-on intervention group





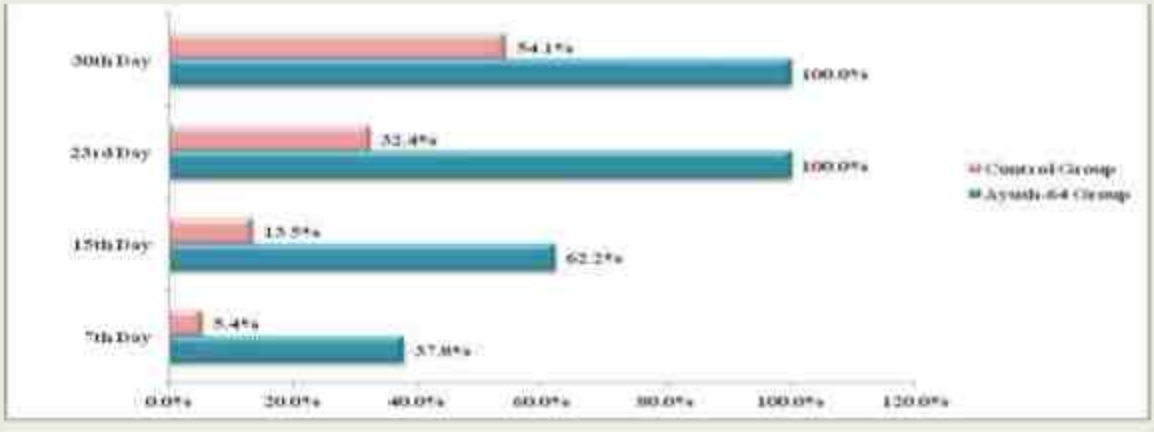
Original Article

AYUSH-64 as an add-on to standard care in asymptomatic and mild cases of COVID-19: A randomized controlled trial

Abstract

A Randomized, Open Label, Active Control, Exploratory Clinical Trial to Evaluate Efficacy and Safety of an AYUSH 64 as Adjunct Treatment to Standard of Care for the management of Mild to Moderate COVID-19

Trial Site	Shri Dhanwantri Ayurvedic College, Chandigarh
	Sample Size: 80
Study Outcomes	Statistically significant difference in the proportion of participants with clinical recovery in AYUSH-64 group
	Proportion of participants with negative RT-PCR was also better in Ayush-64 group
	Proportion of participants with improvement in HRCT chest was also statistically significant in the AYUSH-64 group.
	AYUSH-64 significantly reduced the levels of pro-inflammatory markers.



Proportion of participants clinically recovered

OSF PREPRINTS

AYUSH-64 as an adjunct to Standard Care in mild to moderate COVID-19: An open-label randomized controlled trial in Chandigarh, India

Harbans Singh[1], Sumit Srivastava[2], Babita Yadav[3], Amit K Rai[3], Sophia Jameela[3], Saroj Muralidharan[2], Rijin Mohan[2], Shikha Chaudhary[2], Richa Singhal[1], Rakesh Rana[3], Shruti Khanduri[3], Bhagwan S Sharma[3], Bhogavalli Chandrasekhararao[3], Narayanam Srikanth[3], Sarika Chaturvedi[4]

In-silico evaluation of compounds of an Ayurvedic drug, AYUSH-64, for their action against SARS-CoV-2 Main Protease

Study site: ICMR-National Institute of Nutrition, Hyderabad

Evaluation of different compounds available in Ayush-64 against SARS-CoV-2 Main Protease (Mpro) via computational molecular docking.

Outcomes: Out of 36 compounds of AYUSH-64 screened, 35 compounds exhibited good binding energies than the positive control of N3 among, the best affinity and interactions of Akuammicine N-Oxide towards the target with binding energy (Auto Dock Vina) of -8.4 kcal/mol and Libdock score of 147.92.

Journal of Ayurveda and Integrative Medicine
Available online 25 February 2021
In Press, Journal Pre-proof

Original Research Article

In silico evaluation of the compounds of the ayurvedic drug, AYUSH-64, for the action against the SARS-CoV-2 main protease

Thrigulla Saketh Ram [a], Marine Munikumar [b] ✉, Vankudavath Naik Raju [c], Parasannanavar Devaraj [d], Naveen Kumar Boiroju [a], Rajkumar Hemalatha [e], P.V.V. Prasad [f], Manohar Gundeti [h], Brijesh S. Sisodia [i], Sharad Pawar [j], G.P. Prasad [k], Mukesh Chincholikar [l], Sumeet Goel [m], Anupam Mangal [n], Sudesh Gaidhani [o], N. Srikanth [p], K.S. Dhiman [q]

The results indicate that AYUSH-64, already marketed and approved drug is a good candidate for repurposing against COVID-19

Evaluation of the immuno-stimulatory potential of Ayurveda management protocol in cohort of Delhi police - An exploratory study
(कोरोना से जंग दिल्ली पुलिस के संग)

Study intervention: Ayurraksha kit (Samshamani vati, AYUSH kadha, Anu taila Nasya)

Sample size: 80,000 Delhi police personnel

Decrease in Incidence among Delhi Police during the peaks of Pandemic compared to Delhi General population

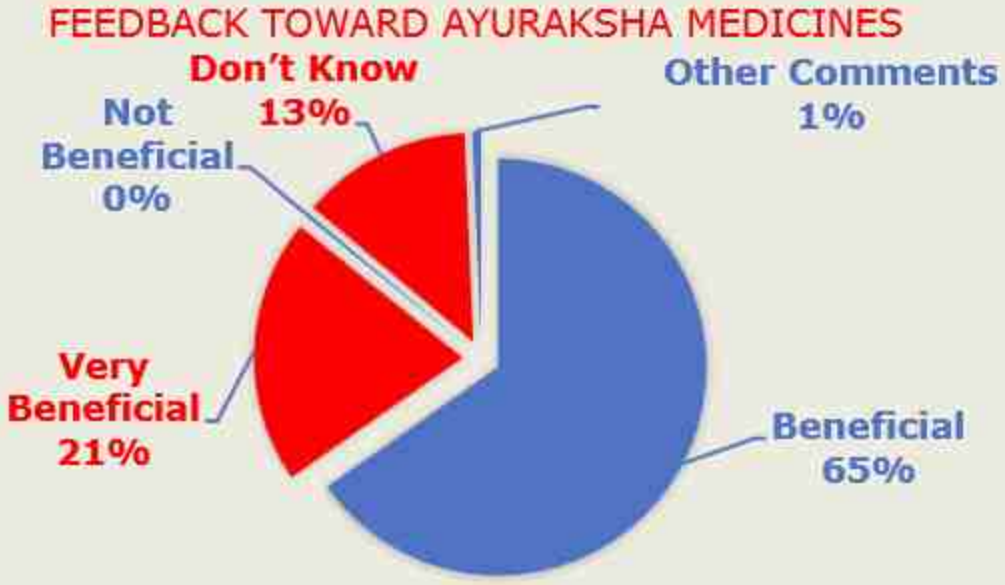
Mortality among Delhi Police was recorded 0.44% compared to 0.95 in general population (Age specific mortality rate)

Delhi Police recorded less incidence and mortality compared to Karnataka, Kolkatta and Mumbai Police

In online survey taken among Delhi Police Personnel, 21% of Delhi Police Personnel found it very beneficial & 65% found it beneficial

Evaluation of the immuno-stimulatory potential of Ayurveda management protocol in cohort of Delhi police - An exploratory study

(कोरोना से जंग दिल्ली पुलिस के संग) (Cont.)



87% of Delhi Police Personnel found it beneficial; (n=56713)

A Study of Ashwagandha in the Prophylaxis against COVID-19 in high risk Healthcare Workers compared to Hydroxychloroquine Sulphate: A Randomized Controlled trial
(AYUSH-CRD collaborative study)

Brief of study

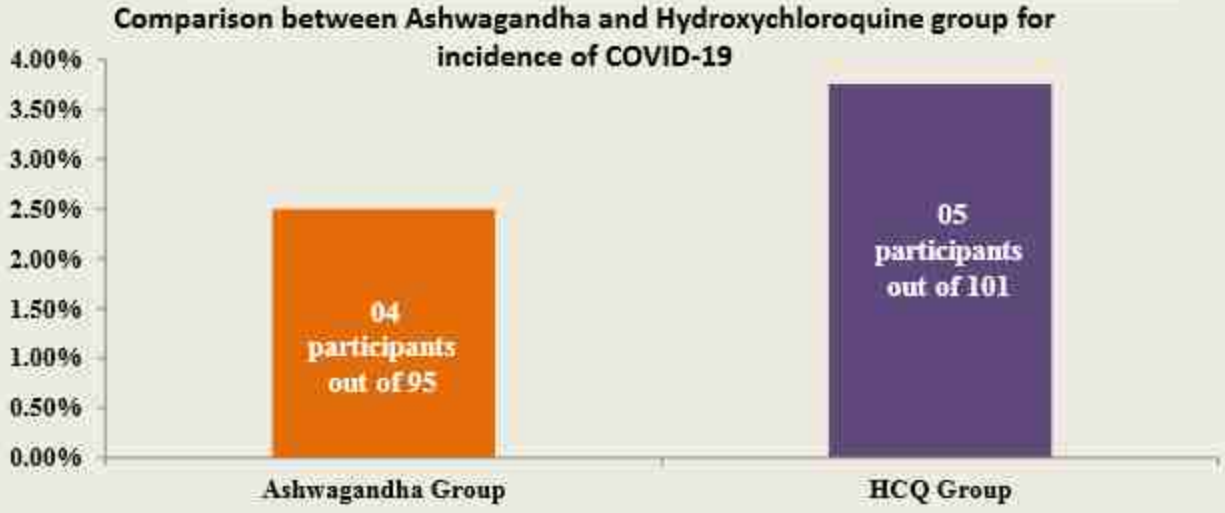
Trial Site: DMIMS Wardha, CARI Mumbai and SDMA&CH Hassan

Sample Size: 400

Study outcomes

Ashwagandha is non-inferior to Hydroxychloroquine in terms of chemoprophylaxis against COVID-19

Ashwagandha has a superior safety profile as significantly more AE in the HCQ group compared to Ashwagandha.




Elsevier Public Health Emergency Collection

Withania somnifera as a Safer Option to Hydroxychloroquine in the Chemoprophylaxis of COVID-19: Results of Interim Analysis

Associated Data

Abstract

Objectives

Published Study Results of Interim Analysis in reputed journal

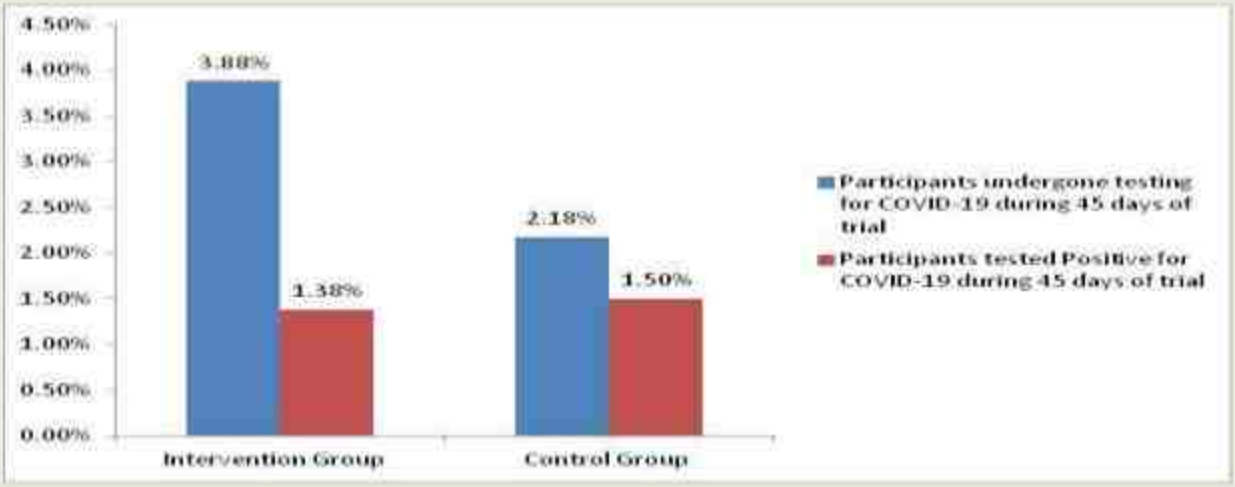
A prospective open label controlled interventional study on the effect of *Ayurvedic* intervention *(Ayurveda Raksha Kit)* as a prophylactic measure in the Pandemic of COVID-19 - A community based study

- **Study site:** 20 peripheral institutes of CCRAS
- **Sample Size: Ayurveda group: 1,78,000; Control group:22000**

- **Control Group**- Standard preventive measures for COVID-19
- **Intervention group- *'Ayurveda Raksha Kit'*** (**Chyawanprash**- 6 gm OD, **Ayush kwath** 50 ml OD, **Samshamani Vati**- 250mg BD, **Anu taila** for instillation BD) along with Standard preventive measures for COVID-19
- **Intervention period:** 1 month

- **Lower incidence of COVID-19 symptoms in the Ayurveda intervention group observed** during each of the follow-up visits

	Ayurveda Group	Control Group
Participants undergone testing for COVID-19 during 45 days of trial	5900 out of 151893 (3.88%)	465 out of 21309 (2.18%)
Participants tested Positive for COVID-19 during 45 days of trial	82 out of 5900 **(1.38%)**	7 out of 465 **(1.50%)**



Impact of the Ayurvedic formulation as add-on to standard of care in COVID-19 patients in a Tertiary Hospital

Study brief

Site: Medanta Hospital, Gurugram

Interventions: Guduchi + Pippali as add-on to standard care

Sample size: 60 (30 in trial group and 30 in control group)

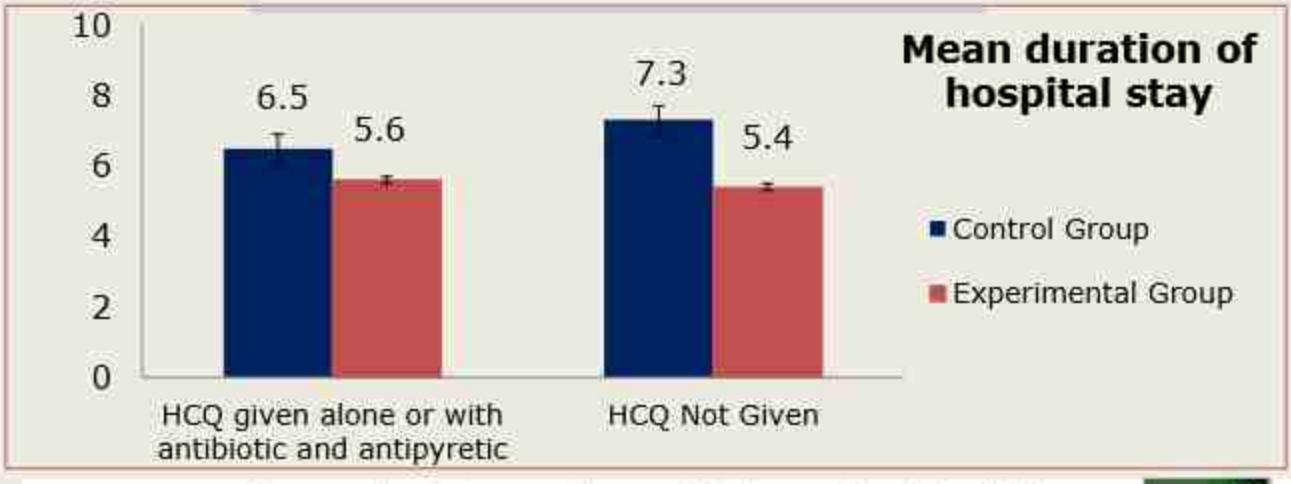
Study Outcomes

No patient progress to critical stage of COVID-19 in the Ayurveda add-on group.

All patients in Ayurveda add-on group turned asymptomatic by 6th day as compared to 40% in the control group.

Mean duration of hospital stay of patients was less in Ayurveda add-on group compared to control group

No case of drug-herb interaction reported



Journal of Ayurveda and Integrative Medicine
Available online 10 June 2021
In Press, Journal Pre-proof

Original Research Article

A Pilot Clinical study of an add on Ayurvedic formulation containing *Guduchi* and *Pippali* in mild to moderate Covid - 19

Impact assessment of effectiveness, acceptance and usage of AYUSH advisories & measures in prevention of COVID 19: A mobile app based population study

The responses categorized as under:

- **Physician (feedback submitted for patients): 1,35,21,245**
- **Public Feedback: 7,23,459**
- **Physician feedback (self): 74,567**

Study Outcomes

- **85.1% of the respondents reported use of AYUSH measures**
- **89.8% respondents agreed to have benefitted** from the practice of AYUSH advisory**.**
- **79.1% of the users responded that the AYUSH measures gave an overall feeling of good health.**
- **63.4% reported improvement in parameters of wellbeing** like sleep, appetite, bowel habits**,** stamina and mental wellbeing**.**

Original Paper

Mobile App–Reported Use of Traditional Medicine for Maintenance of Health in India During the COVID-19 Pandemic: Cross-sectional Questionnaire Study

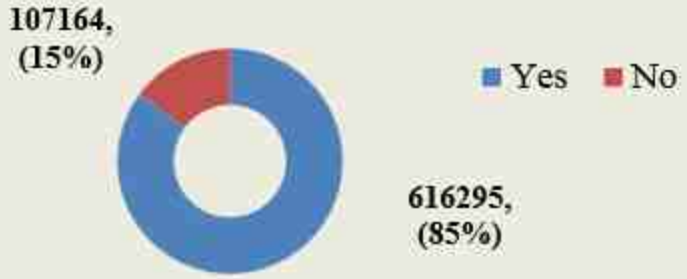
N Srikanth[1*], MD; Rakesh Rana[1*], MSc, MCA, PhD; Richa Singhal[1*], MSTAT, PhD; Sophia Jameela[1*], MD; Rajeshwari Singh[1*], MD; Shruti Khanduri[1], MD; Arunabh Tripathi[1*], MSc, PhD; Sumeet Goel[1*], MD; Leena Chhatre[2*], MD; Ashwin Chandra[2*], MD; B C S Rao[1*], MD; K S Dhiman[1], MD, PhD

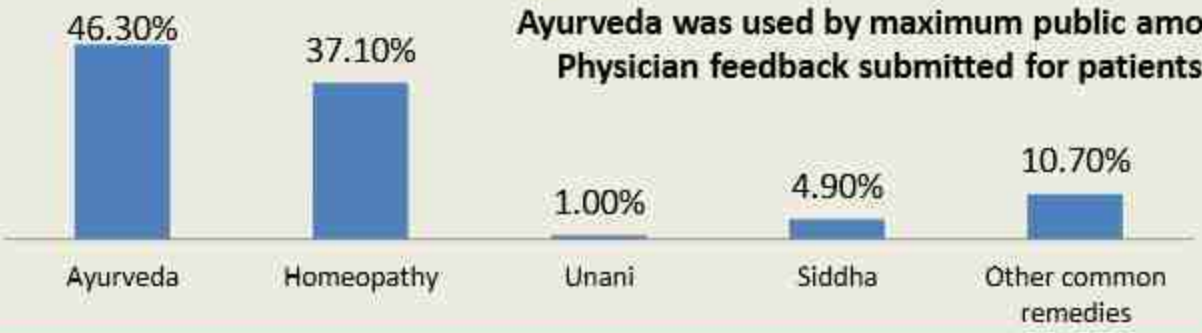
[1]Central Council for Research in Ayurvedic Sciences, Ministry of AYUSH, Delhi, India

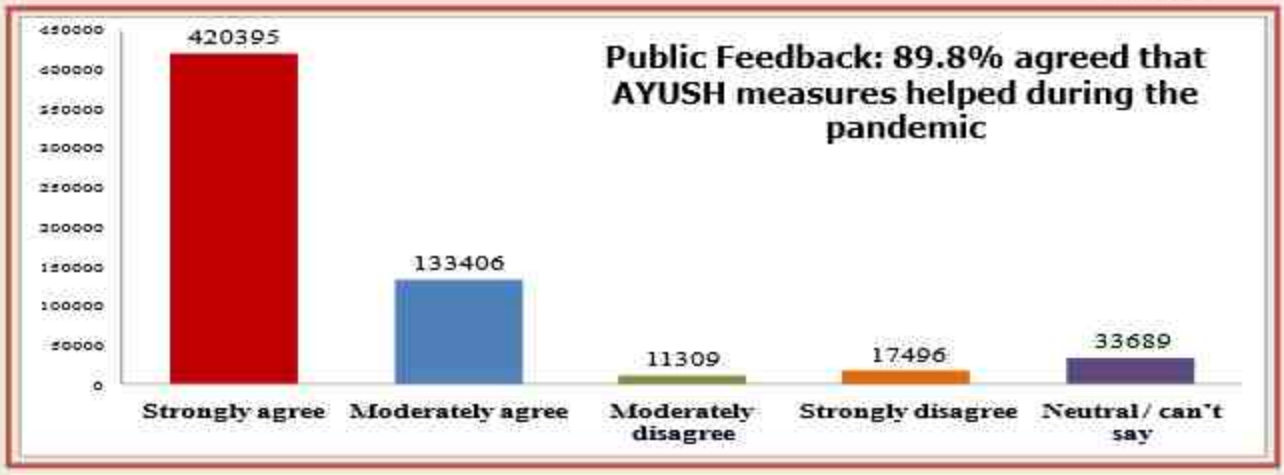
[2]Ministry of AYUSH, Government of India, Delhi, India

*these authors contributed equally

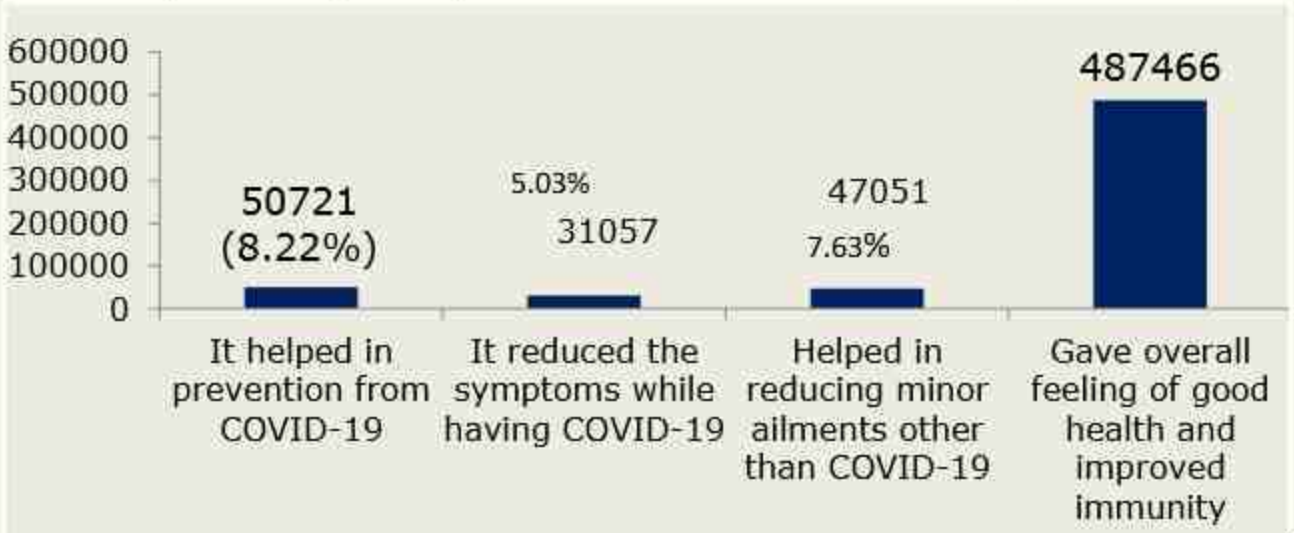
Among public feedbacks received (n- 723459), usage of AYUSH based preventive measures for COVID - 19







Response of participants submitted by AYUSH Physicians



Intranasal administration of *Anu oil* results in low lung viral load in hamster SARS-CoV2 infection model

To understand the protective efficacy of Anu Taila against SARS-CoV-2 infection in hamster was studies in collaboration with DBT and compared with Remdesivir

Lungs isolated from the euthanized animals on day 4 post challenge showed lesser regions of pneumonitis and inflammation

Hamsters receiving intranasal Anu oil (AO) did not lose body weight as compared to the SARS-CoV-2 infected (I) hamsters and mimicked the percentage mass change of the unchallenged control (UI)

frontiers in Pharmacology

ORIGINAL RESEARCH

Effect of Prophylactic Use of Intranasal Oil Formulations in the Hamster Model of COVID-19

Zaigham Abbas Rizvi[1], Manas Ranjan Tripathy[1], Nishant Sharma[2], Sandeep Goswami[1], N Srikanth[3], J. L. N. Sastry[4], Shailendra Mani[5], Milan Surjit[2], Amit Awasthi[1] and Madhu Dikshit[5]**

[1]Immuno-biology Laboratory, Infection and Immunology Centre, Translational Health Science and Technology Institute, NCR-Biotech Science Cluster, Faridabad, India, [2]Infection and Immunology Centre, Translational Health Science and Technology Institute, NCR-Biotech Science Cluster, Faridabad, India, [3]DG(H), Central Council for Ayurvedic Sciences, New Delhi, India, [4]CEO National Medicinal Plants Board, Ministry of AYUSH, New Delhi, India, [5]Non-communicable Disease Centre, Translational Health Science and Technology Institute, NCR-Biotech Science Cluster, Faridabad, India

Severe acute respiratory syndrome coronavirus 2 (SARS-CoV2) infection initiates with viral entry in the upper respiratory tract, leading to coronavirus disease 2019 (COVID-19). Severe COVID-19 is characterized by pulmonary pathologies associated with respiratory failure. Thus, therapeutics aimed at inhibiting the entry of the virus or its internalization in the upper respiratory tract are of interest. Herein, we report the prophylactic application of two intranasal formulations provided by the National Medicinal Plant Board (NMPB), Anu oil and til tailya, in the hamster model of SARS-CoV-2 infection. Prophylactic intra-nasal instillation of these oil formulations exhibited reduced viral load in lungs and resulted in reduced body weight loss and lung-pneumonitis. In line with reduced viral load, histopathological analysis revealed a reduction in lung pathology in the Anu oil group as compared to the control infected group. However, the til tailya group did not show a significant reduction in lung pathology. Furthermore, molecular analysis using mRNA expression profiling indicated reduced expression of pro-inflammatory cytokine genes, including Th1 and Th17 cytokines for both the intranasal formulations as a result of decreased viral load. Together, the prophylactic intranasal application of Anu oil seems to be useful in limiting both viral load and severity in SARS-CoV2 infection in the hamster model.

Keywords: COVID-19, intranasal, herbal, AYUSH, prophylactic

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Edited by:
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Specialty section:
This article was submitted to Experimental Pharmacology and Drug Discovery,

Intranasal administration of *Anu oil* results in low lung viral load in hamster SARS-CoV2 infection model (Cont.)

Splenomegaly, which is another clinical parameter of SARS-CoV2 associated pathology in hamster, showed significant mitigation in Anu oil group.

Anu taila showed better result in combating the effect of SARS-CoV-2 infection as seen by low viral load in lungs in the Golden Syrian hamsters challenged with SARS-CoV-2.

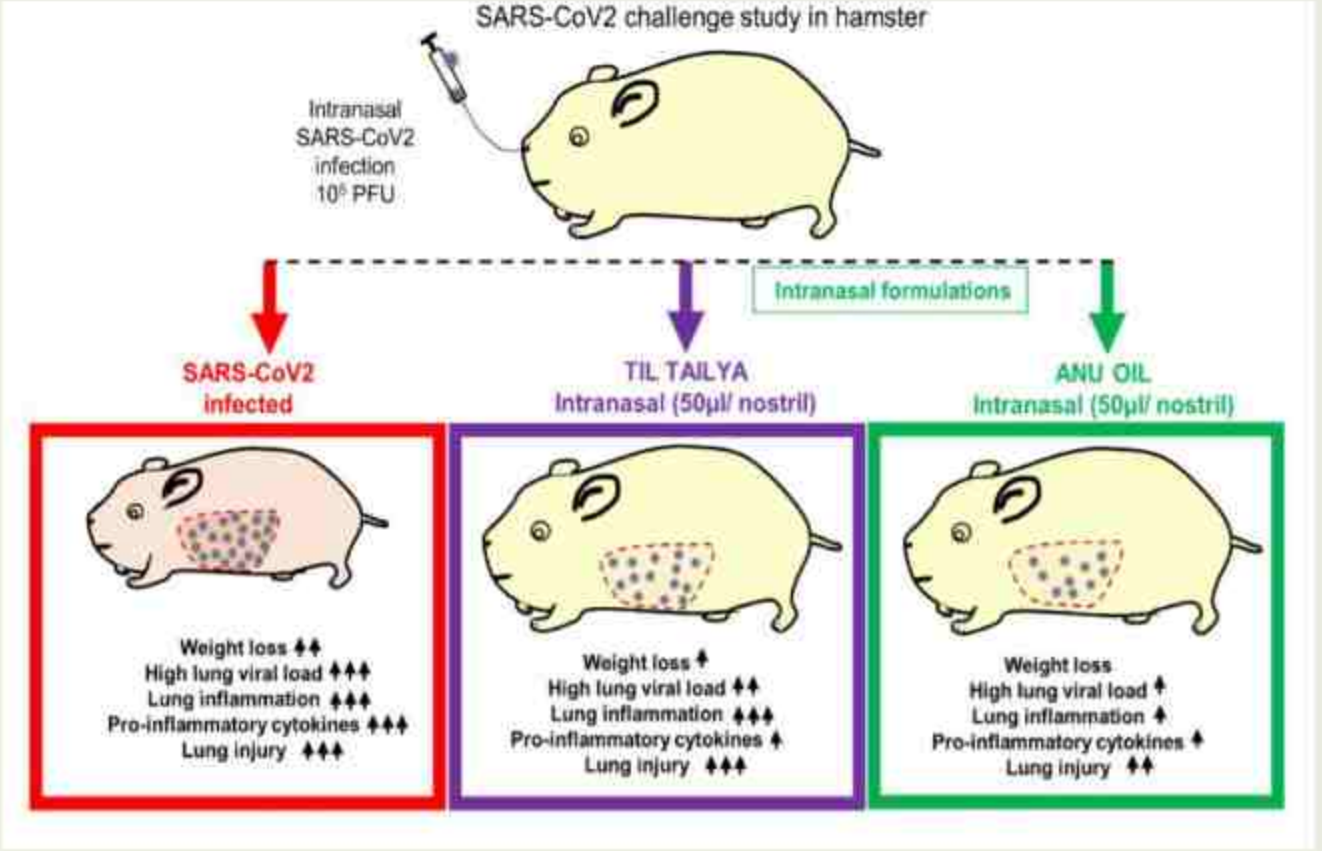

Fig: Depiction of protective effect of Anu Tail Nasya on Weight loss, Viral load in lungs, inflammatory markers and Lung injury

Significant protection is seen in all parameters

In-silico study of RdRp and Mpro of SARS-CoV-2 to find its inhibitor from the ingredients of AYUSH Kwath (kadha)

- **Study Site:** IIT Varanasi (BHU)
- Main protease (M^{pro}) and RNA dependent RNA polymerase (RdRp) are used as a potential targets for screening the herbal compound.
- The study involves the use of computational tools to analyze ligands, and SARS-Cov-2 proteins target M^{pro} and RdRp.
- **Study Outcomes**

  The study showed Beta-Sitosterol as common and potential inhibitors of M^{pro} and RdRP in the ingredients of AYUSH Kwatha

Table: **Molecular docking results of compounds from herbal sources with the RdRp and M^{pro} of Covid-19.**

Compounds	Sources of compound	Binding energy (Kcal/mol)	
		Mpro	RdRp
Inhibitor N3 (standard)	Chemical	-5.42	-
Remdesivir (standard)	Chemical	-	-2.94
Curcumene	Ginger	-6.36	-4.98
Humulene	Black pepper, Cinnamon	-6.11	-4.53
Selinene	Black pepper, Cinnamon	-6.53	-5.63
Astragalin	Black pepper	-7.75	-5.02
Bisabolene	Black pepper	-6.72	-5.13
Carvacrol	Tulsi	-5.16	-5.27
Eugenol	Tulsi, Cinnamon	-4.92	-5.00
Gingerol	Ginger	-6.05	-4.37
Shogaol	Ginger	-6.33	-4.86
Zingiberene	Ginger	-6.94	-5.24
Phellandrene	Ginger, Cinnamon	-5.42	-4.71
Pinene	Ginger, Cinnamon	-5.64	-4.75
Beta-Sitosterol	Tulsi, Cinnamon	-9.58	-6.11

Clinical outcome of Ayurveda treatment on COVID -19 patients: a retrospective cohort study

Site: Samaras COVID care center, Ahmedabad, Gujarat

Study interventions: Along with conventional care, Ayurveda protocol comprising of *Dashamula+Pathyadi kwatha with Trikatu, Sanshamani* vati, AYUSH -64 tablet, and *Yastimadhu Ghana* tablet. (till discharge) (n=541 analyzed)

Study period: 15th April 2020 to discharged or referred up to 31st May 2020

Study Outcomes: **Incidence of COVID-19 symptoms and duration of symptomatic phase** were less in the Ayurveda add-on group.

Published in reputed Journal

Integrative medicine in COVID-19- Original Article

Journal of Evidence-Based Integrative Medicine
Volume 26: 1-7
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Add-on Ayurveda Treatment for Early Stage COVID-19: A Single Center Retrospective Cohort Study From Gujarat, India

Anup Thakar, PhD[1], Kalpesh Panara, PhD[1], Falgun Patel, MD (Ayu)[2], Shital Bhagiya, PhD[3], Mandip Goyal, PhD[1], Sagar Bhinde, MD (Ayu)[1], Swapnil Chaudhari, PhD[1], and Sarika Chaturvedi, PhD[4]

Abstract

The retrospective cohort study aimed to evaluate the clinical outcomes of Ayurveda treatment exposure as an add-on to conventional care in early stage COVID-19 patients admitted at Samaras COVID care center, Ahmedabad, India. Conventional care included Vitamin-c, Azithromycin, and Paracetamol. Ayurveda formulations used as add-on were *Dashamula* and *Pathyadi* decoctions along with *Trikatu* powder, *Sanshamani* tablet, AYUSH-64 tablet AND *Yastimadhu Ghana* tablet for oral administration. Considering Add-on Ayurveda medicines as exposure of interest, patients who received Add-on Ayurveda medicines at least for 7 days were included in the exposed group while those who received only conventional care in unexposed group. Data was collected through record review and telephonic interviews. The outcomes of interest were the development of symptoms, duration of symptomatic phase in those progressing to symptomatic stage and mortality. Total 762 participants were included-[541 (71%) in the exposed group and 221 (29%) in the unexposed. Progression to symptomatic phase did not differ significantly between groups [27.6% in exposed, 24.6% in unexposed, adjusted RR 0.85; 95% CI 0.6-1.2]. The total duration of symptomatic phase among those progressing to the symptomatic stage was significantly decreased in the exposed group ($\bar{x} = 3.66 \pm 1.55$ days in exposed ($n = 133$); $\bar{x} = 5.34 \pm 3.35$ days in unexposed ($n = 61$), $p < 0.001$). No mortality was observed in either of the groups. Ayurveda Treatment as adjunctive to conventional care reduced the duration of symptomatic phase in early stage COVID-19 as compared to standalone conventional care. Add-on Ayurveda treatment has promising potential for management of early stage COVID-19.

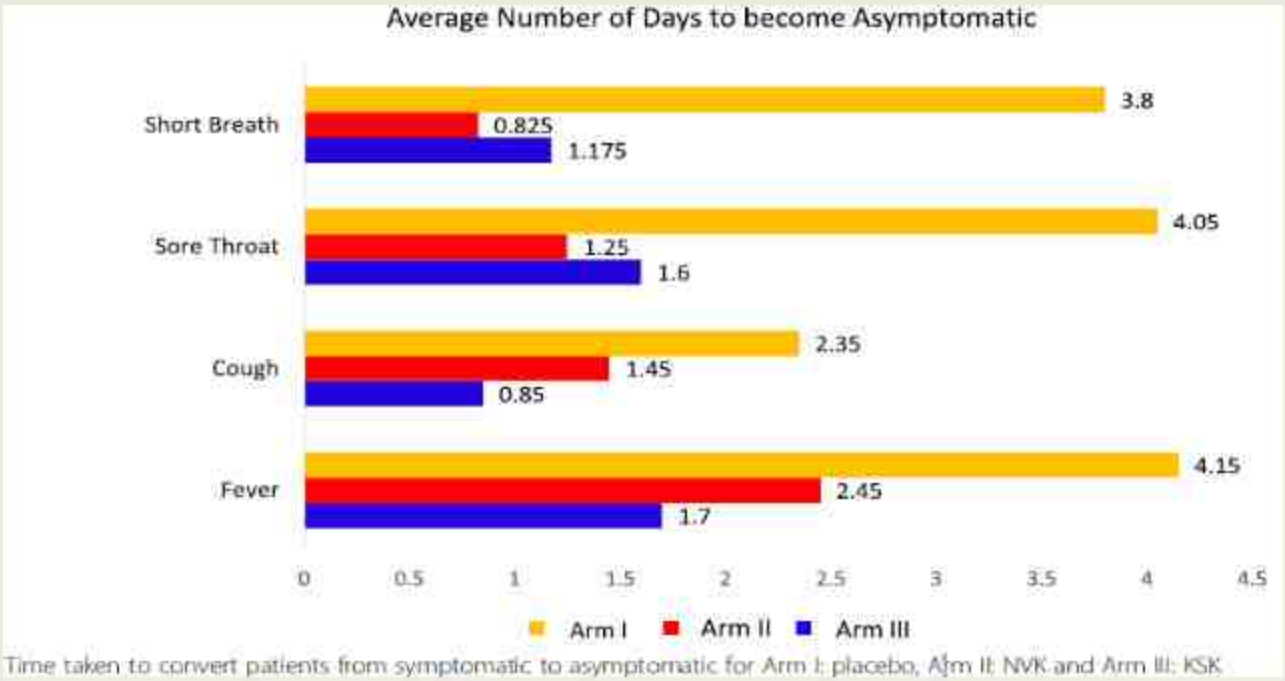
Siddha interventions along with standard of care in mild to moderate COVID-19

Study Site: Government Institute of Medical Sciences, Greater Noida, Uttar Pradesh

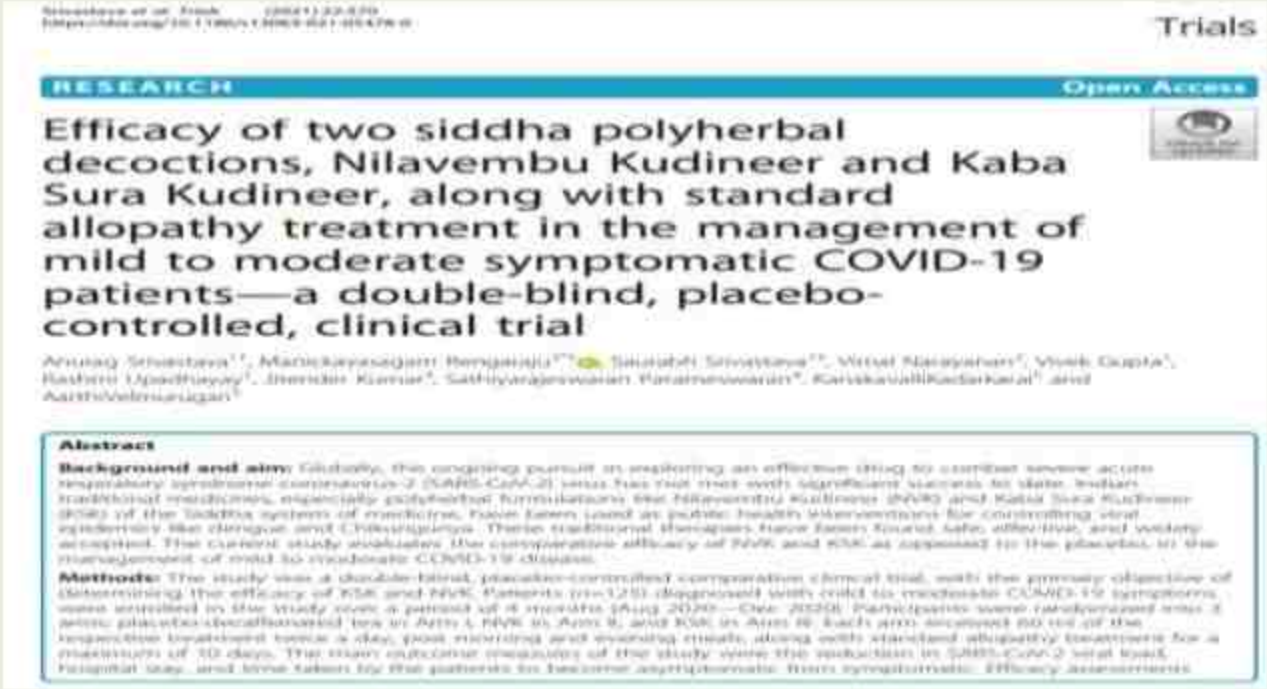
Study Design: Randomized double-blind placebo-controlled trial

Sample Size: 125

Intervention: Nilavembu Kudineer and Kabasura Kudineer along with SOC



Time taken to convert patients from symptomatic to asymptomatic for Arm I: placebo, Arm II: NVK and Arm III: KSK



Trials

RESEARCH Open Access

Efficacy of two siddha polyherbal decoctions, Nilavembu Kudineer and Kaba Sura Kudineer, along with standard allopathy treatment in the management of mild to moderate symptomatic COVID-19 patients—a double-blind, placebo-controlled, clinical trial

Abstract

Background and aim: Globally, the ongoing pursuit on exploring an effective drug to combat severe acute respiratory syndrome coronavirus-2 (SARS-CoV-2) virus has not met with significant success to date. Indian traditional medicines, especially polyherbal formulations like Nilavembu Kudineer (NVK) and Kaba Sura Kudineer (KSK) of the Siddha system of medicine, have been used as public health interventions for controlling viral epidemics like dengue and Chikungunya. These traditional therapies have been found safe, effective, and widely accepted. The current study evaluates the comparative efficacy of NVK and KSK as opposed to the placebo in the management of mild to moderate COVID-19 disease.

Methods: The study was a double-blind, placebo-controlled comparative clinical trial, with the primary objective of determining the efficacy of KSK and NVK. Patients (n=125) diagnosed with mild to moderate COVID-19 symptoms were enrolled in the study over a period of 4 months (Aug 2020—Dec 2020). Participants were randomized into 3 arms: placebo (decoction mixed tea in Arm I, NVK in Arm II, and KSK in Arm III. Each arm received 60 ml of the respective treatment twice a day, post morning and evening meals, along with standard allopathy treatment for a maximum of 10 days. The main outcome measures of the study were the reduction in SARS-CoV-2 viral load, hospital stay, and time taken for the patients to become asymptomatic from symptomatic. Efficacy assessments

In Silico computational screening of Kabasura Kudineer - Official Siddha Formulation and JACOM against SARS-CoV-2 spike protein

Cresset Flare software was used for molecular docking studies against the spike protein SARSCoV-2.

Also conducted in silico prediction studies on the **pharmacokinetics** (ADME) properties and the **safety profile** using online pkCSM and SwissADME web servers.

Totally 37 compounds were screened, of these **9 compounds showed high binding affinity against SARS-CoV-2** spike protein.

All the phytoconstituents were free from carcinogenic and tumorigenic properties


Contents lists available at ScienceDirect

Journal of Ayurveda and Integrative Medicine

journal homepage: http://elsevier.com/locate/jaim

Original Research Article (Experimental)

In Silico computational screening of *Kabasura Kudineer* - Official Siddha Formulation and JACOM against SARS-CoV-2 spike protein

Gangarapu Kiran [a,1], L. Karthik [b,1], M.S. Shree Devi [c,*], P. Sathiyarajeswaran [c],

Efficacy of Pranayama in Preventing COVID-19 in Exposed Healthcare Professionals: A Randomized Controlled Trial

250 participants, comprising 123 in the intervention group and 127 in the control group, completed the study.

Only one participant in the Intervention group tested positive, while 9 participants in the control group

Two Pranayama modules, 30 minutes for the morning and 15 minute for the evening

Funded by MDNIY, Ministry of Ayush. Study done by Director MDNIY, Dr Rakesh Sarval, Additional Secretary NITI Ayog and scientists from Lady Hardinge Medical College, New Delhi and AIIMS New Delhi

Publication of Research Outcomes

MoA constituted an Advisory panel to facilitate AYUSH researchers in disseminating the outcomes of the research studies on COVID-19 through scientific publications in journals of high repute.

The panel include eminent researchers and senior faculty of various disciplines

Manuscripts drafted: 84

Manuscripts published: 28 including 03 Case Reports, 03 Study Protocols and 02 Editorials

Manuscripts Accepted for Publication – 08

Manuscripts submitted to indexed Journals- 43

Manuscripts available as Preprints – 27

Further Initiatives

The Ministry is in consultation with experts to visualise Ayush preparedness and initiatives for future preparedness for addressing the challenge of COVID-19

Research initiatives	Initiated clinical trial titled "**A study of Ashwagandha administration in participants vaccinated againstCOVID-19 on safety, immunogenicity, and protection: A randomized, double blind, placebo controlled, multi-centric clinical trial**" to explore the safety and immunogenicity of Ashwagandha in people who received COVISHIELD vaccine.
	Initiated project titled "**Assessment of integration of AYUSH into the public health system for combating COVID 19**" in collaboration with **PHFI, sponsored by WHO**
	A research study titled "A Randomized control trial to evaluate the efficacy of Ayurvedic interventions (Agastya Haritaki and Ashwagandha) and Yoga in **long term effects of COVID-19**" to explore the efficacy of Ayurveda interventions and Yoga on Post COVID-19 sequel.
	Initiated clinical trial titled "The impact of **Chyawanprash on immunogenicity when administered after COVID-19 vaccination** in health care personnel - An open-label, prospective randomized controlled study"
	Constitution of the Interdisciplinary Technical Review Committee (ITRC) to examine the applications/claims on patent and proprietary ASU&H medicines/classical ASU&H medicines with new indication or re-purposing of licensed patent and proprietary, ASU&H medicines for COVID-19. The committee reviews applications in the light of quality standards, preclinical safety requirements of the drug(s), and clinical efficacy with appropriate rationale

Research Publications

List of Published Articles

(20 Original Research; 03 Case reports; 03 Study Protocols; 02 Editorial)

1. Srikanth N, Rana R, Singhal R, et al. Mobile App-Reported Use of Traditional Medicine for Maintenance of Health in India during the COVID-19 Pandemic: Cross-sectional Questionnaire Study. *JMIRx Med.* 2021;2(2):e25703. Published 2021 May 7. doi:10.2196/25703 (Pg no. 58-59)

2. Ram TS, Munikumar M, Raju VN, et al. *In silico* evaluation of the compounds of the ayurvedic drug, AYUSH-64, for the action against the SARS-CoV-2 main protease [published online ahead of print, 2021 Feb 25]. *J Ayurveda Integr Med.* 2021:10.1016/j.jaim.2021.02.004. (Pg no. 60)

3. Kataria S, Sharma P, Ram JP, et al. A Pilot Clinical study of an add on Ayurvedic formulation containing *Guduchi* and *Pippali* in mild to moderate Covid- 19 [published onlineahead of print, 2021 Jun 10]. *J Ayurveda Integr Med.* 2021:10.1016/j.jaim.2021.05.008. (Pg no. 61-62)

4. Nesari TM, Bhardwaj A, ShriKrishna R, et al. Neem (Azadirachta Indica A. Juss) Capsules for Prophylaxis of COVID-19 Infection: A Pilot, Double-Blind, Randomized Controlled Trial [published online ahead of print, 2021 Apr 23]. *Altern Ther Health Med.* 2021: AT6831. (Pg no. 63)

5. Kiran G, Karthik L, Shree Devi MS, et al. In Silico computational screening of Kabasura Kudineer - Official Siddha Formulation and JACOM against SARS-CoV-2 spike protein [published online ahead of print, 2020 May 25]. *J Ayurveda Integr Med.* 2020;S0975- 9476(20)30024-3. doi:10.1016/j.jaim.2020.05.009 (Pg no. 64)

6. Yadav B, Rai A, Mundada PS, *et al.* Safety and efficacy of Ayurvedic interventions and Yoga on long term effects of COVID-19: A structured summary of a study protocol for a randomized controlled trial. *Trials* 2021; 22:378. https://doi.org/10.1186/s13063-021-05326- 1 (Pg no. 65-66)

7. Natarajan S, Anbarasi C, Sathiyarajeswaran P, et al. The efficacy of Siddha Medicine, Kabasura Kudineer (KSK) compared to Vitamin C & Zinc (CZ) supplementation in the management of asymptomatic COVID-19 cases: A structured summary of a study protocol for a randomised controlled trial. Trials 2020; 21:892. (Pg no. 67-68)

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1. A Retrospective Study on Efficacy and Safety of Guduchi Ghan Vati for Covid-19 Asymptomatic Patients. https://www.medrxiv.org/content/10.1101/2020.07.23.20160424v1 (Pg no. 95-96)

2. Chyawanprash for the prevention of COVID-19 infection among healthcare workers: ARandomized Controlled Trial. https://www.medrxiv.org/content/10.1101/2021.02.17.21251899v2 [Published in peer reviewed Journal mentioned at Sr. No. 26 in the list of published articles]

3. Guduchi Ghanavati to Improve Immune Status and General Health in the Population at HighRisk of COVID-19: Results of An Open-Label Non-Randomized Clinical Trial from India. https://europepmc.org/article/ppr/ppr296363 (Pg no. 97)

4. In-Vitro Immunomodulatory Activity and Thrombolytic Potential of Kabasura Kudineer (KSK), an Official Siddha Polyherbal Formulation. https://ssrn.com/abstract=3670659 (Pg no. 98-99)

5. Repurposing of Medicinal plants used in Siddha formulations as Potential Protease Inhibitors of COVID-19: An in silico approach. https://ssrn.com/abstract=3650390 (Pg no. 100-101)

6. Coadministration of AYUSH 64 as an adjunct to Standard of Care in mild and moderate COVID-19: A randomised, controlled, multicentric clinical trial https://www.medrxiv.org/content/10.1101/2021.06.12.21258345v1 (Pg no. 102-103)

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8. Efficacy of AYUSH 64 as add-on therapy in early stage COVID 19 - An open-label randomized controlled pilot study. https://osf.io/t8wza/ (Pg no. 104-105)

9. Efficacy and safety of Guduchighan Vati in asymptomatic and mild to moderate cases ofCOVID-19: A randomized controlled pilot study. https://osf.io/c8f9h (Pg no. 106-107)

10. AYUSH-64 as add-on to standard care in asymptomatic and mild cases of COVID-19: Arandomized controlled trial. https://osf.io/pgraf/ (Pg no. 108-109)

11. Perception and practices followed by AYUSH practitioners and health seekers for prevention of COVID-19: Cross-sectional analysis of an app-based data. https://osf.io/b6jqv/ (Pg no. 110)

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13. Efficacy of Pranayama in Preventing COVID-19 in Exposed Health careProfessionals: A Randomized Controlled Trial. https://osf.io/c3qub/ (Pg no. 114-116)

14. A Retrospective analysis of Ayurvedic clinical management of symptomatic COVID-19 patients. https://osf.io/zxktu (Pg no. 117)

15. Neem (Azadirachta Indica A. Juss) Capsules for Prophylaxis of COVID-19 Infection: A Pilot, Double-Blind, Randomized Controlled Trial. https://ayushportal.nic.in/pdf/books/6831.pdf [Published in peer reviewed Journal mentioned at Sr. No. 2 in the list of published articles]

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18. Utilization of AYUSH advocacies and measures in the Indian population for the prevention of COVID-19: Insights from a mobile application https://preprints.jmir.org/preprint/25703 [Published in peer reviewed Journal mentioned at Sr. No. 3 in the list of published articles]

19. Add-on Ayurveda Treatment for early stage COVID-19: A single centre retrospective cohortstudy from Gujarat, India. https://osf.io/2ta3j/ [Published in peer reviewed Journal mentioned at Sr. No. 4 in the list of published articles]

20. Randomized, double blind, placebo controlled, clinical trial to study co-administration of Ashwagandha on safety, immunogenicity, and protection with COVID-19 vaccine – A Study Protocol. https://www.medrxiv.org/content/10.1101/2021.07.02.21259886v1 (Pg no. 118-119)

21. AYUSH-64 as an adjunct to Standard Care in mild to moderate COVID-19: An open- label randomized controlled trial in Chandigarh, India. https://osf.io/xyuas/ (Pg no. 120-121)

22. Effect of an Ayurvedic intervention (Ayush-64) in mild to moderate COVID-19: An exploratory prospective single arm clinical trial. https://osf.io/azb9t/ (Pg no. 122)

Original Paper

Mobile App–Reported Use of Traditional Medicine for Maintenance of Health in India During the COVID-19 Pandemic: Cross-sectional Questionnaire Study

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Authors' Response to Peer-Review Reports: https://med.jmirx.org/2021/2/e29626/

Abstract

Background: India follows a pluralistic system for strategic and focused health care delivery in which traditional systems of medicine such as Ayurveda, yoga and naturopathy, Unani, Siddha, Sowa Rigpa, and homoeopathy (AYUSH) coexist with contemporary medicine, and this system functions under the Ministry of AYUSH (MoA). The MoA developed a mobile app, called AYUSH Sanjivani, to document the trends of the use of AYUSH-based traditional and holistic measures by the public across India. Analysis of the data generated through this app can help monitor the extent of the use of AYUSH measures for maintenance of health during the COVID-19 pandemic and aid effective health promotion and communication efforts focused on targeted health care delivery during the pandemic.

Objective: The purpose of the study was to determine the extent of use of AYUSH measures by the public in India for maintenance of health during the COVID-19 pandemic as reported through the AYUSH Sanjivani mobile app.

Methods: Cross-sectional analysis of the data generated through the Ayush Sanjivani app from May 4 to July 31, 2020, was performed to study the pattern and extent of the use of AYUSH-based measures by the Indian population. The responses of the respondents in terms of demographic profile, use pattern, and benefits obtained; the association between the use of AYUSH-based measures and symptomatic status; and the association between the duration of use of AYUSH-based measures and the outcome of COVID-19 testing were evaluated based on bivariate and multivariate logistic regression analysis.

Results: Data from 723,459 respondents were used for the analysis, among whom 616,295 (85.2%) reported that they had been using AYUSH measures for maintenance of health during the COVID-19 pandemic. Among these 616,295 users, 553,801 (89.8%) either strongly or moderately agreed to have benefitted from AYUSH measures. Ayurveda and homeopathic measures and interventions were the most preferred by the respondents across India. Among the 359,785 AYUSH users who described their overall improvement in general health, 144,927 (40.3%) rated it as good, 30,848 (8.6%) as moderate, and 133,046 (40.3%) as slight. Respondents who had been using AYUSH measures for less than 30 days were more likely to be COVID-19–positive

among those who were tested (odds ratio 1.52, 95% CI 1.44-1.60). The odds of nonusers of AYUSH measures being symptomatic if they tested positive were greater than those of AYUSH users (odds ratio 4.01, 95% CI 3.61-4.59).

Conclusions: The findings of this cross-sectional analysis assert that a large proportion of the representative population practiced AYUSH measures across different geographic locations of the country during the COVID-19 pandemic and benefitted considerably in terms of general well-being, with a possible impact on their quality of life and specific domains of health.

(JMIRx Med 2021;2(2):e25703) doi: 10.2196/25703

KEYWORDS

AYUSH Sanjivani app; COVID-19; traditional medicine; Ayurveda; Siddha; Unani; homeopathy

Introduction

Coronaviruses, a large family of single-stranded RNA viruses, can infect animals and humans, causing respiratory, gastrointestinal, hepatic, and neurologic diseases [1]. To date, 6 human coronaviruses (HCoVs) have been identified, including the alpha coronaviruses HCoVs-NL63 and HCoVs-229E and the beta coronaviruses HCoVs-OC43, HCoVs-HKU1, and severe acute respiratory syndrome coronavirus (SARS-CoV) [2]. New coronaviruses appear to emerge periodically in humans owing to the high prevalence and wide distribution of coronaviruses, the large genetic diversity and frequent recombination of their genomes, and the increase of human-animal interface activities [3]. The first case of COVID-19 in India was reported on January 31, 2020 [4]. The World Health Organization observed that with appropriate integration, traditional medicine would be a significant option to balance curative services with preventive care, which can help address the unique health challenges of the 21st century [5].

Clinical evidence from a study on the effects of Chinese traditional medicine in the treatment of SARS-CoV-2 demonstrated significant results, and the study proposed that herbal medicine has a beneficial effect in the treatment and prevention of epidemic diseases [6]. A Cochrane systematic review in this area reported that herbal medicine combined with western medicine may improve symptoms and quality of life in SARS-CoV patients [7]. The National Health Commission in China has declared the use of herbal medicine combined with contemporary medicine as a treatment for COVID-19 and has issued many guidelines on herbal medicine–related therapy [8]. The acronym AYUSH stands for Ayurveda, yoga and naturopathy, Unani, Siddha, and homeopathy; these indigenous systems of medicine are practiced in India under the Ministry of AYUSH (MoA). Considering the present scenario and penetration of the AYUSH system into the mainstream health care system in India for preventive and curative purposes, the MoA released an advisory to the public for maintenance of general health and well-being during the COVID-19 pandemic on March 6, 2020 [9]. Although India is a country that follows a pluralistic approach to health care, data regarding the use of traditional systems of medicine or health-seeking trends of people are not available in the public domain. There are reports in the press regarding the use of AYUSH prophylactic measures for COVID-19 [10] as well as for lifestyle and other diseases; however, the extent of their use and the outcomes and benefits obtained are not known. Health care delivery, as well as research in times of natural disasters and epidemics or pandemics, is challenging [11]. The concept of infodemiology has evolved significantly with the ever-increasing penetration of the internet in society and is being efficiently being used to nowcast epidemics, quantify the different trends in epidemics, and document and synthesize data on the use of health care services and other public health–related issues [12,13].

The government of India has taken the initiative to use and integrate the preventive, curative, and rehabilitative potential of AYUSH systems of medicine to strengthen the health care delivery system, and the AYUSH Sanjivani app was developed through a consultative process among experts in the field of AYUSH and information technology (IT) by the MoA to record the patterns and trends of the use of preventive measures adopted by the public to enhance immunity and maintain health during the COVID-19 pandemic. The AYUSH Sanjivani app was intended to motivate and persuade users to achieve a status of healthy well-being while thwarting the tendency of the masses to use untested and unproven remedies or over-the-counter or self-prescription measures, especially when faced with the threat of the pandemic and the physical, physiological, social and economic ramifications of the containment measures required of the public.

Through recent initiatives in smart devices, mobile apps have become a convenient, easy-to-use, and less time-consuming method to generate data from the public. Self-reported health status and health care service use are indispensable indicators to assess the performance and attitude of any health system in the absence of recorded health administration data [14]. An app-based survey has advantages such as wider population access, better response rates, lower cost, ease of analysis, ease of use for participants, assurance of user anonymity and preferences, greater flexibility, and faster data synthesis compared to traditional epidemiological and surveillance methods. Various previous research studies in the field of mobile-based health apps and the adoption of information technology have identified individual preferences and motivations to use these apps based on socioeconomic characteristics, demographics, access to health care facilities, perceptions about the usefulness of the apps, and the effect of existing or perceived disease conditions [15-18].

Hence, a cross-sectional analysis of the data generated from the app was performed to determine use trends of AYUSH measures by the public during the COVID-19 pandemic.

The primary objective of the cross-sectional analysis was to determine the extent of use of AYUSH advocacies and measures

Journal of Ayurveda and Integrative Medicine xxx (xxxx) xxx

Contents lists available at ScienceDirect

Journal of Ayurveda and Integrative Medicine

journal homepage: http://elsevier.com/locate/jaim

Original Research Article (Experimental)

In silico evaluation of the compounds of the ayurvedic drug, AYUSH-64, for the action against the SARS-CoV-2 main protease

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ARTICLE INFO

Article history:
Received 23 December 2020
Received in revised form
12 January 2021
Accepted 17 February 2021
Available online xxx

Keywords:
COVID-19
SARS-CoV-2
AYUSH-64
Main protease
Molecular docking
Dynamics simulations

ABSTRACT

Background: Outbreak of Corona Virus Disease in late 2019 (COVID-19) has become a pandemic global Public health emergency. Since there is no approved anti-viral drug or vaccine declared for the disease and investigating existing drugs against the COVID-19.

Objective: AYUSH-64 is an Ayurvedic formulation, developed and patented by Central Council of Research in Ayurvedic Sciences, India, has been in clinical use as anti-malarial, anti-inflammatory, anti-pyretic drug for few decades. Thus, the present study was undertaken to evaluate AYUSH-64 compounds available in this drug against Severe Acute Respiratory Syndrome-Corona Virus (SARS-CoV-2) Main Protease (M^{pro}; PDB ID: 6LU7) via *in silico* techniques.

Materials and methods: Different molecular docking software's of Discovery studio and Auto Dock Vina were used for drugs from selected AYUSH-64 compounds against SARS-CoV-2. We also conducted 100 ns period of molecular dynamics simulations with Desmond and further MM/GBSA for the best complex of AYUSH-64 with M^{pro} of SARS-CoV-2.

Results: Among 36 compounds of four ingredients of AYUSH-64 screened, 35 observed to exhibits good binding energies than the published positive co−crystal compound of N3 pepetide. The best affinity and interactions of Akuammicine N-Oxide (from *Alstonia scholaris*) towards the M^{pro} with binding energy (AutoDock Vina) of −8.4 kcal/mol and Discovery studio of Libdock score of 147.92 kcal/mol. Further, molecular dynamics simulations with MM-GBSA were also performed for M^{pro}− Akuammicine N-Oxide docked complex to identify the stability, specific interaction between the enzyme and the ligand. Akuammicine N-Oxide is strongly formed h-bonds with crucial M^{pro} residues, Cys145, and His164.

Conclusion: The results provide lead that, the presence of M^{pro}− Akuammicine N-Oxide with highest M^{pro} binding energy along with other 34 chemical compounds having similar activity as part of AYUSH-64 make it a suitable candidate for repurposing to management of COVID-19 by further validating through experimental, clinical studies.

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Peer review under responsibility of Transdisciplinary University, Bangalore.

https://doi.org/10.1016/j.jaim.2021.02.004

Please cite this article as: T.S. Ram, M. Munikumar, V.N. Raju *et al.*, *In silico* evaluation of the compounds of the ayurvedic drug, AYUSH-64, for the action against the SARS-CoV-2 main protease, J Ayurveda Integr Med, https://doi.org/10.1016/j.jaim.2021.02.004

J Ayurveda Integr Med. 2021 Jun 10
doi: 10.1016/j.jaim.2021.05.008 [Epub ahead of print]
PMCID: PMC8189796
PMID: 34127896

A Pilot Clinical study of an add on Ayurvedic formulation containing *Guduchi* and *Pippali* in mild to moderate Covid - 19

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Received 2021 Jan 24; Revised 2021 May 8; Accepted 2021 May 24.

Abstract

After declaration of Covid – 19 as pandemic by WHO, countries adopted several measures to contain the spread as well as test and treat the patients. Further, as no effective management protocols to address this pandemic were available, a need was felt to explore the integration of modern and traditional medicines to treat Covid 19 cases. In view of this an exploratory nonrandomized prospective study has been undertaken for comparing the outcomes of traditional Ayurvedic classical formulation of ***Tinospora cordifolia*** (*Guduchi*) and ***Piper longum*** (*Pippali*) as an add on to standard of care (SOC) using modern medicine with SOC alone. This has been done in mild and moderate Covid – 19 cases, at a tertiary care integrative Medicine hospital in the National Capital Region, Gurgaon, India.

The outcomes have been evaluated in terms of the duration of hospital stay, the time to clinical recovery, safety and non-interference/interaction of Ayurvedic and Further, long term impact of Covid – 19 treatment has been evaluated using quality of life questionnaire after 3 months of discharge.

Findings of present study reveals that the Ayurveda add-on formulation of *Tinospora cordifolia* (*Guduchi*) and *Piper longum (Pippali*) has reduced the length of hospital stay and improve the recovery time. General feeling of wellbeing and activity levels were better in the 3 month follow-up post discharge in the Ayurveda add-on group.

It is suggested that this formulation needs further investigated to provide more information on effective and safe herbal add-on to SOC for better outcomes to treatment of COVID-19 disease.

Keywords: Covid 19, Ayurveda, Tinospora cordifolia, Piper longum

Introduction

Alarming levels of spread and severity of disease forced the WHO to declare COVID – 19 a pandemic on March 11, 2020 and no country has since been safe from its wrath. Countries have adopted several measures to detect, test, treat, isolate and, trace in order to stop the disease transmission and contain the spread among its populations. As there is no current standard best practice to treat the disease countries are working with all resources in the arsenal ([1]).

There are claims from various quarters, especially from Traditional Chinese Medicine (TCM) Ren J-l, Zhang A.-H., Wang X.-J. Traditional Chinese medicine for covid-19 treatment and ([2], [3]) Korean oriental medicine (Association of Korean Medicine News 2020. Announcement of the first version of Oriental Medicice Clinical Practice Guideline by the National University Network of Traditional Medicine Department of Internal Medicine ([4]) and Indian systems of medicine, collectively known as AYUSH (Ayurveda, Yoga and Naturopathy, Unani, Siddha and Homeopathy) ([5]). Ayurveda is an experiential, intuitive and holistic, whereas that of the modern medicine is based more on experimental, analytical and reductive reasoning ([6]).

Ministry of Health and Family Welfare (MoHFW) in India has published several clinical management protocols to standardize covid care over the months of March, April, May and June and have modified them in line with the international current best practices ([7]). Ministry of AYUSH has also released several guidelines to each of its practitioners that suggest preventive and precautionary strategies ([8]). Ayurveda has potential and possibilities to be employed both for prevention and treatment of COVID-19.

Ayurvedic texts have proposed models to predict outbreaks and propagation of epidemics as well as general guidelines for prevention and management of epidemics. The Susruta Samhita, one of the classical text books of Ayurveda has described the possibility of epidemic outbreaks of severe respiratory illnesses exhibiting a spectrum of symptoms like cough, breathing difficulties, fever, headache, running nose and even anosmia (which is a symptom that has been reported in a subset of COVID-19 patients) ([9]).

An Ayurvedic assessment of the disease can help to classify the clinical presentations of COVID-19 on the basis of the *Tridosa* (three dosa which are Vata, Pitta, and Kapha) which forms the framework and logic around which Ayurveda understands disease and health. The standard methodology of deciphering the *dosa* base of the pathology through signs and symptoms using the algorithm of Ayurveda logic is equally applicable in understanding the disease spectrum of COVID-19 infection ([10]). At present, based on the available data, we have some preliminary understanding of the stages and

ORIGINAL RESEARCH

Neem (Azadirachta Indica A. Juss) Capsules for Prophylaxis of COVID-19 Infection: A Pilot, Double-Blind, Randomized Controlled Trial

Tanuja Manoj Nesari, MD; Anju Bhardwaj, MD; Rajagopala ShriKrishna, MD; Galib Ruknuddin, MD; Shivani Ghildiyal, MD; Asim Das, MD; Anil Kumar Pandey, MD; Nidhi Chaudhary, MD; Girish Soman, MTech; Mohini Barde, MD

ABSTRACT

Context • SARS-CoV-2 is a global public-health concern. Interventions to prevent infection are urgently needed. The anti-inflammatory and antiviral effects of neem make it a potential agent for COVID-19 prophylaxis.

Objective • The study intended to evaluate the prophylactic effects of neem capsules for persons at high risk of COVID-19 infection due to contact with COVID-19 positive patients.

Design • The research team designed a prospective, randomized, double-blind, placebo-controlled, parallel-design study.

Setting • The study was conducted at a single center in India.

Participants • Participants were 190 healthcare workers at the hospital or relatives of patients with COVID-19 infection.

Intervention • Of the 190 participants, 95 were in the intervention group and 95 in the control group. Participants received 50 mg of a proprietary, patent-pending, neem-leaf extract or a placebo orally in capsules, twice a day for 28 days.

Outcome Measures • The number of individuals positive for COVID-19 between baseline and follow-up on day 56 was the primary outcome measure. Secondary measures included an evaluation of neem's safety and its effects on quality of life (QOL) and changes in biomarkers.

Results • The mean age of participants was 36.97 years, and 68.42% were male. Total 13 subjects tested positive during the study. All were asymptomatic. Of the 154 participants who completed the study *per-protocol*, 11 tested positive, 3 in the intervention group and 8 in the control group. The probability of COVID-19 infection in participants receiving the intervention was 0.45 times that of participants receiving the placebo, a relative risk of 0.45, with the effectiveness of the intervention being around 55%. Treatment-emergent adverse events (TEAEs) in both groups were minimal and were of grade 1 or 2 in severity. Biomarkers and QOL remained stable in both groups.

Conclusions • The study found a reduced risk of COVID-19 infection in participants receiving neem capsules, which demonstrates its potential as a prophylactic treatment for the prevention of COVID-19 infection. The findings warrant further investigation in clinical trials. (*Altern Ther Health Med.* [E-pub ahead of print.])

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Severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) has caused a worldwide pandemic and is a cause of global public-health concern. By the beginning of 2021, over 100-million cases and more than two-million deaths had been reported worldwide.[1] The SARS-CoV-2 infection has been found to be both highly contagious and 5-to-50-fold more lethal than seasonal influenza, with an estimated mortality rate of 0.5-5%.[2] Interventions to prevent COVID-19 are urgently needed.

Healthcare workers (HCW), people involved in essential services, and relatives of patients with COVID-19 are at increased risk due to the rapid transmission of SARS-CoV-2. Preventive options such as social distancing, hand washing, and wearing masks are suggested and used to reduce the risk of the infection. Additionally, use of hydroxychloroquine (HCQ) chemoprophylaxis, which not only has limited

Journal of Ayurveda and Integrative Medicine xxx (xxxx) xxx

Contents lists available at ScienceDirect

Journal of Ayurveda and Integrative Medicine

journal homepage: http://elsevier.com/locate/jaim

Original Research Article (Experimental)

In Silico computational screening of *Kabasura Kudineer* - Official Siddha Formulation and JACOM against SARS-CoV-2 spike protein

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ARTICLE INFO

Article history:
Received 21 April 2020
Received in revised form
6 May 2020
Accepted 8 May 2020
Available online xxx

Keywords:
SARS-CoV-2
Spike protein
Kabasura Kudineer
JACOM
Molecular docking

ABSTRACT

Background: Siddha Medicine is a valuable therapeutic choice which is classically used for treating viral respiratory infections, this principle of medicine is proven to contain antiviral compounds.
Objective: The study is aimed to execute the *In Silico* computational studies of phytoconstituents of Siddha official formulation *Kabasura Kudineer* and novel herbal preparation - JACOM which are commonly used in treating viral fever and respiratory infectious diseases and could be affective against the ongoing pandemic novel corona virus disease SARS-CoV-2.
Method: Cresset Flare software was used for molecular docking studies against the spike protein SARS-CoV-2 (PDB ID: 6VSB). Further, we also conducted *in silico* prediction studies on the pharmacokinetics (ADME) properties and the safety profile in order to identify the best drug candidates by using online pkCSM and SwissADME web servers.
Results: Totally 37 compounds were screened, of these 9 compounds showed high binding affinity against SARS-CoV-2 spike protein. All the phytoconstituents were free from carcinogenic and tumorigenic properties. Based on these, we proposed the new formulation called as "SNACK–V"
Conclusion: Based on further experiments and clinical trials, these formulations could be used for effective treatment of COVID-19.

1. Introduction

The novel Coronavirus disease-2019 (COVID-19) is an ongoing pandemic caused by Severe Acute Respiratory Syndrome Corona-Virus 2 (SARS-CoV-2) [1]. COVID-19 has been declared a pandemic disease by WHO which has severely affected the livelihood of the population. SARS-CoV-2 has spread across the continents, as of April 11, 2020, has led to a total of 16,99,676 cases with a mortality of 1,02,734 among the registered cases. Presently, quarantine and symptomatic treatment protocol for disease management exists and there are no specific antiviral drugs available to combat this virus. As per Ministry of Health and Family Welfare, Govt. of India, in India there are 7447 Active cases and 239 deaths as on April 11, 2020; these data commensurate the impending risk facing the country. This pandemic is still ongoing, hence there is an urgent need to find new preventive and therapeutic agents as soon as possible [2].

Knowledge of Microbes and their Disease spread is clearly mentioned in Siddha which is evinced by "*Kirumiyal vandha thodam perugavundu lines mentioned in Guru naadi*"[3]. Siddha holistic approach will be helpful in combating COVID 19 using both therapeutic and non-therapeutic interventions. Siddhar's have advised evidence based treatment approach to understand a disease (*Noi naadi*), its etiology (*Mudhal Naadi*) based on those, fix a treatment (*Athu Thanikka Vainaadi*). As per basic Siddha Concept, Siddhar

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https://doi.org/10.1016/j.jaim.2020.05.009

Yadav et al. Trials (2021) 22:378
https://doi.org/10.1186/s13063-021-05326-1

Trials

LETTER Open Access

Safety and efficacy of Ayurvedic interventions and Yoga on long term effects of COVID-19: A structured summary of a study protocol for a randomized controlled trial

Babita Yadav*, Amit Rai, Pallavi Suresh Mundada, Richa Singhal, B. C. S. Rao, Rakesh Rana and Narayanam Srikanth

Abstract

Objectives: Primary Objective
• To assess the efficacy of Ayurveda interventions and Yoga in rehabilitation of COVID-19 cases suffering with long term effects of COVID 19 as compared to WHO Rehabilitation Self-Management after COVID-19- Related Illness.
Secondary Objective
• To assess the safety of Ayurvedic interventions in cases suffering with long term effects of COVID 19

Trial design: Multi-centric, randomized, controlled, parallel group, open-label, exploratory study. The study duration is 9 months and the intervention period is 90 days from the day of enrolment of the participant.

Participants: Patients of either sex between 18 to 60 years, ambulatory, willing to participate, with history (not more than 4 weeks) of positive RT-PCR for COVID-19 or IgM antibodies positivity for SARS CoV-2, but having negative RT-PCR for COVID-19 at the time of screening will be considered eligible for enrolment in the study. Critically ill patients with ARDS (acute respiratory distress syndrome), requiring invasive respiratory support in the intensive care unit, known case of any malignancy, immune-compromised state (e.g. HIV), diabetes mellitus, active pulmonary tuberculosis, past history of any chronic respiratory disease, motor neuron disease, multiple sclerosis, stroke, impaired cognition, atrial fibrillation, acute coronary syndrome, myocardial infarction, severe arrhythmia, concurrent serious hepatic disease or renal disease, pregnant or lactating women, patients on immunosuppressive medications, history of hypersensitivity to the trial drugs or their ingredients, depressive illness (before COVID-19), diagnosed psychotic illnesses, substance dependence or alcoholism will be excluded.
The trial will be conducted at two medical colleges in Maharashtra, India.

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Intervention and comparator: Intervention Arm (Group-I): Ayurveda interventions including Agastya Haritaki six gram and Ashwagandha tablet 500 mg twice daily orally after meals with warm water and two sessions of yoga (morning 30 minutes and evening 15 minutes) daily for 90 days, as per the post-COVID-19 care protocol provided in National Clinical Management Protocol based on Ayurveda and Yoga for management of COVID-19 published by Ministry of AYUSH, Government of India.
Comparator Arm (Group-II): WHO Rehabilitation Self-Management after COVID-19 related illness for 90 days.
The trial drugs are being procured from a GMP certified pharmaceutical company.

Main outcomes: Primary Outcome: Change in respiratory function to be assessed by San Diego shortness of breath Questionnaire, 6-minutes walk test and pulmonary function test.
Secondary Outcomes:

- Change in High-resolution Computed Tomography (HRCT) Chest
- Change in Fatigue score assessed by Modified Fatigue Impact Scale
- Change in Anxiety score assessed by Hospital Anxiety and Depression Scale Score
- Change in Sleep Quality assessed by Pittsburgh Sleep Quality Index
- Change in the quality of life assessed by COV19-QoL scale
- Safety of the interventions will be assessed by comparing hematological and biochemical investigations before and after the intervention period and Adverse Event/ Adverse drug reaction

Timelines for Outcome assessment: Subjective parameters and clinical assessment will be assessed at baseline, 15th day, 30th day, 60th day and 90th day. Laboratory parameters (CBC, LFT, KFT, HbA1c, Hs-CRP, D-dimer), Pulmonary function test and HRCT Chest will be done at baseline and after completion of study period i.e. 90th day.

Randomisation: Statistical package for Social Sciences (SPSS) version 15.0 is used to generate the random number sequences. The participants will be randomized to two study groups in the ratio of 1:1.

Blinding (masking): The study is open-label design. However, the outcome assessor will be kept blinded regarding the study group allocation of the participants.

Numbers to be randomised (sample size) Sample size: The sample size for the study is calculated assuming improvement in 6-minutes walk test by 40 meter in Group I and a change of 10 meter in Group II with a standard deviation of 50 meter based on the results of the previous studies, with 95% Confidence Level (α = 0.05) and 80% power and expecting a dropout rate of 20%. The number of participants to be enrolled in the study should be approximately 55 in each group. Hence, a total of 110 participants will be enrolled in the trial at each study site.

Trial Status: Participants' recruitment started on 1st May 2021. Anticipated end of recruitment is August 2021. Protocol number: CCRAS-01 Protocol version number: 1.1, 13th January 2021.

Trial registration: The trial is prospectively registered with the Clinical Trial Registry of India (CTRI) on 03rd March 2021 [CTRI/2021/03/031686].

Full protocol: The full protocol is attached 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.

Keywords: Ashwagandha, Agastya Haritaki, Post-COVID, long-COVID, Respiratory function, SARS-CoV-2, Yoga, WHO, randomised controlled trial, protocol, COVID-19

Supplementary Information

The online version contains supplementary material available at https://doi.org/10.1186/s13063-021-05326-1.

Additional file 1: Full protocol of Ayurveda interventions and Yoga in Long Covid.

Acknowledgements
Dr. R G Reddy, Assistant Director and Dr. Shekhar Namburi, Research Officer, Regional Ayurveda Research Institute, Nagpur for coordinating the collaboration for conducting this multi-center study. Dr. B. S. Sharma and Dr. Shruti Khanduri for coordinating the trial drug procurement.

Authors' Contributions
BY conceived the study. PM and AR initiated the study design. Protocol was finalized with inputs from BCSR and NS. RS provided statistical inputs. All authors contributed to refinement of the study protocol and approved the final manuscript.

Funding
Central Council for Research in Ayurvedic Sciences, Under Ministry of AYUSH, Government of India. The funding agency has designed this study and will analyze the data and publish the results as both medicines are classical Ayurveda formulations. It has no role in manufacturing and marketing the trial drugs.

Natarajan et al. Trials (2020) 21:892
https://doi.org/10.1186/s13063-020-04823-z

LETTER Open Access

The efficacy of Siddha Medicine, *Kabasura Kudineer (KSK)* compared to Vitamin C & Zinc (CZ) supplementation in the management of asymptomatic COVID-19 cases: A structured summary of a study protocol for a randomised controlled trial

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Abstract

Objectives: The primary objectives of this study are to determine efficacy of Siddha medicine, *Kabasura kudineer* in reduction of SARS-CoV-2 viral load and reducing the onset of symptoms in asymptomatic COVID-19 when compared to Vitamin C and Zinc (CZ) supplementation. In addition, the trial will examine the changes in the immunological markers of the Siddha medicine against control.
The secondary objectives of the trial are to evaluate the safety of the Siddha medicine and to document clinical profile of asymptomatic COVID-19 as per principles of Siddha system of Medicine.

Trial design: A single centre, open-label, parallel group (1:1 allocation ratio), exploratory randomized controlled trial.

Participants: Cases admitted at non-hospital settings designated as COVID Care Centre and managed by the State Government Stanley Medical College, Chennai, Tamil Nadu, India will be recruited. Eligible participants will be those tested positive for COVID-19 by Reverse Transcriptase Polymerase Chain reaction (RT-PCR) aged 18 to 55 years without any symptoms and co-morbidities like diabetes mellitus, hypertension and bronchial asthma. Those pregnant or lactating, with severe respiratory disease, already participating in COVID trials and with severe illness like malignancy will be excluded.

Intervention and comparator: Adopting traditional methods, decoction of *Kabasura kudineer* will be prepared by boiling 5g of KSK powder in 240 ml water and reduced to one-fourth (60ml) and filtered. The KSK group will receive a dose of 60ml decoction, orally in the morning and evening after food for 14 days. The control group will receive Vitamin C (60000 IU) and Zinc tablets (100mg) orally in the morning and evening respectively for 14 days.

(Continued on next page)

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(Continued from previous page)

Main outcomes: The primary outcomes are the reduction in the SARS-CoV-2 load [as measured by cyclic threshold (CT) value of RT-PCR] from the baseline to that of seventh day of the treatment, prevention of progression of asymptomatic to symptomatic state (clinical symptoms like fever, cough and breathlessness) and changes in the immunity markers [Interleukins (IL) 6, IL10, IL2, Interferon gamma (IFNγ) and Tumor Necrosis Factor (TNF) alpha]. Clinical assessment of COVID-19 as per standard Siddha system of medicine principles and the occurrence of adverse effects will be documented as secondary outcomes.

Randomisation: The assignment to the study or control group will be allocated in equal numbers through randomization using random number generation in Microsoft Excel by a statistician who is not involved in the trial. The allocation scheme will be made by an independent statistician using a sealed envelope. The participants will be allocated immediately after the eligibility assessment and informed consent procedures.

Blinding (masking): This study is unblinded. The investigators will be blinded to data analysis, which will be carried out by a statistician who is not involved in the trial.

Numbers to be randomised (sample size): Sample size could not be calculated, as there is no prior trial on KSK. This trial will be a pilot trial. Hence, we intend to recruit 60 participants in total using a 1:1 allocation ratio, with 30 participants randomised into each arm.

Trial status: Protocol version 2.0 dated 16th May 2020. Recruitment is completed. The trial started recruitment on the 25th May 2020. We anticipate study including data analysis will finish on November 2020. We also stated that protocol was submitted before the end of data collection.

Trial registration: The study protocol was registered with clinical trial registry of India (CTRI) with CTRI/2020/05/025215 on 16 May 2020.

Full protocol: The full protocol is attached as an additional file, accessible from the Trials website (Additional file 1). In the interest in expediting dissemination of this material, the familiar formatting has been eliminated; this Letter serves as a summary of the key elements of the full protocol. The study protocol has been reported in accordance with the Standard Protocol Items: Recommendations for Clinical Interventional Trials (SPIRIT) guidelines (Additional file 2).

Keywords: COVID-19, Randomised controlled trial, protocol, Siddha Medicine, Herbal decoction

Supplementary information

Supplementary information accompanies this paper at https://doi.org/10.1186/s13063-020-04823-z.

Additional file 1. Full Study Protocol.

Additional file 2. SPIRIT 2013 Checklist: Recommended items to address in a clinical trial protocol and related documents.

Acknowledgements
The authors acknowledge significant support from the COVID Care Center and Government Stanley Medical College, Chennai.

Authors' contributions
NS, AC, MP initiated the study and concept development. NS, AC, MP, SP, BP contributed to the study design. PP, PM, KK, BP supervised the project. NS, AC obtained necessary approvals. NS, AC, GA, KN and PA involved in the study conduct. All authors contributed to refinement of the study protocol and approved the final manuscript.

Funding
The research is funded by the Central Council for Research in Siddha, Ministry of AYUSH, Government of India. The funding body had no role in the design of the study and collection, analysis, and interpretation of data and in writing the manuscript.

Availability of data and materials
All patient data will be kept confidential and personal identifiers of the study participants will not be disclosed to the public. Only the study investigators will have access to the study data.

Ethics approval and consent to participate
We certify that this trial has received ethical approval from the institutional human ethics committee of Government Stanley Medical College, Chennai, India on May 16, 2020. The purpose of the trial will be explained to all eligible SARS-CoV-2 confirmed patients. Informed consent will be obtained from all eligible participants willing to participate in the trial. Each participant will be informed that participation in the trial is voluntary and that s/he is free to withdraw, without justification, from the trial at any time without consequences and without affecting professional responsibilities. Informed consent will seek approval to collect blood samples and clinical data for the intended purpose of this trial.

Consent for publication
Not applicable.

Competing interests
The authors declare that they have no competing interests.

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Received: 14 October 2020 Accepted: 16 October 2020
Published online: 27 October 2020

Publisher's Note

Srivastava et al. Trials (2021) 22:130
https://doi.org/10.1186/s13063-021-05041-x

Trials

LETTER Open Access

A double blinded placebo controlled comparative clinical trial to evaluate the effectiveness of Siddha medicines, Kaba Sura Kudineer (KSK) & Nilavembu Kudineer (NVK) along with standard Allopathy treatment in the management of symptomatic COVID 19 patients - a structured summary of a study protocol for a randomized controlled trial

Anurag Srivastava[1], Manickavasagam Rengaraju[2*], Saurabh Srivastava[1], Vimal Narayan[2], Vivek Gupta[1] and Rashmi Upadhayay[1]

Abstract

Objectives: The primary objectives of the study are to determine the effectiveness of the Kaba Sura Kudineer (KSK) & Nilavembu Kudineer (NVK) along with standard Allopathy Treatment to compared with Placebo (Decaffeinated Tea) with standard Allopathy Treatment in the management of Symptomatic COVID 19 patients and also in reduction of Hospital Stay Time & Changes in Immunological (IL6) and Bio Chemical Markers (Ferritin, CRP, D-Dimer and LDH). The secondary objectives are to evaluate the safety of the trial medicines and their effects in the reduce the risks of the disease. In addition, to document the profile of Symptomatic COVID 19 patients as per Siddha Principles.

Trial Design: A Double Blinded, Three arm, Single Centre, Placebo Controlled, Exploratory and comparative Randomized Controlled Trial

Participants: Patients who were admitted to the COVID Care Centre at Govt. Institute of Medical Sciences, Noida in India will be recruited. These will be patients with Mild and Moderate symptoms with laboratory confirmed COVID 19 (RT – PCR Tested Positive) aged 18-65, willing and consenting to participate.

(Continued on next page)

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(Continued from previous page)

Intervention and comparator:

Arm I: Decaffeinated Tea (Placebo – similar in taste and appearance to the other Two Decoctions), 60 Ml Morning and Night after Food, along with standard Allopathy Treatment for 10 days.

Arm II: Nilavembu Kudineer (The Siddha Medicines which is used as a standard Anti-Viral drug for the past Pandemics by Siddha Physicians) 60 Ml Morning and Night after Food, along with standard Allopathy Treatment for 10 days.

Arm III: Kaba Sura Kudineer (The Siddha Medicine which is proposed to be used as a Treatment for COVID 19 based on Siddha Literature) 60 Ml Morning and Night after Food, along with standard Allopathy Treatment for 10 days.

The investigational drugs are registered products under the Govt.of India and bought from GMP Certified Manufacturing Units.

Main Outcomes:

Primary outcomes:

1. Reduction in Viral load of SARS-CoV-2 at the end of treatment (10 days). 2. Time taken to convert Patient from symptomatic to Asymptomatic based on Reduction in clinical symptoms (10 days). 3. Effect of drugs inflammatory markers (IL6,) at the end of treatment (10 days). 4. Reduction in hospital stay time (20 days follow up). (Based on RT PCR CT Value 3rd, 6th if needed 10th day). (Based on IL 6 Value needed 10th day or IL6 value on turning negative. (entry level/exit level).

Secondary outcomes (10 days):

1. Reduction in use of Intensive Supportive Care. 2. Reduction in incidence of complications (Acute Respiratory Distress Syndrome, other systemic complications). 3. MuLBSTA score for viral pneumonia (multinodular infiltration, hypo-lymphocytosis, bacterial co infection, Total Leucocyte Count (TLC $\leq$ 0.8 x 10^{9}/L), smoking history, hypertension and age) score. 4. Laboratory markers (Haematological & Biochemical Markers). 5. Adverse events/effects Siddha-based measurements. 6. Siddha Udaliyal assessment by using Yakkai Ilakkanam (YI) Tool to diagnose body condition for covid-19 patients.

Randomisation: The assignment of the participants into 3 Groups will be allocated in 1:1:1 Ratio through randomization Blocks in Microsoft Excel by a Statistician who is not involved in the study. The allocation scheme will be made by another statistician by using a closed envelope after the assessment of eligibility and Informed consent procedures. The groups will be balanced for age and sex with 3:1 Ratio in each group for mild: severe COVID-19 symptoms.

Blinding: The Study is Double Blinded. Participants and Investigators were blinded.

Numbers to be randomized (Sample size): Sample size could not be calculated, Since there are no prior trials on KSK and NVK as a comparative trial. In addition, there are no prior trials on KSK and NVK in this region.
A total Number of 120 Patients, 40 each in 3 groups will be recruited in 1:1:1 Ratio.

Trial Status: Protocol Number : SCRUND GIMS Noida Study 1,Version: 2.0 Protocol Date : 20.08.2020
The recruitment period is completed for the trial. The Trial started its recruitment on 22.8.2020. We anticipate study including data analysis will finish in January 2021.
This is to state that it was a late submission from authors for publication of the protocol to the BMC, after enrolment in the study was over.

Trial Registration: The trial protocol was registered with CTRI (Clinical Trial Registry of India) and number is CTRI/2020/08/027286 on 21.08.2020

Full Protocol: The full Protocol is attached as an additional file, Accessible from the Trials website (Additional file 1). In the interest in expediting dissemination of this material, the familiar formatting has been eliminated. This letter serves as a summary of the key elements of the full protocol. The Study protocol has been reported in accordance with the SPIRIT guidelines.

Keywords: COVID 19, Randomised Controlled Trial, Protocol, Siddha Medicine, Herbal, CAM,

Journal of Evidence-Based Integrative Medicine
Volume 26: 1-7

DOI: 10.1177/2515690X211020685
journals.sagepub.com/home/cam
SAGE

Add-on Ayurveda Treatment for Early Stage COVID-19: A Single Center Retrospective Cohort Study From Gujarat, India

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Abstract

The retrospective cohort study aimed to evaluate the clinical outcomes of Ayurveda treatment exposure as an add-on to conventional care in early stage COVID-19 patients admitted at Samaras COVID care center, Ahmedabad, India. Conventional care included Vitamin-c, Azithromycin, and Paracetamol. Ayurveda formulations used as add-on were *Dashamula* and *Pathyadi* decoctions along with *Trikatu* powder, *Sanshamani* tablet, AYUSH-64 tablet AND *Yastimadhu Ghana* tablet for oral administration. Considering Add-on Ayurveda medicines as exposure of interest, patients who received Add-on Ayurveda medicines at least for 7 days were included in the exposed group while those who received only conventional care in unexposed group. Data was collected through record review and telephonic interviews. The outcomes of interest were the development of symptoms, duration of symptomatic phase in those progressing to symptomatic stage and mortality. Total 762 participants were included-[541 (71%) in the exposed group and 221 (29%) in the unexposed. Progression to symptomatic phase did not differ significantly between groups [27.6% in exposed, 24.6% in unexposed, adjusted RR 0.85; 95% CI 0.6-1.2]. The total duration of symptomatic phase among those progressing to the symptomatic stage was significantly decreased in the exposed group ($x = 3.66 \pm 1.55$ days in exposed ($n = 133$); $x = 5.34 \pm 3.35$ days in unexposed ($n = 61$), $p < 0.001$). No mortality was observed in either of the groups. Ayurveda Treatment as adjunctive to conventional care reduced the duration of symptomatic phase in early stage COVID-19 as compared to standalone conventional care. Add-on Ayurveda treatment has promising potential for management of early stage COVID-19.

Keywords

Ayurveda, COVID-19, cohort study, complementary medicine, SARS-CoV-2

Received January 20, 2021. Received revised April 12, 2021. Accepted for publication May 9, 2021.

Introduction

A worldwide outbreak of severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) and the resulting COVID-19 cases and fatalities has challenged health systems globally. Globally, a total of 125 million cases including 2.7 million deaths have been reported by March 25, 2021.[1] Most of the patients with SARS-Cov-2 infection develop a mild illness, approximately 14% develop a severe disease that requires hospitalization and oxygen support, and 5% require admission to an intensive care unit.[2] As of now, mainly symptomatic supportive treatment is being provided to the patients whereas seriously ill individuals are treated with organ support.[3] The drug discovery process is accelerated at the moment with much focus on repurposing existing drugs.[4] The majority of the drugs used for treatment worldwide fall primarily under antiviral, antimalarial, anti-inflammatory, monoclonal antibodies

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European Journal of Molecular & Clinical Medicine

ISSN 2515-8260 Volume 07, Issue 10, 2020

Survival analysis to assess the length of stay of novel coronavirus (COVID-19) patients under Integrated Medicine - Zinc, Vitamin C & Kabasura Kudineer (ZVcKK)

Retrospective Study to assess the length of stay of novel coronavirus (COVID-19) patients in GMC & ESIH Coimbatore who were under- Integrated Medicine -Zinc, Vitamin C & Kabasura Kudineer (ZVcKK)

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Conflict of Interest: The authors declare that they have no conflict of interest.
Ethical approval: "For this type of study consent is obtained."
The personal identifiers such as name and address of the patient's records were removed to ensure the confidentiality and anonymity. Collection of information regarding the age, gender, address, and all other information collected from patients were also kept confidential and as this study is a data observation gone for ethical committee approval.
Ethics committee of GMC-ESI – Coimbatore – No: 20911/2020.
Informed consent: "For this type of study formal consent is obtained."

Abstract: Objective: COVID19 pandemic out of all odds has created an opportunity to offer treatment in an integrative manner. This study measures the Length of stay (LS) of patients in an integrative way as done earlier in China and Vietnam. Length of stay,

ISSN 2515-8260 Volume 07, Issue 10, 2020

Clinical presentations, and Comorbidities were analyzed among COVID19 patients in ESI Hospital, Coimbatore, Tamil Nadu, India.

Method: ***Retrospective cross-sectional data on 251 Positive COVID19 patients of both sexes irrespective of age admitted from 27 March 2020 and 26 April 2020 cases were included in the study. The final discharge date is taken as 5th May 2020. Kaplan Meier survival analysis was adopted.***

Results: ***Male, female ratio were 141(56.2%): 83(33.1%), 12 (4.8%) Male Child and 15 (6.0%) were Female child. 5.2% of the patients were in the age group greater than 60, 75.3% were in the age group 20-60, and the remaining 19.5% were 0-20 age group. 84.9% of patients were Asymptomatic, while fever and cough were the main symptoms recorded in the remaining cases. CT scan was done for 7 patients. No mortality and no serious adverse events were reported. Comorbidity is 15% and does not influence hospital length of stay. The overall median length of stay is 12 days for those who were under ZVcKK (Median ST CI- 11.59-12.41).***

Conclusion: ***This study recorded a median of 12 days in the Length of stay and 13.5 days in the Length of stay average. Comparing earlier studies, patients taking ZVcKK have savings of 7 days. i.e., the relief speed is higher while using ZVcKK.***

Keywords: ***COVID-19, Integrated Medicine, Vit.C and Zinc tablets, Kabasura Kudineer, Kaplan Meier survival analysis, Siddha Medicine.***

1. INTRODUCTION

Following the first-ever reported case in Wuhan in December 2019, PHEI (Public Health Emergency of International concern) was announced by WHO in January [1]. SARS-CoV-2 has spread widely across all continents; as of the latest situation report on August 16, 2020, by WHO, a total of 21, 294, 845 cases with mortality of 7,61, 779 have been reported [2]. There are 2 647 316 cases in India and 51,045 deaths as of August 16, 2020; these data represent the imminent risk facing the country [3]. India declared an emergency alert in March 2020. Transmission of virus spreads via physical contact with infected individuals, contaminated surfaces, and droplets [4]. COVID-19 commonly reported symptoms are fever, vomiting, chills, headache, dyspnoea, nausea, sore throat, coughing up blood, shortness of breath, myalgia, diarrhea, and malaise. The severe infection leads to pneumonia, acute respiratory distress syndrome (ARDS), and sometimes multi-organ failures such as kidney failure and even death [5]. With its strong internal and external medications, the linage of Siddha medicine has been in vogue to treat viral diseases [6]. At Present, treatment aspects are isolation and treating symptoms stands as the only option or vaccine therapy Due to the non-availability of proved therapies. Therefore, it is necessary to develop a treatment for COVID-19. Based on the Siddha system of Medicine advisory given by the Ministry of AYUSH, India for COVID-19 mentioned stages of medicines for treatment, prophylaxis, and related convalescence. Kabasura Kudineer (KSK) found its place in the advisory of the Ministry of AYUSH [7]. The Tamilnadu government advocates zinc and Vitamin c. Administration of CBE – ESI took a positive step to contain Covid19 through Integrated approaches. In this regard, the benefit offered by Integrated Medicine -Zinc – (150 mg),

Published online in http://ijam.co.in ISSN No: 0976-5921

International Journal of Ayurvedic Medicine, Vol 11 (4), 765-772

In Silico Docking Analysis of Poly Herbal Formulation *Aadathodai Kudineer* used in Siddha medicine in inhibiting Main Protease and ACE2 Receptor Spike protein SARS-CoV-2

Research Article

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Abstract

Corona virus disease (COVID-19) is an infectious pandemic disease caused by the newly discovered novel corona virus. World Health Organization has declared the global health emergency due to COVID19 outbreak. Currently, there is no specific treatment or vaccine for fighting against this infectious disease. *Aadathodai Kudineer* is a drug indicated for *Iya Erumal, Kozhai Kattu, Kabasuram.* Upon the mortality and severity of the disease COVID19, we tried to identify the possible inhibition of phytocomponents of *Aadathodai Kudineer* in inhibiting Main Protease and ACE2 Receptor Spike protein SARS-CoV-2 through molecular docking studies. Methodology: In Silico molecular docking analysis was performed for phytocomponents present in the *Aadathodai Kudineer* formulation for targets main protease and ACE2 Receptor Spike protein, PDB ID: 6LU7 and PDB ID: 2AJF using Autodock tool. ADME properties was also predicted for all the above compounds. Results: Among the 9 active Phytocompounds present in the *Aadathodai Kudineer* formulation, Lupeol showed high binding affinity with COVID19 main protease and ACE2 receptor which shows the promising contrivance of protease inhibition. The ADME suggested that the formulation is free from toxic. Conclusion: The phytocomponents showed possible affinity towards these targets and has the lead molecules that inhibits COVID19 main protease and ACE2 receptor.

Key Words: *Siddha formulation, Aadathodai Kudineer, SARS-CoV-2, COVID19, Molecular docking, ADME.*

Introduction

On 31st December 2019, 27 cases of pneumonia of unknown aetiology were recognized in Wuhan City, Hubei area in China. The causative organism was recognized from throat swab tests led by the Chinese Centre for Disease Control and Prevention (CCDC) on seventh January 2020, and was along these lines named Severe Acute Respiratory Syndrome Coronavirus (SARS-CoV-2). The World Health Organization (WHO) named this infection as COVID-19. On 30th January 2020, the WHO proclaimed the Chinese episode of COVID-19 to be a Public Health Emergency of International Concern representing a high hazard to nations with weak wellbeing frameworks (1).

As of 27 July 2020, following data has been reported throughout the world, India & Tamil Nadu. More than 16.4 million cases of COVID-19 have been reported in 185 countries and territories, resulting in more than 6,46,641 deaths. More than 9.51 million people have recovered (2). The Ministry of Health and Family Welfare of India has confirmed a total of 14,35,453 cases, 9,17,567 recoveries (including 1 migration) and 32771 deaths in India. The Department of Health and Family Welfare of Tamil Nadu has confirmed a total of 2,13,723 cases, including 3493 deaths and 1,56,526 recoveries. Around 53703 active cases are reported (3).

The World Health Organization (WHO) welcomes innovations around the world including repurposing drugs, traditional medicines and developing new therapies in the search for potential treatments for COVID-19 (4). In China, traditional Chinese medicine is very useful to control and prevention and treatment for COVID 19 patients. In integrated approach is very success full treatment in COVID 19 patients in china (5).

Among six recognized streams of Indian Medicine System, Siddha medicine is one such traditional medicine originating in Tamil Nadu, India and practiced over centuries (6). Siddha system of medicine has played a major role in treating the diseases such as dengue, chikungunya. Both the TN Govt and union ministry of AYUSH has recommended an herbal siddha medicine called *Nilavembu Kudineer* as a treatment for dengue (7). This COVID 19 Pandemic Ministry of AYUSH publish the "Guidelines for Siddha Practitioners for COVID 19".

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Case Report

Access this article online

Quick Response Code:

Website: www.ayucare.org

DOI: 10.4103/jacr.jacr_57_20

Three case reports of moderate COVID-19 infection managed through Ayurvedic approach

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Abstract:

Coronavirus disease 2019 (COVID-19), a global pandemic, is resulting in significant morbidity and mortality worldwide. The overburden of the disease is due to the vicious circulating virus characteristics, lack of potent vaccine, complications and limitations of the existing medicine and aggravation of disease along with comorbid conditions in elderly people, etc. In the present scenario, effective traditional treatment modalities should be scientifically applied to reduce the impact of massive disaster. Here is the necessity to develop an appropriate treatment protocol from the field of Ayurveda. This is a documentation of three confirmed COVID-19 cases managed with Ayurvedic medication with minimum number of hospital stay compared with the national average. Ayurvedic management has a significant positive impact on the mental and physical quality of life in COVID-19 patients. Both the physical and mental scores got improved of more than 50% percentage in each case after treatment. Ayurvedic science has a unique approach to COVID -19 and can be adopted wisely to overcome the current crisis. Marked radiological changes were observed in three cases. Ayurvedic interventions can be used to counteract the pathogenesis of SARS-CoV-2.

KEYWORDS: Acute respiratory distress syndrome, COVID-19, SARS-CoV-2

INTRODUCTION

The pandemic outbreak of coronavirus disease 2019 (COVID-19) caused significant morbidity and mortality, finally led to an emergency of major international concern.[1] The virus has created an unfavorable socioeconomic impact globally. The initial clusters of cases were reported in December 2019 at Wuhan. The current testimonies indicate that SARS-CoV-2 spread to humans through transmission from wild animals illegally sold in the Huanan Seafood Wholesale Market.[2] On January 7, 2020, the causative agent was identified as a new coronavirus (2019-nCoV), and the disease was later named as COVID-19 by the WHO.[3] The COVID-19 has spread across the world at a vicious pace, gripping more than 218 countries, 16 lakh deaths, and more than 20 million active cases in the mid of December.[4] Compared with other viral diseases, the hallmark of the novel coronavirus is the wide range of disease severity experienced by the patients. Only a minority of COVID-19 patients require hospitalization, the effects of infection for these people are dramatic, in some life threatening cases. Infection with SARS-CoV-2 causes severe pneumonia, intermittent fever, and cough. Symptoms of rhinorrhea, pharyngitis, and sneezing have been less commonly observed. Patients often develop acute respiratory distress syndrome within two days of hospital admission, requiring ventilatory support. It has been observed that during this phase, the mortality tends to be high. For this infectious pathology, there is no specific proven treatment

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Submitted: 08-Aug-2020
Revised: 03-Dec-2020
Accepted: 14-Dec-2020
Published: 18-Jan-2021

How to cite this article: Arshath Jyothi PS, Dileep A, Devarajan D, Sharma A, Kumari S, Rathuri S, *et al*. Three case reports of moderate COVID-19 infection managed through Ayurvedic approach. J Ayurveda Case Rep 2020;3:84-90.

Case Report

Access this article online

Quick Response Code:

Website: www.ayucare.org

DOI: 10.4103/jacr.jacr_9_21

Efficacy of Ayurveda and Yoga in the management of SARS-CoV-2: Two case reports

Raja Ram Mahto, Arshath Jyothi, Aparna Dileep[1], Archana Shukla, Aleena Gauri[2]

Abstract:

The current worldwide coronavirus disease 2019 (COVID-19) pandemic has caused a huge threat to public health. It includes a spectrum of clinical severity extended from asymptomatic to critical pneumonia, acute respiratory distress syndrome, and even death. Recent evidences have suggested that inflammatory responses play a critical role in the progression of COVID-19. Inflammatory markers such as C-reactive protein, lactate dehydrogenase, D-DIMER have been reported to be significantly associated with the high risks of the development of severe COVID-19. In this context, two cases diagnosed with COVID-19 were managed through Ayurvedic intervention is presented here. The patients of moderate COVID-19 were recovered from the symptoms with the personalized holistic treatment approaches.

KEYWORDS: Acute respiratory distress syndrome, Ayurveda, inflammatory markers, SARS-CoV-2

INTRODUCTION

A cluster of cases of pneumonia reported in a comparatively minor province of china in December 2019, eventually spread over the entire globe. Coronavirus disease 2019, also called COVID-19, a global pandemic resulted in significant morbidity and mortality worldwide.[1] According to experts, not only the health but also other integral sectors of economy were highly affected, disrupting our life styles. Currently, we are living a new normal life style. Till date, lack of effective management strategy, complications and limitations of the existing medicines, aggravation of disease along with comorbid conditions in elderly people, etc., are add on burden to the pandemic. Accumulating evidences have suggested that inflammatory responses play a critical role in the progression of COVID-19.[2] Inflammatory responses triggered by rapid viral replication of SARS-CoV-2 and cellular destruction can recruit macrophages and monocytes and induce the release of cytokines and chemokines. These cytokines and chemokines then attract immune cells and activate immune responses, leading to cytokine storms and further exacerbations of situations. Several inflammatory markers have some tracing and detecting accuracy for disease severity and fatality.

The Ministry of AYUSH has set up an Interdisciplinary Committee for Integration of Ayurveda and *Yoga* interventions and released "National Clinical Management Protocol to combat COVID-19" specially focusing on mild-to-moderate cases.[3] The selection of these drugs is based on published scientific evidence, literary research supported by scientific relevance and rationale in support of repurposing of these medicines in COVID-19 and outcomes and trends of completed and ongoing studies taken up by the Ministry of AYUSH on a large cohort across India. Even though it is said to be a new disease entity to world, it is not beyond the fundamental *Tridosha sidhanta* of Ayurveda.[4] The current

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Submitted: 29-Jan-2021
Revised: 16-Feb-2021
Accepted: 18-Feb-2021
Published: 18-Mar-2021

How to cite this article: Mahto RR, Jyothi A, Dileep A, Shukla A, Gauri A. Efficacy of Ayurveda and Yoga in the management of SARS-CoV-2: Two case reports. J Ayurveda Case Rep 2020;3:127-32.

www.ijacare.in ISSN: 2457-0443
INTERNATIONAL JOURNAL OF AYUSH CASE REPORTS (IJA-CARE)

Siddha and Biomedicine Integrative Management of Novel Corona Virus Disease - A Case Report

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Abstract:

In the wake of Covid-19 pandemic, Traditional Siddha Medicine has gained wide popularity in Tamilnadu. A 39 year old female Covid positive patient is presented here under who was introduced with the combined therapy of Siddha and biomedicine along with dietary advice and standard quarantine care. The subject had all the peculiar clinical features of Covid 19. *Nilavembu kudineer* (NVK) was administered twice daily at the dose of 60 ml along with the prescribed biomedicine. Qualitative SARS-COV-2 RT-PCR test was used as the confirmatory test for Covid 19 along with basic haematological and biochemical parameters. After the initiation of integrative medicine, the subject showed improvement symptomatically and gradual disappearance of symptoms without adverse effects. RT-PCR after 14 days of therapy reported negative and the subject was greatly relieved. This case report suggests the importance of safer and effective integrative drug therapy using Traditional Siddha Medicine and biomedicine.

Keywords: Alternative medicine, Covid-19, Integrative and Complementary Medicine, *Nilavembu kudineer*, SARS Cov-2, *Siddha*

Received: 18.09.2020 Revised: 25.09.2020 Accepted: 28.09.2020

Quick Response code

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Journal of Ayurveda and Integrative Medicine 12 (2021) 1–3

Contents lists available at ScienceDirect

Journal of Ayurveda and Integrative Medicine

journal homepage: http://elsevier.com/locate/jaim

Editorial

The journey with COVID-19: Initiatives by Ministry of AYUSH

The outbreak of the COVID-19 pandemic challenged the healthcare systems globally. Worldwide, researchers and clinicians are struggling with this crisis. The pandemic has accentuated the need to strengthen health systems and accelerate research and development (R&D) programmes. The Ministry of Health and Family Welfare (MoHFW), Government of India took rapid measures in the control, prevention, and treatment of COVID-19 by issuing several advisories and guidelines. A well-organized public health and hygiene awareness campaign promoting use of mask, physical distancing, hand-washing as well as effective sanitization, lockdowns, quarantine and epidemiological monitoring has immensely helped in controlling the disease spread, and reducing the morbidity and mortality as compared to several other countries. One more possible cause for lower rates of morbidity and mortality in India could be the use of immunity promoting interventions from the ancient traditional systems of medicine involving Ayurveda, Yoga & Naturopathy, Unani, Siddha, Sowa Rigpa, and Homeopathy (AYUSH) and several home remedies based on traditional knowledge.

Admittedly, strengths of modern medicine in managing the symptomatic treatment and critical care of COVID-19 have helped tremendously. However, modern medicine has limitations in providing a better immunological and mental status for effective prophylaxis and prevention as well as promoting well-being with improved quality of life. The approach of AYUSH systems for strengthening host defence may be useful as an effective, safer, accessible, and affordable prophylaxis in management of COVID-19. Hence, use of AYUSH systems has increased globally during the pandemic.

The Ministry of AYUSH (MoA), Government of India has undertaken several R&D and public health initiatives to harness the potential of AYUSH systems to contain the impact of the COVID-19 pandemic. These initiatives aim at creating public awareness regarding measures to improve immunity and mitigate the impact of the pandemic. They also provide guidelines to AYUSH stakeholders to address this pandemic scenario effectively. The year 2020 has been a challenging period that made the healthcare researchers and stakeholders wiser than before [1]. An overview of the experiences, challenges, and success stories of the MoA during the COVID-19 pandemic is provided in this editorial.

1. Guidelines and advisories

The MoA issued various guidelines and advisories to improve immunity and advised simple home remedies easily accessible to the general public. It also recommended a set of self-care guidelines duly vetted by eminent Ayurveda experts for preventive health measures, with special reference to respiratory health and enhancing immunity.

The treatment recommended by the practitioners of AYUSH systems may vary across the country. However, in times of a public health emergency like COVID-19, it is essential to have a considerable degree of uniformity in the management of the disease. Hence, guidelines for registered practitioners of respective AYUSH systems were prepared by the MoA through concerned team of experts to address the issue [2]. Considering the urgent need for delivering healthcare services to the public during lockdown period, the Ministry also published 'Telemedicine Practice Guidelines' for AYUSH practitioners. The Ministry also issued an order to prevent dissemination of misleading information about AYUSH interventions and advertising claims for COVID-19.

Apart from guidelines and advisories, the MoA also launched campaigns such as 'AYUSH for Immunity' to disseminate the health promotion messages in the general public and set-up an AYUSH COVID-19 Dashboard to furnish the details of guidelines related to AYUSH measures for improving immunity, official communications, research undertaken on COVID-19, measures for prophylaxis and management. The National Repository on AYUSH COVID-19 clinical and other R&D initiatives have been developed to disseminate information related to AYUSH R&D initiatives, COVID-19 related AYUSH clinical trials and scientific publications and is available on the AYUSH Research Portal of the MoA.

The efforts by the MoA led to a cascade effect and several State Governments issued guidelines regarding prophylaxis and management of asymptomatic and mild cases through AYUSH modalities and conduction of research studies on COVID-19. The MoA also issued directives to all State/UT licensing authorities and drug controllers of AYUSH to expedite the process of approval/license/license renewal for manufacturing of ASU immunity-boosting healthcare products and sanitizers.

2. Mobilization of human resources

The MoA envisioned maximum stakeholder mobilization and encouraged the AYUSH institutes across the country for optimum utilization of available infrastructure and staff to combat the COVID-19 pandemic. As a result, several AYUSH hospitals in different regions of the country were designated as quarantine and COVID care centres by the respective State Governments. The Hon'ble Prime Minister of India, Shri Narendra Modi also addressed the AYUSH stakeholders to provide their services in this crisis situation. Total 8,32,445 AYUSH practitioners, paramedic staff and

Peer review under responsibility of Transdisciplinary University, Bangalore.

https://doi.org/10.1016/j.jaim.2021.03.009

Yoga and Meditation as an Adjunct Interventional Strategy for COVID-19 Management

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Ann Natl Acad Med Sci (India) 2021;00:1–3

There is ample evidence and expanding coverage on the COVID-19 virus spread across the world today. The increasing burden of cases has not only overwhelmed our fragile public health care system but also stressed our economy due to lockdowns. The last one year of the pandemic has subjected our health care systems, social support systems, and resilience of our citizens to testing times, as a result of antipandemic measures. Evidence-based treatment guidelines have been formulated, revised, and advocated by both Ministry of Health and Family Welfare and Ministry of AYUSH in the last one year for health care practitioners to treat COVID-19 patients. There has been a clamor for improving one's "immunity" and being healthy and fit to reduce the impact of COVID-19. While the COVID-19 may infect anybody, the predilection, severity of symptoms, and ability to resist virus infection does depend on physiological and psychological status of one's health. This is evident from epidemiological characteristics of this disease severely affecting the elderly and those with comorbid conditions. Although the evidence for role of a healthy lifestyle as a primary prevention of COVID is still uncertain, it nevertheless is known to influence the trajectory of the disease in those affected. Yoga and meditation as a mind, body and lifestyle intervention has gained popularity in recent times. Ever since the declaration of International Day of Yoga (June 21) by the United Nations General Assembly in 2014, yoga, as a health promotion intervention, has gained popularity globally with due support from majority of the nations and the World Health Organization (WHO). The present editorial highlights the role of yoga in prevention and management of COVID and COVID-like acute respiratory illnesses.

The resurgence of COVID-19 in 2021 has enhanced the burden on the health care resources in our country, with an exponential increase in the number of cases. The highlighting of deaths due to lack of oxygen beds by the media has created a panic in the country. People are more anxious than ever before if they have contracted COVID due to uncertainty in trajectory and ensuing respiratory distress. It has become impossible under these circumstances to pay attention to and mitigate the psychological distress of every patient who is under home isolation or under hospitalization. The accompanying psychological distress in COVID-19 patients is often ignored and not managed. There have been reports of anxiety and acute depression, leading to suicides during home isolation and in COVID care hospitals. Social isolation has led to anxiety and led to severe mental health issues in those with preexisting anxiety or depressive disorders. The constant fear of getting infection, unbearable stress, long working hours, helplessness, and distress watching infected patients die alone has caused burnout stress in frontline health care workers. All these point to a pandemic of psychological distress accompanying COVID-19.[1]

COVID-19 patients have had to contend with stress due to fear of worsening of symptoms, respiratory distress, hypoxia, fatigue, insomnia, and other symptoms during COVID-19 infection, which are amplified due to isolation anxiety.[2] The anxiety and uncertainty about the trajectory and course of illness among COVID-19 positive patients, those suspected of COVID-19, and those in quarantine can lead to psychologic distress which, in turn, can downregulate their immune defenses and increase the chance and severity of infection, similar to earlier studies. Studies have shown psychological stress to enhance the rates of infection in communities during a flu season. Even among the health care workers, impending anxiety and stress can downregulate immune responses and defenses that can lead them to contract this infection and increase its severity.[3]

Treatment protocols for people with COVID-19 should address both the physiological and psychological needs of the patients and health service providers. Providing psychological treatment and support may reduce the burden of

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DOI https://doi.org/10.1055/s-0041-1731611
ISSN 0379-038X

Thieme Medical and Scientific Publishers Pvt. Ltd. A-12, 2nd Floor, Sector 2, Noida-201301 UP, India

Original Article

Clinical evaluation of *Chyawanprash* as a preventive measure during the COVID-19 pandemic: An open-label, multicentric, randomized, comparative, prospective, and interventional community-based clinical study on healthy individuals

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Abstract

Background: *Chyawanprash* is a classical Ayurveda polyherbal formulation that has proven immunomodulatory potential. **Aim:** The present clinical study was conducted to evaluate *Chyawanprash* for prophylaxis of COVID-19 infection. Materials & Methods: It was an Open-label, Multicentric, Randomized, Comparative, Prospective, and Interventional Community-based Clinical Study. The study was conducted at five sites across Maharashtra, Gujarat, and Rajasthan between May 2020 and November 2020. **Materials and Methods:** A total of 771 subjects were screened in the study; of whom, 721 subjects were randomized into two groups. Subjects in the DCP group who fell into the category of 13 years to 70 years were given *Chyawanprash* as a study intervention to be taken in a dose of one teaspoonful (approx. 12g) twice daily and children aged 5 to 12 years were given ½ teaspoonful (approx. 6g) twice daily followed by a cup of milk (approx. 200mL). Subjects in the control group were advised to consume one cup of milk (approx. 200mL) twice daily. The incidence of COVID-19 was assessed by reverse transcription polymerase chain reaction (RT-PCR)/antigen testing, which was conducted as per applicable guidelines and the severity of infection was assessed by using the World Health Organization (WHO) ordinal scale. The incidence and severity of non-COVID-19 infections was also assessed during the intervention period of 90 days. **Results:** Overall, 696 subjects completed the study, of whom 351 subjects were in the Chyawanprash (DCP) group and 345 were in the control group. In the DCP group, out of the 351 subjects who had completed the study, 42 were tested with RT-PCR/antigen and one subject was found to be positive for COVID-19. In the control group, out of the 345 subjects, 28 were tested with RT-PCR/Antigen and eight subjects were found to be positive for COVID-19. In the DCP group, the incidence was statistically significant lesser as compared with the control group. A total of 43 subjects in the control group and 41 subjects in the DCP group had symptoms of Influenza Like Illness (ILI). The DCP group also showed a statistically significant improvement in quality of life (QoL), as assessed by the Quality of Life Enjoyment and Satisfaction Questionnaire – Short Form (Q-LES-Q-SF) when compared with the control group. **Conclusion:** The outcome of the present study suggests and supports the prophylaxis potential of *Chyawanprash* as one of the preventive remedies for COVID-19 as recommended by the AYUSH fraternity. The beneficial effects may be due to the synergistic effects of the potent herbs that are known to have immune-boosting effects in healthy individuals.

Keywords: *Chyawanprash*, COVID-19, immunity, RT-PCR, WHO ordinal scale

Introduction

In the current global health scenario, the SARS-CoV-2-associated pandemic COVID-19 is a matter of concern:

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Received: 22-03-2021, Revised: 06-04-2021, Accepted: 10-04-2021, Published: 10-06-2021

Access this article online

Quick Response Code:

Website: www.joinsysmed.com

DOI: 10.4103/JISM.JISM_27_21

How to cite this article: Godatwar PK, Deshpande S, JoshiDeshmukh PS, Deshpande VS, Ghungralekar R, Tamoli S, *et al.* Clinical evaluation of *Chyawanprash* as a preventive measure during the COVID-19 pandemic: An open-label, multicentric, randomized, comparative, prospective, and interventional community-based clinical study on healthy individuals. J Indian Sys Medicine 2021;9:104-13.

Complementary Therapies in Medicine 62 (2021) 102768

Contents lists available at ScienceDirect

Complementary Therapies in Medicine

journal homepage: www.elsevier.com/locate/ctim

Short Communication

Withania somnifera as a safer option to hydroxychloroquine in the chemoprophylaxis of COVID-19: Results of interim analysis

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ARTICLE INFO

Keywords:
COVID-19
Chemoprophylaxis
Ashwagandha
Hydroxychloroquine
Ayurveda

ABSTRACT

Objectives: To study the efficacy and safety of *Withania somnifera* (WS, Ashwagandha) in the prophylaxis against COVID-19 in high risk health care workers (HCW) in comparison to hydroxychloroquine (HCQ). To evaluate the general physical and mental health benefits of Ashwagandha.

Methods: A 16 week randomized prospective, open-label, parallel efficacy, two arm, multi-centre study. The primary efficacy measure was 'failure of prophylaxis' as confirmed COVID-19 by quantitative Reverse Transcription Polymerase Chain Reaction (RT-PCR) at any time during the study period. This study on 400 participants from three centres was designed to establish non-inferiority for WS to HCQ for prophylaxis against COVID-19 at 80 % power and significance $p < 0.025$, one-sided. The interim analysis was carried out on 160 participants after completion of 8 weeks.

Results: Participants in both the arms were well-matched at the baseline characteristics. Forty participants in the HCQ group and 26 participants in the WS group reported mild AE. The symptoms of confirmed COVID-19 were found to be 3.7 % (95 % CI 1.3–10.5 %) in the HCQ and 1.3 % (95 % CI 0.02–6.7 %) in the WS arm amongst the first 160 participants completing 8 weeks.

Conclusion: Our intent was to explore a safer option to HCQ. We report that WS was not found inferior to HCQ and its efficacy was within the 15 % non-inferiority margin set *a priori*. WS as an immunomodulator has other clinical benefits including reducing mental stress. The final report of this study is expected by end of August 2021.

1. Introduction

A large number of health care workers (HCW) engaged in combatting COVID-19 have fallen prey to the virus. This is despite extensive use of personal protection equipment, strict personal discipline and other preventive measures such as social distancing, use of face mask, handwashing, and use of drugs like hydroxychloroquine HCQ as prophylactic agents. Chemoprophylaxis against SARS-CoV-2 is needed; however, there are no proven drugs yet. This study was initiated when vaccines were not available in India. Earlier studies have shown that HCQ was

Withania somnifera (WS); health care workers (HCW); hydroxychloroquine (HCQ); Reverse Transcription Polymerase Chain Reaction (RT-PCR).

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https://doi.org/10.1016/j.ctim.2021.102768
Received 6 July 2021; Received in revised form 11 August 2021; Accepted 12 August 2021
Available online 18 August 2021

Available online on 15.08.2021 at http://jddtonline.info

Journal of Drug Delivery and Therapeutics

Open Access to Pharmaceutical and Medical Research

Open Access Full Text Article

Research Article

In-Silico Evaluation of *Tiryaq-E-Wabai*, an Unani Formulation for its Potency against SARS-CoV-2 Spike Glycoprotein and Main Protease

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Article Info:

Article History:

Received 06 June 2021
Reviewed 11 July 2021
Accepted 19 July 2021
Published 15 August 2021

Cite this article as:

Ahmed NZ, Davis GDJ, Anwar N, Khan AA, Meena RP, Afnaan Z, Sri MD, *In-Silico* Evaluation of *Tiryaq-E-Wabai*, an Unani Formulation for its Potency against SARS-CoV-2 Spike Glycoprotein and Main Protease. Journal of Drug Delivery and Therapeutics. 2021; 11(4-S):86-100

DOI: http://dx.doi.org/10.22270/jddt.v11i4-S.4993

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Abstract

COVID-19 was originated in Wuhan, China, in December 2019 and has been declared a pandemic disease by WHO. The number of infected cases continues unabated and so far, no specific drug approved for targeted therapy. Hence, there is a need for drug discovery from traditional medicine. *Tiryaq-e-Wabai* is a well-documented formulation in Unani medicine for its wide use as prophylaxis during epidemics of cholera, plague and other earlier epidemic diseases. The objective of the current study is to generate in-silico evidence and evaluate the potency of *Tiryaq-e-Wabai* against SARS-CoV-2 spike (S) glycoprotein and main protease (3CLpro). The structures of all phytocompounds used in this study were retrieved from PubChem database and some were built using Marvin Sketch. The protein structure of the SARS-CoV-2 S glycoprotein and 3CLpro was retrieved from the PDB ID: 6LZG and 7BQY respectively. AutoDock Vina was used to predict top ranking poses with best scores. The results of the molecular docking showed that phytocompounds of *Tiryaq-e-Wabai* exhibited good docking power with spike glycoprotein and 3CLpro. Among tested compounds Crocin from Zafran and Aloin A from Sibr showed strong binding to spike glycoprotein and 3CLpro respectively. Molecular dynamics simulation confirmed the stability of the S glycoprotein-Crocin and 3CLpro-Aloin A complexes. The Unani formulation *Tiryaq-e-Wabai* has great potential to inhibit the SARS-CoV-2, which have to be substantiated with further *in-vitro* and *in-vivo* studies.

Keywords: In-silico study, SARS-CoV-2, *Tiryaq-e-Wabai*, Unani formulation, Crocin, Aloin A

INTRODUCTION

COVID-19, the current pandemic is caused by Severe Acute Respiratory Syndrome Corona-Virus 2 (SARS-CoV-2) and originated in Wuhan, China, in December 2019[1-2]. The virus could infect human with symptoms similar to Severe Acute Respiratory Syndrome (SARS) and Middle East Respiratory Syndrome (MERS)[3]. SARS-CoV-2 infection has been reported across 223 countries and India has the largest number of confirmed cases in Asia as per the latest reports[4]. The number of infected cases continues to soar high and effective targeted therapy options for COVID-19 remains limited. A number of research studies are in progress to find out a potent drug to curb the grave situation. Many traditional drugs, being used for millennia in Ayurveda, Unani, Siddha systems, have been reported to possess significant antiviral activities against a wide range of viruses[5]. A recent study demonstrated a high binding affinity of a Siddha formulation with spike protein of SARS-CoV-2[6]. These reports support the hypothesis that traditional drugs may also have a significant potential against SARS-CoV-2.

Tiryaq-e-Wabai is a well-documented Unani formulation for its wide use as prophylaxis and treatment during epidemics of cholera, plague and other epidemic diseases. It is comprised of 3 ingredients, *viz* Sibr (*Aloe barbadensis*), Murr Makki (*Commiphora mirrha*) and Zafran (*Crocus sativus*)[7-10]. Zakariya Razi (Rhazes, 865-925 CE) narrates *'whoever has used a mixture of two part of Sibr, one part zafran and one part Murr Makki, remained protected during epidemics'*[11]. It is stated that the use of *Tiryaq-e-Wabai* thrice a week on alternate days in a single dose of 500 mg, with *Arq-e-Gulab* 60 ml or *Arq-e-Badiyan* 120 ml, may protect the individual from infection during epidemics[12-15]. The formulation ingredients fall under the category of *Tiryaqi Advia* (literally – antidote drugs) and are considered to be very effective in SARS like conditions especially in respiratory distress[7,13,16] These drugs have been reported for wide-ranging pharmacological activities. The formulation has been reported to possess immune-stimulation activity in immunocompromised elderly persons[17].

The medicinal use of Sibr (*Aloe vera*) can be traced thousands year back in the history. It has been used for various diseases in Unani medicine including digestive, respiratory, nervous system disorders and skin disorders. It is mentioned that the use of Sibr in any form: oral intake, fumigation, and spraying has promising effects during

Srivastava et al. Trials (2021) 22:570
https://doi.org/10.1186/s13063-021-05478-0

Trials

RESEARCH Open Access

Efficacy of two siddha polyherbal decoctions, Nilavembu Kudineer and Kaba Sura Kudineer, along with standard allopathy treatment in the management of mild to moderate symptomatic COVID-19 patients—a double-blind, placebo-controlled, clinical trial

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Abstract

Background and aim: Globally, the ongoing pursuit in exploring an effective drug to combat severe acute respiratory syndrome coronavirus-2 (SARS-CoV-2) virus has not met with significant success to date. Indian traditional medicines, especially polyherbal formulations like Nilavembu Kudineer (NVK) and Kaba Sura Kudineer (KSK) of the Siddha system of medicine, have been used as public health interventions for controlling viral epidemics like dengue and Chikungunya. These traditional therapies have been found safe, effective, and widely accepted. The current study evaluates the comparative efficacy of NVK and KSK as opposed to the placebo, in the management of mild to moderate COVID-19 disease.

Methods: The study was a double-blind, placebo-controlled comparative clinical trial, with the primary objective of determining the efficacy of KSK and NVK. Patients (n=125) diagnosed with mild to moderate COVID-19 symptoms were enrolled in the study over a period of 4 months (Aug 2020—Dec 2020). Participants were randomized into 3 arms; placebo-decaffeinated tea in Arm I, NVK in Arm II, and KSK in Arm III. Each arm received 60 ml of the respective treatment twice a day, post morning and evening meals, along with standard allopathy treatment for a maximum of 10 days. The main outcome measures of the study were the reduction in SARS-CoV-2 viral load, hospital stay, and time taken by the patients to become asymptomatic from symptomatic. Efficacy assessments

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included clinical symptoms (fever, cough, and breathlessness) each day and real-time reverse transcription-polymerase chain reaction (RT-PCR), liver function test (LFT), renal function test (RFT), and electrolytes and electrocardiogram (ECG) at baseline (day 0) and days 3, 6, and 10. Post-treatment, participants were followed up for 30 days via phone for adverse effects if any. Effects of drugs on inflammatory markers (IL6) at the end of treatment were also recorded. Adverse events (AE) were monitored throughout the study.

Results: The results revealed that when compared to patients in the placebo arm, those in NVK and KSK arms showed a statistically significant reduction in hospital stay time, reduction in viral load of SARS-CoV-2, and the time taken to become symptomatic from asymptomatic. Out of 125 COVID-19 patients recruited, 120 completed the study; two from the placebo group developed severe symptoms and were shifted to the intensive care unit (ICU) and three patients from Arms II and III withdrew from the study. The mean age of females (n=60) and males (n=60) enrolled was between 40.2 and 44.3 years, respectively. Results were more promising for all the patients in NVK and KSK arms as all enrolled participants (100%) under this group got discharged by day 6 as compared to only 42.5% (n=17) from the placebo group on that day. The hospital stay time for patients in Arm I was significantly longer (mean [SD]=8.4 [2.0] days) as compared to the Arms II and III (mean [SD]=4.7 [1.5] and 4.2 [1.5] days, respectively (Kruskal-Wallis test, P=0.0001). Patients in the three groups took a significantly different number of days to become asymptomatic. While Arm II and III patients took mean of 2.5 and 1.7 days, respectively, Arm I, patients took a mean of 4.2 days (Kruskal-Wallis test, P=0.0001). In all, two adverse events were recorded, one for vomiting and one for diarrhea lasting a day in Arm I and Arm II, respectively. The mean value of interleukin-6 (IL6) was significantly different in comparison to the placebo-decaffeinated tea arm (NVK=2.6 and KSK=2.2, placebo=4.0, P=0.02). The other blood biochemical parameters like C-reactive protein (CRP), lactate dehydrogenase (LDH), ferritin, and D-dimer that were analyzed at the baseline and at the time of discharge from the hospital, were not significantly different in the three arms.

Conclusion: NVK and KSK arms showed a statistically significant reduction in hospital stay time, reduction in viral load of SARS-CoV-2, and time taken for patients to become asymptomatic from symptomatic, when compared to the placebo (decaffeinated tea). The primary outcome measures of the KSK arm were significantly better than those in the NVK arm.

Keywords: Mild to moderate COVID-19, Siddha medicine, Kaba Sura Kudineer, Nilavembu Kudineer, Double-blinded RCT

Introduction

Globally, there has been an ongoing pursuit in exploring an effective treatment to combat severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2). However, this quest across various treatment verticals has led to despair amongst the scientific community [1]. In India, the role of traditional treatments especially Siddha medicines in the management of various diseases is well known that has proven effective, safe, and widely accepted across all ages. During the chikungunya and dengue epidemic in the year 2015 in Tamilnadu, India, the administration of Nilavembu Kudineer (NVK) played a major role in controlling the morbidity [2]. Siddha medicine has contributed to lowering the disease burden during public health emergencies. These medicines could be repurposed for the management of COVID-19. However, there is limited evidence for the integrative treatment approach (standard of care, allopathy treatment along with Siddha medication) in the management of COVID-19.

COVID-19 is a respiratory tract infection caused by a newly emergent coronavirus, SARS-CoV-2, that was first reported in December 2019. At present, we have limited evidence from randomized clinical trials to support pharmacological treatments from conventional medicine for COVID-19 [3].

According to Siddha Medical Literature, the symptoms and signs of COVID-19 including cold, cough, and fever are analogous to Kaba Suram [4, 5].Standard Siddha medicines for tackling these conditions are Kabasurakudineer (KSK) and Nilavembu Kudineer (NVK). NVK was one of the essential medicines used as anti-viral Siddha drugs, especially in the treatment of chikungunya and dengue during the past outbreaks [6]. Recent in vitro studies have revealed that ethanolic extract of NVK has anti-viral properties against chikungunya and dengue [2, 7]. Toxicity studies utilizing NVK as per Organisation for Economic Co-operation and Development (OECD) guidelines found it to be safe for consumption. Apart from this, antipyretic, anti-microbial, anti-inflammatory, and immunostimulant activities of NVK have also been proven by phytochemical screening studies [8]. Recent clinical studies have revealed the prophylactic and anti-viral activities of NVK in viral fevers [9, 10]. These

Original Research

Chyawanprash as add on to the standard of care in preventing COVID-19 infection among apparently healthy health care workers – A single arm, longitudinal study

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Date of Submission : 21 Apr 2021 || **Date of Acceptance:** 2 Jul 2021

Abstract

Objective: To assess the efficacy and safety of *Chyawanprash* in preventing SARS-CoV-2 infection among health care personnel working at COVID-19 isolation ward.

Setting: A hospital designated as COVID-19 care centre in Delhi, India

Participants: Apparently healthy health care workers (HCWs) of age 20 to 60 years who were RT PCR negative and asymptomatic but possibly had exposure to active cases of COVID- 19, with or without co-morbid conditions were included. Pregnant and lactating females, volunteers with malignancy, uncontrolled blood sugar, chronic renal failure, chronic heart failure, hematological disorders, and those on immunosuppressants were excluded from the study.

Interventions: *Chyawanprash,* an Ayurvedic *rasayana* medicine 12 gm orally with warm water twice daily for 30 days along with standard preventive measures adopted by the institute. **Primary Outcome:** Incidence of COVID-19 infection confirmed by RT-PCR test. **Secondary Outcomes:** Evaluation of safety of the study drug through hematological & biochemical investigations and occurrence of any adverse drug reaction or adverse events; number of participants developing any other bacterial, viral or fungal infection during the study period and changes in inflammatory and immune markers.

Results: At the end of study period, out of total 50 participants enrolled, two were COVID -19 positive. Incidence rate in similar population in the same study setting prior to commencing (9.71%) and after completing the study period (1.79%) was compared with incidence of COVID-19 during treatment period (1.09%). So, *Chyawanprash* showed protection rate of 98.91%. It was well tolerated by all the study participants, when administered for 30 days.

Conclusions: The infection rate at the hospital dropped significantly following administration of *Chyawanprash.* As *Chyawanprash* shows potential of a prophylactic agent against infection by SARS-CoV-2 infection, and is safe when used in the recommended daily dosage, a randomized controlled trial to prove its prophylactic efficacy can be designed on larger sample size.

Trial Registration: Clinical Trial Registry of India CTRI/2020/05/025425 on 28/05/2020

Keywords – Ayurveda, Prophylactic, *Rasayana*, SARS-CoV-2

How to cite the article

Jindal N, Rajput Shivshankar , Yadav Babita , Mundada Pallavi , Singhal Richa , Varshney Shalini et al. Chyawanprash as add on to the standard of care in preventing COVID-19 infection among apparently healthy health care workers – A single arm, longitudinal study, Ann Ayurvedic Med. 2021; 10(3) 204-219 DOI:10.5455/AAM.73639

Original Article

AYUSH-64 as an add-on to standard care in asymptomatic and mild cases of COVID-19: A randomized controlled trial

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Abstract

Background: The evidence on the efficacy and safety of Ayurveda interventions as an add-on to the standard conventional care for coronavirus disease-2019 (COVID-19) is limited. **Aim and objective:** This study was planned to explore the potential of AYUSH-64 as an add-on to conventional care in improving the clinical recovery and negative reverse transcription–polymerase chain reaction (RT-PCR) conversion in asymptomatic and mild COVID-19 cases. **Materials and methods:** An open-label randomized controlled study was conducted at Government Medical College, Nagpur, Maharashtra, India, with a sample size of 60 participants. In this study, asymptomatic or mild COVID-19 patients were randomized and allocated into intervention and control groups (CG) in a 1:1 ratio. AYUSH-64 two capsules (500 mg each) were administered thrice daily, after food with water for 30 days along with standard care in the intervention group (IG), while the CG received only standard care. The primary outcome was the proportion of participants who turned RT-PCR negative for COVID-19 at 7th, 15th, 22nd and 30th days. Secondary outcomes were the proportion of participants who attained clinical recovery at 7th, 15th, 22nd and 30th days, change in laboratory parameters on the 30th day and incidence of adverse drug reactions/adverse events. The data were compared within group using paired sample *t*-test/Wilcoxon signed-rank test and between group using independent sample *t*-test/Mann–Whitney test. **Results:** Statistically significant difference was not observed in the proportion of participants who turned RT-PCR negative during each of the follow-ups ($P = 0.134$) and both groups demonstrated comparable efficacy. The clinical recovery in terms of complete relief in symptoms in the symptomatic participants was 60% and 37% on day 15 ($P = 0.098$) and 100% and 85.2% on day 30 ($P = 0.112$) in the intervention and CG, respectively. The improvement in the inflammatory markers such as interleukin (IL)-6, tumor necrosis factor-α (TNF-α), and D-dimer was statistically significant ($P < 0.05$) in the IG, whereas in the CG, it was statistically significant for D-dimer only. None of the participants developed any complications nor were any significant ADR/AE observed in the groups. **Conclusions:** In patients with asymptomatic and mild COVID-19, AYUSH-64, as add-on to standard conventional care, contributed to improved clinical recovery and demonstrated potential in reducing the levels of pro-inflammatory markers such as IL-6 and TNF-α. Further, both the groups demonstrated comparable efficacy regarding negative RT-PCR for COVID-19.

Keywords: Ayurveda, AYUSH-64, coronavirus disease-2019, pandemic, SARS-CoV-2

Introduction

Coronavirus disease-2019 (COVID-19) has affected more than 181 million people around the world and around 3.9 million deaths have been reported globally as of 30th June 2021.[1] The physical, psychological, social and economic consequences of the pandemic have been very severe and have affected the world in the most unprecedented manner. Potential therapeutic and prophylactic agents should ideally have antiviral properties against SARS-CoV-2, immunomodulatory properties, and therapeutic adjuvant activity with drugs used while being safe and tolerable.[2] Although several therapeutic interventions such as hydroxychloroquine, corticosteroids, and antivirals have been suggested and tried, the outcomes have not been much promising. The current medical strategy for the

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Access this article online

Quick Response Code:

Website: www.ayujournal.org

DOI: 10.4103/ayu.ayu_14_21

How to cite this article: Reddy RG, Gosavi RV, Yadav B, Rai AK, Holay MP, Talekar M, *et al*. AYUSH-64 as an add-on to standard care in asymptomatic and mild cases of COVID-19: A randomized controlled trial. AYU 2020;41:107-16.

Submitted: 25-Jan-2021 **Revised:** 01-Jul-2021
Accepted: 06-Jul-2021 **Published:** 23-Oct-2021

frontiers in Pharmacology

ORIGINAL RESEARCH
published: 14 October 2021
doi: 10.3389/fphar.2021.746729

Effect of Prophylactic Use of Intranasal Oil Formulations in the Hamster Model of COVID-19

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Severe acute respiratory syndrome coronavirus 2 (SARS-CoV2) infection initiates with viral entry in the upper respiratory tract, leading to coronavirus disease 2019 (COVID-19). Severe COVID-19 is characterized by pulmonary pathologies associated with respiratory failure. Thus, therapeutics aimed at inhibiting the entry of the virus or its internalization in the upper respiratory tract are of interest. Herein, we report the prophylactic application of two intranasal formulations provided by the National Medicinal Plant Board (NMPB), Anu oil and til tailya, in the hamster model of SARS-CoV-2 infection. Prophylactic intra-nasal instillation of these oil formulations exhibited reduced viral load in lungs and resulted in reduced body weight loss and lung-pneumonitis. In line with reduced viral load, histopathological analysis revealed a reduction in lung pathology in the Anu oil group as compared to the control infected group. However, the til tailya group did not show a significant reduction in lung pathology. Furthermore, molecular analysis using mRNA expression profiling indicated reduced expression of pro-inflammatory cytokine genes, including Th1 and Th17 cytokines for both the intranasal formulations as a result of decreased viral load. Together, the prophylactic intranasal application of Anu oil seems to be useful in limiting both viral load and severity in SARS-CoV2 infection in the hamster model.

Keywords: COVID-19, intranasal, herbal, AYUSH, prophylactic

OPEN ACCESS

Edited by:
Brijesh Kumar Singh,
Duke-NUS Medical School, Singapore

Reviewed by:
Pradeep Bist,
Duke-NUS Medical School, Singapore
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Specialty section:
This article was submitted to Experimental Pharmacology and Drug Discovery, a section of the journal Frontiers in Pharmacology

Received: 24 July 2021
Accepted: 10 September 2021
Published: 14 October 2021

Citation:
Rizvi ZA, Tripathy MR, Sharma N, Goswami S, Srikanth N, Sastry JN, Mani S, Surjit M, Awasthi A and Dikshit M (2021) Effect of Prophylactic Use of Intranasal Oil Formulations in the Hamster Model of COVID-19. Front. Pharmacol. 12:746729. doi: 10.3389/fphar.2021.746729

INTRODUCTION

Since the first report of Coronavirus Disease (COVID-19) in Wuhan in December 2019, a number of COVID-19 incidences have exploded around the globe leading it to be declared a pandemic by the WHO (Chen and Li, 2020; Wang et al., 2020) (https://www.ecdc.europa.eu/en/geographical-distribution-2019-ncov-cases). As of September 6, 2021, the total number of coronavirus infection incidences was 221,846,104 with around 4,586,516 deaths globally, with 441,075 mortalities in India alone. The majority of the coronavirus cases are asymptomatic and do not require aggressive treatment. However, an estimated 13.8% of the infected individuals are at risk of developing a severe form of COVID-19, which could be characterized by either one or all of the following COVID-19 symptoms: respiratory distress, high fever, loss of taste and smell, and diarrhea (Chen and Li, 2020; Wang et al., 2020). In addition, up to around 6% of COVID-19 cases end up with respiratory failure due to cytokine storm, cardiovascular complications, and

Original Article

A survey among Ayurveda wholesalers and retailers in Pune city for understanding the demand for Ayurvedic medicines during the COVID-19 pandemic

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Abstract

Background: After the outbreak of Covid-19, a set of guidelines for boosting immunity and self-care measures were promoted by the Ayurveda, Yoga, Naturopathy, Unani, Siddha Sowa Riga, and Homeopathy (AYUSH) department. Pune has surpassed many metro cities of India and is recognized as one of the worst-hit places of Covid-19. Ayurveda is very popular among the citizens of Pune, but there is a lack of systematic data regarding the demand for Ayurveda products and the impact of the pandemic on the sales of Ayurveda medicines. **Objective:** This survey was planned to collect information from Ayurveda medicine retailers regarding the trends in the usage and demand for Ayurveda medicines among the citizens of Pune in the background of Covid-19. **Materials and Methods:** It was a semi-structured questionnaire-based survey study consisting of 43 questions to assess the demand for Ayurveda medicines during the Covid-19 pandemic in Pune city. The study was conducted from August 2020 to September 2020, and the respondents were selected by the convenience sampling method. Data were collected from a total of 33 respondents (retailers and wholesalers of Ayurveda medicine). **Analysis:** The data of the completed questionnaire were systematically summarized in Microsoft excel sheet 2007, and descriptive analysis, including percentages, was used. **Result:** The survey shows that certain raw herbs such as *Ashwagandha* (*Withania somnifera* L.), *Guduchi* (*Tinospora cordifolia* Miers), and finished products such as AYUSH *Kwatha* (Formulation to be prepared as a decoction), *Chyavanprasha* were in high demand during the Covid-19 outbreak. However, the demand for *Amritarishta*, *Guduchi Ghana Vati*, and *Ashwagandha* tablet was also high. **Conclusion:** These preliminary data of the survey study demonstrate the need for conducting similar studies in larger sample sizes across the country, which would enable the concerned authorities to frame policies.

Keywords: Ayurveda medicines, AYUSH, corona, over the counter, trend

Introduction

In the wake of the Covid-19 pandemic, the medical community worldwide is relentlessly working toward developing effective pharmacotherapeutics. The complexities of management of the illness tend to be limited in modern medicine, whereas the dynamic appraisal of evidence concerning the same has widened the scope of AYUSH at the national level.[1] Traditional medical systems such as Ayurveda have an equal opportunity owing to the practice-based evidence-building strategy.[2]

The Ministry of AYUSH has taken up this opportunity to utilize the vast potential of Ayurveda, releasing a set of guidelines for boosting immunity and self-care measures based on Ayurveda principles and resulting in a surge in the demand for Ayurvedic medicine.[3]

Chyavanaprash, *Sanshamani Vati* (tablet), and AYUSH *Kwatha* (Formulation to be prepared as a decoction) are a few formulations; *Guduchi* (*Tinospora cordifolia* Miers.),

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Received: 13-05-2021. Revised: 19-07-2021, Accepted: 25-07-2021, Published: 28-09-2021.

Access this article online

Quick Response Code:

Website: www.jism.org

DOI: 10.4103/jism.jism_42_21

How to cite this article: Kolhe R, Pushpan R, Prasad GP, Gurav A, Srikanth N. A survey among Ayurveda wholesalers and retailers in Pune city for understanding the demand for Ayurvedic medicines during the COVID-19 pandemic. J Indian Sys Medicine 2021;9:191-5.

Natarajan et al. Trials (2021) 22:623
https://doi.org/10.1186/s13063-021-05583-0

Trials

RESEARCH Open Access

Kabasura Kudineer (KSK), a poly-herbal Siddha medicine, reduced SARS-CoV-2 viral load in asymptomatic COVID-19 individuals as compared to vitamin C and zinc supplementation: findings from a prospective, exploratory, open-labeled, comparative, randomized controlled trial, Tamil Nadu, India

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Abstract

Introduction: Despite several ongoing efforts in biomedicine and traditional medicine, there are no drugs or vaccines for coronavirus disease 2019 (COVID-19) as of May 2020; Kabasura Kudineer (KSK), a polyherbal formulation from India's Siddha system of medicine, has been traditionally used for clinical presentations similar to that of COVID-19. We explored the efficacy of KSK in reducing viral load and preventing the disease progression in asymptomatic, COVID-19 cases.

Methods: A prospective, single-center, open-labeled, randomized, controlled trial was conducted in a COVID Care Centre in Chennai, India. We recruited reverse-transcription polymerase chain reaction (RT-PCR)-confirmed COVID-19 of 18 to 55 years of age, without clinical symptoms and co-morbidities. They were randomized (1:1 ratio) to KSK (60 mL twice daily for 7 days) or standard of care (7 days supplementation of vitamin C 60,000 IU morning daily and zinc 100 mg evening daily) groups. The primary outcomes were reduction in the SARS-CoV-2 load [as measured by cyclic threshold (CT) value of RT-PCR], prevention of progression of asymptomatic to symptomatic state, and changes in the immunity markers including interleukins (IL-6, IL-10, IL-2), interferon gamma (IFNγ), and tumor necrosis factor (TNF α). Siddha clinical assessment and the occurrence of adverse effects were documented as secondary outcomes. Paired *t*-test was used in statistical analysis.

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Results: Viral load in terms of the CT value (RdRp: 95% CI = 1.89 to 5.74) declined significantly on the seventh day in the KSK group and that of the control group, more pronounced in the study group. None progressed to the symptomatic state. There was no significant difference in the biochemical parameters. We did not observe any changes in the Siddha-based clinical examination and adverse events in both groups.

Conclusion: KSK significantly reduced SARS-CoV-2 viral load among asymptomatic COVID-19 cases and did not record any adverse effect, indicating the use of KSK in the strategy against COVID-19. Larger, multi-centric trials can strengthen the current findings.

Trial registration: Clinical Trial Registry of India CTRI2020/05/025215. Registered on 16 May 2020

Keywords: Siddha medicine, Polyherbal decoction, Asymptomatic COVID-19 cases, Kabasura Kudineer, AYUSH, Traditional medicine

Background

Severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) infection causing coronavirus disease 2019 (COVID-19) has affected more than 190 million people and caused 408,600 deaths globally as of 20th July 2021 [1]. Clinical symptoms of COVID-19 include mild illness (upper respiratory tract infections, fever, anorexia, malaise, muscle pain, sore throat, dyspnea, nasal congestion, headache), pneumonia, severe pneumonia, acute respiratory failure, sepsis, and septic shock [2]. Confirmatory diagnosis of COVID-19 is done through real-time reverse transcription-polymerase chain reaction assay (RT-PCR) [3]. People who are COVID-19-positive but do not exhibit any of the symptoms are termed asymptomatic [4]. These asymptomatic COVID-19 individuals could contribute to the rapid and extensive spread of SARS-CoV-2 [5]. The prevalence of asymptomatic individuals among SARS-CoV-2-infected people is about 40–45% [6].

Despite intensive ongoing efforts at drug discovery and vaccine development, there are no proven interventions, as of May 2020 [7]. Due to the novel nature of the viral infection, the trials have explored drugs/formulations from both modern and traditional medical systems [8]. In the Indian context, Ayurveda, yoga and naturopathy, Unani, Siddha, Sowa-Rigpa, and homoeopathy (collectively called as AYUSH) are traditional medical systems recognized and patronized by the government under the Indian Ministry of AYUSH. Of the AYUSH systems, Ayurveda, yoga, and Siddha systems of medicine are indigenous to India. While Ayurveda has a wider presence, the Siddha system of medicine is rooted in the southern Indian state of Tamil Nadu and is practiced in ethnic Tamil populations of the world.

The Siddha system of medicine defines *Uyirthathukkal* (three humors, namely *Vali* (*Vatham*), *Azhal* (*Pitham*), and *Iyam* (*Kabam*)) and *Udalkattugal* (*Saaram*, *Senneer*, *Oon*, *Kozhuppu*, *Enbu*, *Moolai*, *Sukkilam/Suronitham*) as fundamental principles of the human body and also conceptualizes unique individual body constitution of every person called as *Udaliyal* [9]. These traditional systems play a vital role in the management of national health care needs [10]. They advocate drugs of herbal, mineral, and animal origins for treating various diseases. Almost 360 thousand traditional formulations/practices of Ayurveda, Siddha, Unani, and Sowa-Rigpa have been transcribed into the Traditional Knowledge Digital Library in India [11]. The reported action of herbal drugs depends on the phytochemical components [12]. Non-specific targeting antiviral therapeutic methods triggered the advancement in research on plant-based antiviral agents. Herbal antiviral formulations have contributed to managing viral infections [13]. It was found after the screening of hundreds of Chinese medicinal herbs, extracts from *Lycoris radiata*, *Artemisia annua*, *Pyrrosia lingua*, and *Lindera aggregata* had anti-SARS-CoV effect [14].

In the context of COVID-19, it is important to revisit the research potential of such antiviral herbal formulations. In fact, one such Siddha classical poly-herbal formulation *Nilavembu kudineer* (made as a decoction) documented antiviral action against the dengue virus [15]. Herbal formulations from the Siddha system of medicine have been widely used during the times of outbreaks of dengue in Tamil Nadu, and specifically, *Nilvembu kudineer* is reported to have contributed to the reduction in severe outcomes due to chikungunya and dengue in Tamil Nadu during 2015 [16]. Further, many such formulations from the Siddha system of medicine have immune-stimulating and inflammation-modulating effects [17]. Hence, on the basis of such documentation in the past, an Indian advisory by the Ministry of AYUSH incorporated the role of the Siddha system of medicine for COVID-19 [18]. On the lines of the national advisory, the state of Tamil Nadu proposed the use of Siddha formulations in the management of asymptomatic and mild COVID-19 through a new scheme, called *Arokkiam* in which *Kabasura Kudineer* is one such polyherbal Siddha formulation [19].

Kabasura Kudineer (KSK) is indicated for use in *Aiya suram* (fever) and *Aiya noigal* (respiratory diseases) in

Access this article online
Quick Response Code:

Website: https://www.jrasccras.com/
DOI: 10.4103/jras.jras_47_21

A randomized controlled trial to evaluate the prophylactic efficacy of *Chyawanprash* in healthcare workers during the COVID-19 pandemic

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Submitted : 18-08-2021
Revised : 18-09-2021
Accepted : 18-09-2021
Published : 14-12-2021

Abstract:

INTRODUCTION: Healthcare workers (HCWs) are high-risk individuals in the management of epidemics caused by highly contagious disorders such as coronavirus disease 2019 (COVID-19). Standard of care (SOC) for the prevention of exposure can be greatly supported with SOC measures to improve the immune response. The purpose of this study was to evaluate the effect of combining *Chyawanprash*, an Ayurvedic formulation, with SOC for prevention versus SOC alone among frontline HCWs through assessment of the proportion of COVID-19 cases among the trial participants during the trial period.

METHODS: This open-label, randomized controlled trial was conducted from June 13, 2020 to September 21, 2020 in an Ayurvedic hospital that was functioning as a COVID-19 care center in New Delhi during the pandemic. HCWs between 25 and 60 years of age working in an environment with the possibility of direct exposure to COVID-19 cases were enrolled and observed for 30 days. The interventions compared were SOC as per institutional guidelines and based on their roles (Group I) and SOC in addition to *Chyawanprash* 12 g twice a day for 30 days (Group II).

RESULTS: Out of the 193 participants who completed the study, no participant in both groups was COVID-19 positive at the end of one month. No adverse drug reaction or any serious adverse event was reported during the study. No clinically significant change in the safety parameters were observed. A statistically significant rise in serum IgG level was seen in Group II, but other inflammatory and immune markers did not show any statistically significant difference. In the post-intervention follow-up, four subjects in Group I and two subjects in Group II reported to have developed COVID-19 disease after 2 months of completion of the study period.

CONCLUSIONS: *Chyawanprash* has an immunomodulatory effect in the intervention group, but a longer-term clinical trial with a bigger sample size is needed to confirm its adaptogenic and preventive efficacy as an add-on to standard prophylactic guidelines for prevention of disease.

TRIAL REGISTRATION: Clinical Trials Registry of India: CTRI/2020/05/025275 [Registered on: 20/05/2020].

Keywords:
Adaptogen, *Chyawanprash*, health personnel, prophylaxis, Rasayana, SARS CoV-2

Key Summary Points

- Whether Ayurvedic formulations such as *Chyawanprash* (*Rasayana* medicine) when given along with the standard preventive measures can protect the HCWs better than the use of standard of care alone was not known. So this study was conducted to explore the same.
- The study revealed that *Chyawanprash* was well tolerated by the participants and the trial group was better protected even after 2 months of the post-intervention period.

How to cite this article: Gupta A, Madan A, Yadav B, Mundada P, Singhal R, Tripathi A, *et al*. A randomized controlled trial to evaluate the prophylactic efficacy of *Chyawanprash* in healthcare workers during the COVID-19 pandemic. J Res Ayurvedic Sci 2021;5:13-25.

Original Article

Access this article online
Quick Response Code:

Website: https://www.jrasccras.com/
DOI: 10.4103/jras.jras_15_21

A retrospective analysis of Ayurvedic clinical management of mild COVID-19 patients

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Abstract:

BACKGROUND: The COVID-19 virus is a new contagious pathogen which has made a huge impact on health, economic and societal perspectives of our country. Early detection, rapid isolation, and adoption of effective infection prevention and control (IPC) measures are key to preventing and controlling COVID-19 infection. Patients are now receiving symptomatic treatment. This retrospective study aims to assess and comprehend the effectiveness of Ayurvedic interventions in the treatment of mild symptomatic COVID-19 patients.

OBJECTIVE: The objective of this study is to analyze the outcome of Ayurvedic interventions in managing mild symptomatic COVID-19-infected cases.

MATERIALS AND METHODS: COVID-19 patients (diagnosed through RT-PCR test) admitted at Shri Dhanwantry Ayurvedic College and Hospital, Chandigarh were treated with Ayurvedic interventions. The data were collected and have been analyzed retrospectively. Data collected were systematically analyzed and presented using appropriate software (SPSS version 21).

RESULTS: The treatment given in this particular study were aimed at dissipating the pathogenesis based on Ayurvedic principles of management. Relief in major clinical symptoms such as fever, cough, and throat pain has been observed in studied cases of COVID-19. The clinical recovery rate observed in this study was 94.3%, which is comparatively high with reference to the current clinical recovery rate, i.e., 69.5% in Chandigarh (India).

CONCLUSION: The Ayurvedic interventions, AYUSH-64, *Agasthya Hareetaki Rasayana*, and *Anu Taila Nasya*, may play a major role in managing mild symptomatic cases of COVID-19.

IEC number: 8-55/2020-CARIRD/TECH/COVID/149

Keywords:
Ayurveda, COVID-19, *Agasthya Hareetaki Rasayana*, AYUSH-64, *Anu Taila*

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Submitted : 23-07-2021
Revised : 23-09-2021
Accepted : 23-09-2021
Published : 23-12-2021

Introduction

The COVID-19 epidemic has impacted the lives of everyone on the planet. Since December 2019, the illness has claimed the lives of over 3 million individuals throughout the world, drastically altering our way of life and social relationships. In January 2020, the World Health Organization (WHO) declared COVID-19 a public health emergency; on March 11, the virus was formally declared a pandemic, the highest level of health emergency.[1] COVID-19 has been confirmed in 179,241,734 instances worldwide as of June 24, 2021, with 3,889,723 fatalities.[2] In India, it has reached around 30,082,778 cases out of which 391,981cases deceased. In Chandigarh, 61,520 have been confirmed till date, out of which 807 cases deceased. The ongoing COVID-19 outbreak in industrialized nations also underlines

How to cite this article: Srivastava S, Singh H, Muralidharan S, Mohan R, Chaudhary S, Rani P, *et al.* A retrospective analysis of Ayurvedic clinical management of mild COVID-19 patients. J Res Ayurvedic Sci 2021;5:80-6.

Clinical outcomes among COVID-19 patients managed with modern and traditional Siddha medicine -A retrospective cohort study, Chennai, Tamil Nadu, India, 2020

Abstract

Background

Kabasura Kudineer (KSK) is a Siddha polyherbal decoction recommended by the Ministry of AYUSH and the Tamil Nadu government to prevent and manage COVID-19 in India. In this context, we aimed to determine the outcome of integrated therapy for COVID-19 using KSK in virologic clearance and length of hospital stay.

Methods

It was a single-centre, retrospective cohort study. We included the COVID-19 patients admitted to SRM Medical College Hospital and Research Centre, Chennai, during May-June 2020.The KSK was administered along with the standard of care for all the patients. We collected demographic, clinical data and laboratory parameters data and were presented as frequencies and proportions.

Results

We collected 204 COVID-19 positive patients' data. The mean (SD) age was 39.5 (13.4) years with a range of 13-79. Majority of the patients were male (n=157; 77%), 28% (n=58) had any co-morbidities and 61% (n=131) were with mild symptoms. Fever (n=57;27.9%) and cough (n=53; 25.9%) were the commonly reported symptoms. Paracetamol (n=135; 66.7%) and Zincovit (n=197, 96.6%) were the commonly administered medicines along with KSK. About 74% of asymptomatic (n=54) and 65% of mild symptomatic (n=85) patients turned negative for COVID-19 in RT-PCR within 4-7 days. There was a significant difference in the blood parameters ($p<0.05$) after the integrated treatment.

Conclusion

The use of KSK with standard care of treatment in COVID-19 treatment had notable results in the duration taken for virologic clearance, thereby reducing the length of hospital stay and improvement in laboratory parameters.

Keywords: Siddha, *Kabasura Kudineer*, COVID-19, AYUSH, Traditional medicine

A Retrospective Study on Efficacy and Safety of Guduchi Ghan Vati for Covid-19 Asymptomatic Patients

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Authors Contribution:

Professor Abhimanyu Kumar contributed to the design and implementation of the research, to the analysis of the results and to the writing of the manuscript

Dr. Govind Prasad involved in planning and supervised the work

Sanjay Srivastav involved in planning, supervised the work and worked with manuscript writing

Dr. Vinod Kumar Gautam involved in planning and supervised the work

Dr. Neha Sharma contributed to the design of the research, to the analysis of the results and to the writing of the manuscript.

Abstract

Background

Coronavirus disease 2019 (Covid-19) has been declared global emergency with immediate safety, preventative and curative measures to control the spread of virus. Confirmed cases are treated with clinical management as they are diagnosed but so far, there is no effective treatment or vaccine yet for Covid-19. Ayurveda has been recommended by preventative and clinical management guidelines in India and several clinical trials are ongoing. But there is no study to assess impact of Ayurveda on Covid-19.

Methods

Objective of present study was to evaluate the clinical outcome in Covid-19 confirmed asymptomatic to mild symptomatic patients who had received Ayurveda and compare with control (who has not received Ayurveda or any support therapy). Patients having Ayurveda intervention (Guduchi Ghan Vati-extract of Tinospora cordifolia) were included from Jodhpur Covid Care Centre and non-recipients were taken from Jaipur Covid Care Centre between May 15 to June 15, 2020. Total 91 patients, who were asymptomatic at the time of hospital admission and between 18 -75 years of age, were included in the study to analyse retrospectively.

Results

In control group, 11.7% developed mild symptoms after average 1.8 days and none in Ayurveda group reported any symptoms. Significant difference was reported between the group of patients taking Guduchi Ghan Vati (n=40) and patients in standard care (n=51) in terms of virologic clearance at day-7 (97.5% vs 15.6% respectively; p=0.000), at day 14 (100% vs 82.3%) days to stay in hospital (6.4 vs 12.8 respectively; p< 0.0001) .

Conclusion

Results of the study suggest that Guduchi Ghan Vati, a common and widely used Ayurveda preparation, could benefit treating asymptomatic Covid-19 patients. Larger, randomised controlled Trials are required to confirm the findings.

Keywords: Ayurveda, Guduchi Ghan Vati, Tinospora cordifolia, Covid-19, Asymptomatic and Mild symptomatic patients

https://clinicaltrials.gov/ct2/show/NCT04480398

Abstract

Full text

Guduchi Ghanavati to Improve Immune Status and General Health in the Population at High Risk of COVID-19: Results o An Open-Label Non-Randomized Clinical Trial from India

Thakar A, Panara K, Shah H, Kalsariya B, Ruparel S, Jain N, Bhatt P, Jani D, Dodia R, Patel F, Salve R, Chaudhari S, Raghavani I Vyas J, Goyal M, Bhinde S

Preprint from SSRN, 10 Mar 2021
DOI: 10.2139/ssrn.3798254 PPR: PPR296363

Preprint

Abstract

Background: Ayurveda, the traditional system of Indian medicine, can offer prophylactic or therapeutic solutions fo COVID-19. Govt of India recommended Guduchi Ghanavati (Ayurveda herbal formulation) as an Immunity enhance and prophylaxis to SARS-CoV-2 during the COVID-19 pandemic. The study aimed to assess the effect of Guduchi Ghanavati as prophylaxis against SARS-CoV-2, as immunity enhancer and on Quality of life in adult volunteers who are at high risk of exposure to SARS-CoV-2. Materials & Methods: Non-randomized, multi-centric, controlled tr was conducted on the population of the community dwelling individuals having good health and were at moderate very high risk of exposure to COVID 19 infection at five cities in Gujarat, India. Participants of the intervention arm received 'Guduchi Ghana' (GG) [extract of Tinospora cordifolia (Willd.) Miers] 1 g/day orally along with standard preventive guidelines (SPG) for SARS-CoV-2 infection (washing hand frequently, physical distancing, and covering th face). Participants of the control group followed standard preventive guidelines only. The outcome measures were the incidence of COVID-19, changes in Immune Status, WHOQOL-BREF, and preliminary safety. Results: a total of 41 incidences of COVID-19 were reported in GG+SPG group (n=15729 analyzed) whereas 16 incidences in SPG only group (n=4845 analyzed) indicating no significant association between the incidence of COVID-19 and Add-on GG intervention (OR, 0.79; CI, 0.44- 1.41 and Adjusted OR, 0.67; CI 0.37-1.21). Analyzing the effect on secondary outcomes, a significant difference (p<0.001) was reported in the mean score of immune status parameters (Immune score, Immune function, and general health) with the higher score in the GG+SPG group. Mean score changes for all four domains (Physical, Psychological, Social relationships, and Environmental) of QOL were also statistically significant ((p<0.001) in GG+SPG group compared to the standalone SPG group with a small effect siz No serious adverse event was reported in both groups. Conclusion: Data of the study supported the routine use of Guduchi Ghanavati to improve immune status and general health without any claim on COVID-19 as pre-exposure prophylaxis.

In-vitro Immunomodulatory activity and Thrombolytic potential of Kabasura Kudineer (KSK), an official Siddha polyherbal formulation

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Abstract:

Coronavirus disease 2019 (COVID-19) caused by the Severe Acute Respiratory Syndrome Coronavirus 2 (SARS-CoV-2), a pandemic, which has led to the spread of mortality and morbidity all over the globe. In this dire situation, there is an urgent requirement for the development and immediate dissemination of treatment against COVID-19. The traditional medicine system of Siddha can be utilized as preventive care to boost the immune system. The vast treasure of knowledge found in Siddha medicine can help in the betterment of humankind. Kabasura Kudineer (KSK) is from the ancient times present as an immune-boosting agent against several diseases. The present experimental setup to investigate the immunomodulatory and thrombolytic potential of KSK. The *in vitro* immunomodulatory models of phagocytosis of *Candida albicans* assay and nitro blue tetrazolium have demonstrated that KSK is giving better results compared with the controls (pooled serum, lipopolysaccharide, and streptokinase). The KSK at the concentrations of 12.5, 25, 50, and 100 µg/ml showed % immune-stimulations of 12.40 %, 20.81 %, 33.53 %, 43.20 % and for NBT showed 19.00 %, 25.50 %, 64.00 %, 71.00 % respectively. And similarly, the thrombolytic activity showed 50 and 100 µg/ml concentration showed 43.83 %, 71.83 % clot lysis respectively; and the control value for the streptokinase showed 83.78 %. Hence, it can be confirmed that KSK has immunomodulatory and thrombolytic properties in *in vitro* models, although the in vivo and the identification of KSK are to be discovered.

Keywords: Kabasura Kudineer (KSK), Immunomodulatory, Thrombolytic, COVID-19, Siddha formulation.

Repurposing of Medicinal plants used in Siddha formulations as Potential Protease Inhibitors of COVID-19: An in silico approach

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Background:

The Coronavirus disease (COVID-19) caused by the virus SARS-CoV-2 has become a global pandemic in a short time has infected about 1,203,959 patients and brought forth death rate about 64,788 among 206 countries as mentioned by WHO in the month of April 2020. Currently, there is no specific treatment or vaccine for fighting against this infectious disease and scientists agree that possible therapeutic may arise through drug repositioning. Herbal medicine are achieving attention because of the extensive therapeutics like potent antiviral, immunomodulatory, anti-inflammatory, and anti-oxidant properties.

Materials and methods

This study was planned to screen herbs from Siddha that have the potential to increase host immune system as well as blocking virus entry in host cells. Official Siddha formulation Kabasura Kudineer, Nilavembu Kudineer, and Novel Siddha formulation – JACOM are already being in use as antiviral, immunomodulatory, anti-inflammatory, and antioxidant. 54 molecules identified and surveyed via docking study. Docking study was performed using Maestro interface (Schrödinger Suite, LLC, NY).

Results:

Out of these 54 Phytoconstituents, 30 Phytoconstituents were found to interact with > 2 protein structures of COVID-19. The docking results indicate that amongst the reported molecules 4 out 5 protein structure (PDB ID: 5R7Y, 5R7Z, 5R80, 5R81 and 5R82) showed promising results of binding to COVID-19 enzyme. So this formulations may be useful as a therapeutic and/or prophylactic agent for restricting viral attachment to the host cells.

Discussion:

The drug repurposing study provide an insight in terms of binding of active ingredients present in different plants used in formulations and targets enzymes for treatment of the COVID19

Key words:

COVID-19, SARS-CoV-2, Siddha Medicine, Medicinal plants, AYUSH.

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Introduction:

COVID–19 disease caused by the novel coronavirus SARS-CoV–2 has been declared as a global pandemic by WHO first emerged in China [1]. SARS-CoV-2 has spread across all continents, as of latest situation report on June 30, 2020 by WHO, a total of 87, 08 008 cases with a mortality of 4, 61,715 have been reported [2]. In India there are 4, 10 461 cases and 13, 254 deaths as on June 30, 2020 these data correspond the imminent risk facing the country. Transmission of virus spreads via droplets, physical contact with infected individuals, contaminated surfaces [3]. COVID-19 commonly reported symptoms are fever, headache, vomiting, chills, dyspnea, nausea, sore throat, coughing up blood, shortness of

Coadministration of AYUSH 64 as an adjunct to Standard of Care in mild and moderate COVID-19: A randomised, controlled, multicentric clinical trial

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Funding Statement: This study was funded by Central Council for Research in Ayurvedic Sciences, Ministry of Ayush, Government of India.

Competing interests: None of the authors have any financial conflict of interest regarding this study. The authors Kuldeep Chuadhary, Alok Srivastava, Govind Reddy, Manohar Gundeti, BCS Rao, Babita Yadav, Narayanam Srikanth work in Central Council for Research in Ayurvedic Sciences (CCRAS), Ministry of AYUSH (MoA), Government of India (GOI), New Delhi. Dr Ashwinikumar Raut was a consultant for the study. Dr Sanjay Tamoli was involved as a CRO. AYUSH-64 is a proprietary formulation of CCRAS.

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Key Words: COVID-19, Standard of Care, Ayurveda, Ayurvedic medicine, Herbal drugs, Adjuvant therapy

ABSTRACT

Objectives: To compare the co-administration of an Ayurvedic drug AYUSH 64 as an adjunct to standard of care (SOC) and SOC for efficacy and safety in the management of COVID-19.

Design: Multicentre, parallel efficacy, randomized, controlled, open label, assessor blind, exploratory trial with a convenience sample. Patients followed to complete 12 weeks of study duration.

Setting: COVID-19 dedicated non-intensive care wards at 1 government hospital, 1 medical college teaching hospital and 1 medical university teaching hospital

Participants: 140 consenting, eligible, hospitalized adult patients suffering from mild and moderate symptomatic COVID-19 and confirmed by a diagnostic (SARS-CoV-2) RT-PCR assay on nasal and throat swab were randomized to SOC or SOC plus AYUSH 64. To be withdrawn if disease becomes severe.

Interventions: Two tablets of AYUSH 64, 500 mg each, twice daily after meals, and continued till study completion. SOC (symptomatic and supportive) as per national guidelines of India for mild and moderate disease.

Main outcome measures: Time period to clinical recovery (CR) from randomization baseline and proportion with CR within 28 days time frame; CR defined in the protocol

Results: 140 patients randomized (70 in each arm); 138 patients with CR qualified for analysis. Both groups were matched at baseline. The mean time to CR from randomization was significantly superior in AYUSH 64 group (95% CI -3.03 to 0.59 days); a higher proportion (69.7%) in the first week ($p=0.046$, Chi-square). No significant differences observed for COVID-19 related blood assays (such as D-Dimer). AYUSH 64 arm showed significant ($p<0.05$) superior persistent improvement in general health, quality of life, fatigue, anxiety, stress, sleep and other psychosocial metrics. 1 patient on SOC required critical care. 48 adverse events (AE) reported in each group. Barring three SAE (in SOC), AE were mild and none were drug related. 22 participants (8 on AYUSH) were withdrawn. No deaths were reported.

Conclusions: AYUSH 64 hastened recovery, reduced hospitalization and improved overall health in mild and moderate COVID-19 when co-administered with SOC under medical supervision. It was safe and well tolerated. Further studies are warranted.

Trial registration: The Clinical Trials Registry India Number CTRI/2020/06/025557

Funding: CCRAS, Ministry of AYUSH, Government of India

Efficacy of AYUSH 64 as add-on therapy in early stage COVID 19 - An open-label randomized controlled pilot study

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ABSTRACT

Background: Efficacy ofAYUSH 64 has been proven in fever and influenza-like illness earlier. Hence it was felt it should be evaluated in COVID 19 which has similar symptom complex. **Aim:** To evaluate the clinical efficacy of AYUSH 64 as an add-on to standard care in early stage COVID-19 patients. **Materials and methods:** After obtaining IEC permission, a single centre, randomized, open labelled, controlled, pilot study was undertaken. Asymptomatic to mild COVID 19 (RT-PCR positive) patients, who gave written informed consent, were randomly allotted either AYUSH 64 for 14 days as an add-on treatment to standard care or standalone standard care. The outcomes variables were changes in WHO ordinal scale for clinical improvement, incidence of development of COVID symptoms, use of oxygen therapy, use of mechanical ventilator, duration of total symptomatic phase, adverse drug reaction,death and changes in laboratory values. **Results:** Among total 115 screened, 80 participants were included, out of which 41 received AYUSH 64 in addition to standard care and 39 only standard care. The mean final WHO score was comparable for both the Groups, however, mean scores in the interventional Group showed downward trend from 7th day onwards as compared to the control Group. Difference in laboratory

values and need for oxygen were not statistically significant in both the Groups. No incidence of the requirement of a mechanical ventilator, adverse drug reaction, and death were observed in either of the Groups. **Conclusion:** The findings of this study show that an integrated approach of AYUSH 64 with standard care did not exert promising difference in core outcomes of COVID-19 when compare to standalone standard care. However, a trend towards lower values was observed in the symptoms in AYUSH 64 add-on group in comparison to standalone standard care.

Keywords: Ayurveda, Indian Traditional System of Medicine, SARS-CoV-2, WHO scale for clinical improvement

1. INTRODUCTION:

The COVID-19 pandemic has generated a worldwide health crisis posing an unparalleledpublic health emergency. Though COVID-19 causes minimal or mild symptoms in most of the cases, significant proportion of individuals require admission to an Intensive Care Unit.[1]As of now, mainly symptomatic supportive treatment is being provided to the patients whereas seriously ill individuals are treated with organ support.[2]As, developing a new drug is a complex process that can take 12–15 years,[3]repurposing of existing drugs is the fastest option for Covid-19 treatment.[4]The majority of the drugs used for its treatment worldwide fall primarily under antiviral, antimalarial, anti-inflammatory, monoclonal antibodies categories.[5] As disease specific drugs are not available, drugs are currently used solely on an empirical basis.[6]These drugs include Ribavirin,Sofosbuvir,Lopinavir, Remdesivir, Ivermectin, Hydroxychloroquine[7] and Favipiravir.[8]Few of these drugs are taken as prophylaxis based on merely expert opinion such as HCQ (Hydroxychloroquine,)[9,10] Vitamin C, Zinc etc. in conventional medicine. A recent study on AYUSH 64 demonstrated that,of the 30 cases of influenza like illness (ILI) treated with it, 28 recovered without any further need for medication.[11]Even in earlier study, an integrative approach involving modern medicine and traditional medicine has reported encouraging outcomes.[12]Hence, it was thought to repurpose AYUSH 64 as add-on to standard care in early stage COVID 19 patients.[13]Therefore, this pilot study was carried out with objectives to evaluate efficacy of AYUSH 64 as add-on to standard care in improving clinical status and to assess its safety in early stage COVID 19 patients.

Efficacy and safety of *Guduchighan Vati* in asymptomatic and mild to moderate cases of COVID-19: A randomized controlled pilot study

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ABSTRACT:

Background: Currently, there is no approved treatment for the management of COVID-19 pandemic. Drug repurposing of existing medications could be a possible way to find out a novel therapeutic entity to combat the COVID-19.

Objectives: To determine the clinical effectiveness and safety profile of an Ayurveda Intervention (*Guduchighan Vati*) in asymptomatic and mild to moderate cases of COVID-19.

Methods: This was an open-label randomized controlled pilot study with a sample size of 30 participants (15 in each arm). The participants were asymptomatic or mild to moderate cases of COVID-19. *Guduchighan Vati* 500 mg twice daily for 10 days was administered in the intervention group as standalone therapy and Hydroxychloroquine in the control group.

Outcome measures: Time to negative RT-PCR for COVID-19, proportion of participants turned RT-PCR negative for COVID-19 at 5th and 10th day, duration to achieve complete clinical recovery, improvement in laboratory parameters and incidence of Adverse Drug Reaction/Adverse Event. The data was compared within group using paired sample t-test/ Wilcoxon signed rank test and between group using independent sample t-test/Mann-Whitney test. The results of RT-PCR test was compared between group using chi-square test.

Results: 93.3% participants turned RT-PCR negative for COVID-19 in the intervention group, as compared to 66.6% participants in control group till 10th day of the study period. However, the results are statistically insignificant ($p = 0.068$) which might be attributed to smaller sample size. All the symptomatic patients in the intervention group were clinically recovered at 5th day whereas 14 out of 15 recovered in the control group. No symptoms were observed at 10th day in both the groups. No adverse drug reaction/serious adverse event were observed during the study period.

Conclusion: *Guduchighan Vati* is a safe and effective treatment for asymptomatic and mild cases of COVID-19 and it lowers the time to RT-PCR negative status without any adverse drug reaction/adverse event.

Registration: Clinical Trial Registry of India - CTRI/2020/07/026840

Keywords: COVID-19, *Guduchi*, *Guduchighan Vati*, SARS-CoV-2, *Tinospora cordifolia*

AYUSH-64 as add-on to standard care in asymptomatic and mild cases of COVID-19: A randomized controlled trial

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ABSTRACT

Background: The evidence on the efficacy and safety of Ayurveda interventions as add-on to the standard conventional care for COVID-19 is limited. This study was planned to explore the potential of AYUSH-64 as add-on to conventional care in improving the clinical recovery and negative RT-PCR conversion in asymptomatic and mild COVID-19 cases.

Materials and Methods: An open-label randomized controlled study was conducted at Government Medical College, Nagpur, Maharashtra, India with a sample size of 60 participants. In this study, asymptomatic or mild COVID-19 patients were randomized and allocated into intervention and control group in 1:1 ratio. AYUSH-64 two capsules (500 mg each) were administered thrice daily, after food with water for 30 days along with standard care in the intervention group, while the control group received only standard care. The effect

of the interventions was assessed in terms of negative RT-PCR for COVID-19, clinical cure rate and inflammatory cytokines.

Outcome measures: Primary outcome was the time to attain negative RT-PCR for COVID-19 and proportion of participants turned RT-PCR negative for COVID-19 at 7^{th}, 15^{th}, 22^{nd} and 30^{th} day respectively in the intervention group compared to the control group. Secondary outcomes were the proportion of participants who attained clinical recovery at 7^{th}, 15^{th}, 22^{nd}, and 30^{th}day; improvement in laboratory parameters on the 30^{th} day (as compared to baseline) and incidence of Adverse Drug Reactions/Adverse Events (ADRs/AEs). The data was compared within group using paired sample t-test/ Wilcoxon signed rank test and between group using independent sample t-test/Mann-Whitney test.

Results: Statistically significant difference was not observed in the proportion of participants who turned RT-PCR negative during each of the follow-ups ($p=0.134$) and both groups demonstrated comparable efficacy. The clinical recovery rate in terms of time taken for complete cure of symptoms in the symptomatic participants was 60% and 37% on day 15 ($p=0.098$) and 100% and 85.2% on day 30 ($p=0.112$), in the intervention and control group respectively which is numerically a better clinical outcome in the intervention group. The improvement in the inflammatory markers such as IL-6, TNF-α and D-dimer was statistically significant in the intervention group ($p<0.05$). None of the participants developed any complications nor were any significant ADR/AE observed in both the groups.

Conclusion: In patients with asymptomatic and mild COVID-19, AYUSH-64 as add-on to standard conventional care, contributed to improving the duration for attaining complete clinical cure and demonstrated potential in reducing the levels of pro-inflammatory markers in the body.

Trial Registration: Clinical Trial Registry of India - CTRI/2020/05/025156

Keywords: Ayurveda, AYUSH-64, COVID-19, Pandemic, SARS-CoV-2

Perception and practices followed by AYUSH practitioners and health seekers for prevention of COVID-19: Cross-sectional analysis of an app-based data

Abstract

AYUSH Sanjivani is a mobile application launched by the Ministry of AYUSH (MoA) to gather information regarding the utilization of AYUSH (Ayurveda, Yoga, Unani, Siddha, and Homeopathy) advocacies for the prevention of COVID-19 infection. A cross-sectional analysis of the data generated through this mobile application has been performed and presented in this article to examine the acceptability and extent of utilization of AYUSH preventive measures in India.

Objectives: The objectives of this cross-sectional analysis was to determine the trends of the utilization of AYUSH measures by the beneficiaries as reported by AYUSH practitioners and by the practitioners themselves for the prevention of COVID-19 and to determine the benefit obtained in terms of self-reported parameters of general well being, the overall impact on general health and in preventing the onset of flu-like symptoms.

Methods: A secondary data analysis was undertaken, utilizing the cross-sectional data generated through the AYUSH Sanjivani App from May to July 2020. The responses in terms of demographic profile, utilization pattern, benefits obtained, the interventions used and the data of beneficiaries in terms of geographic location and interventions prescribed were analyzed statistically to assess the trends of the utilization of AYUSH measures for prophylaxis.

Results: Data of 74,568 AYUSH physicians and 1,35,21,245 beneficiaries/health seekers whose data were reported by 3623 AYUSH practitioners were used for analysis. AYUSH advocacies/measures were utilized by 69,195 (92.8%) physicians for prophylaxis. *Samshamani Vati, Chyavanprash,* and Arsenicum Album-30 were the most commonly used AYUSH interventions. Improvement in terms of appetite, bowel movements, sleep, mental well being, stamina, change in pre-existing disease, and change in disposition were reported by 42400 (61.3%) physicians. Maximum beneficiaries were from the state of Gujarat followed by Madhya Pradesh. Arsenicum Album-30 was the most commonly prescribed/distributed intervention among the beneficiaries/ health seekers.

Conclusion: Maximum physicians have reported having benefited from the use of AYUSH prophylactic measures for the prevention of COVID-19. Moreover, a good proportion of the Indian population was provided the AYUSH prophylactic measures as recorded in the app.

Keywords: AYUSH Sanjivani app, COVID-19, prophylaxis, AYUSH advisory, *Samshamani Vati, Arsenicum Album-30*

An Open label prospective interventional study to assess the prophylactic effect of Guduchi Ghan Vati in COVID-19: A community-based study in a containment zone of Himachal Pradesh, India

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Abstract

Background: Outbreak of SARS-CoV-2 is *Janapadoddhwamsa Vikara* (epidemic disease) in *Ayurveda*, where *Rasayana* drugs (immunomodulators or rejuvenating therapy) have been advocated for controlling the diseases. Therefore, *Guduchi Ghan Vati*,

containing a drug *Guduchi* (*Tinospora cordifolia*), a plant is selected for prevention of COVID-19.

Objectives: To know the efficacy and safety of *Ayurvedic* intervention i.e. *Guduchi Ghan Vati* in prevention of COVID-19 infection among the community of containment areas.

Methods: It is an open label, prospective, non-randomized, community based interventional study, carried out from 06 May to 23 June, 2020, in a containment zone Bijhari area of District Hamirpur of Himachal Pradesh, India. *Guduchi Ghan Vati* was provided to the community in dose of 500 mg twice a day with luke warm water on empty stomach for 30 days. Their demographic and health related data and Follow up of the same subjects was done on the 30th day through telephonic interviews using the E-format (google forms).

Results: Total 1165 participants' data were analysed to assess the efficacy and safety of *Guduchi Ghan Vati*. In the sample 85.2 % participants had no systemic disorders whereas 13.8 % participants were taking concomitant medicines for other morbidities. Incidence of COVID-19 positive cases was only 0.1% (n=01).

Conclusion: Ayurvedic intervention (*Guduchi Ghan Vati*) was found to be safe and effective as a prophylactic measure for COVID-19 infection. This intervention was helpful in improving physical and psychological well-being with minimal adverse drug Reaction/Adverse Effect.

Keywords: *Ayurveda, Guduchi Ghan Vati, Efficacy, COVID-19, Prophylaxis, Containment Zone*

Introduction

Coronavirus disease 2019 (Covid-19) is a new threat to the global population. The World Health Organization documented SARS-CoV-2 as a public health concern in March 2020.[1] India has the world's fastest growing outbreak of COVID-19 in absolute numbers according to WHO, reporting more than 5·6 million infections as of Sept 22,2020.[2]

The COVID-19 risk is greater in older people and patients having other health problems such as lung diseases, heart diseases, diabetes and cancer.[3] Studies show that

Efficacy of Pranayama in Preventing COVID-19 in Exposed Healthcare Professionals: A Randomized Controlled Trial

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ABSTRACT

Background: The global outbreak of COVID-19 has created a challenging situation, especially among the frontline Health Care Professionals (HCPs), who are routinely exposed and thus at a relatively higher risk of infection. A few studies have shown the practice of Pranayama, a component of Yoga, to be effective in improving immune function and reducing infection. However, no clinical trial on the efficacy of Pranayama in preventing COVID-19 has been conducted.

Aim & Objective: This randomized clinical trial assessed the effect of Pranayama in preventing COVID-19 infection in Health Care Professionals (HCPs) routinely exposed to COVID-19 cases.

Methodology: The study was conducted at 5 different COVID-19 hospitals in New Delhi, India during September-November, 2020. 280 HCPs assigned duties with COVID-19 patients who were found negative in COVID-19 antibody test in pre-intervention assessment were recruited and randomly assigned to intervention and control groups. The intervention group practiced especially designed Pranayama modules twice a day (morning and evening) for 28 days under the supervision of Yoga instructors through online mode, while those in the control group were advised general fitness practices (like walking, jogging, running). Participants who became symptomatic underwent RTPCR / Point of Care Rapid Antigen test for confirmation of COVID 19 diagnosis. All the patients also underwent antibody testing for COVID-19 on 28th day of the intervention to detect asymptomatic infection.

Results: 250 participants, comprising 123 in the intervention group and 127 in the control group, completed the study. The intervention and control groups had comparable demographics and baseline characteristics. Three participants (all controls) developed COVID 19 symptoms during the study. On the completion of the study, only one participant in the Intervention group

tested positive, while 9 participants in the control group (Including three symptomatic participants) tested positive for COVID-19 antibodies. This difference was statistically significant (P-value: 0.01).

Conclusion: Practice of our especially designed Pranayama module, every day for 28 days was highly effective in preventing COVID-19 infection in exposed healthcare professionals (HCPs).

CTRI Number: **CTRI/2020/07/026667**

Keywords: COVID-19, Pranayama, Health Care Professionals, Yoga, Pandemic, Prevention

A Retrospective analysis of Ayurvedic clinical management of symptomatic COVID-19 patients

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ABSTRACT

Background: The COVID-19 virus is a new pathogen that is highly contagious which has made a huge impact on health, economic and societal of our country. Prevention and control of COVID-19 infection focuses on early recognition, immediate isolation and implementation of appropriate infection prevention and control (IPC) measures. As of now symptomatic care is given to the patients. This particular retrospective study is done to analyze and understands the outcome of Ayurvedic Interventions in the management of mild symptomatic COVID-19 patients.

Objective: To analyze the outcome of Ayurvedic interventions in managing mild symptomatic COVID-19 infected cases

Materials and methods: Lab confirmed COVID-19 infected patients admitted at Shri Dhanwantry Ayurvedic College and hospital, Chandigarh was treated with Ayurvedic interventions. The data was collected and has been analyzed retrospectively. Data collected was being systematically analyzed and presented using appropriate software (SPSS version 21).

Result: The interventions were administered in this particular study were aimed at dissipating the pathogenesis based on Ayurvedic principles of management. Increased clinical recovery rate was observed in major symptoms of COVID-19 i.e. Fever, cough and sore throat.

Conclusion: The clinical recovery rate was observed in this study is 94.3% which is comparatively high in reference to current clinical recovery rate i.e. 69.5% in Chandigarh.

Ethical Clearance Number: 8-55/2020-CARIRD/TECH/COVID/149 (Dated: 02/07/2020)

Keywords: COVID-19, Ayurveda, Ayurvedic care, Clinical management

INTRODUCTION:

COVID-19 has emerged as the latest pandemic, which is affecting human health and economy across the globe. Global incidence of COVID-19 infection has crossed 12,552,765 cases [1]. In India it has reached around 8,49,553 cases out of which 22,674 cases have been deceased. In Chandigarh, 559 have been confirmed till date out of which 8 cases has been deceased. The occurrence of the ongoing COVID-19 in developed countries also highlights the fact that

Main Manuscript

Randomized, double blind, placebo controlled, clinical trial to study co-administration of Ashwagandha on safety, immunogenicity, and protection with COVID-19 vaccine – A Study Protocol

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Funding Statement: This study was funded by Central Council for Research in Ayurvedic Sciences (CCRAS), Ministry of AYUSH (MoA), Government of India.

Competing interests: None of the authors have any competing interest regarding this study. The authors BCS Rao, Babita Yadav, Narayanam Srikanth work at CCRAS, MoA, Government of India (GOI), New Delhi. Arvind Chopra is chief clinical coordinator designated by MoA. Bhushan Patwardhan is Chairman Interdisciplinary AYUSH R & D Task Force on COVID-19 established by MoA.

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Key Words: COVID-19, Vaccine, Immunogenicity, Immuno adjuvant, Ayurveda, Ayurvedic medicine,

ABSTRACT

Introduction The government of India has rolled out COVID-19 vaccine program for individuals who are 18 years of age and above and priority is being given to the elderly, and individuals with morbidity. Oxford-AstraZeneca COVID-19 vaccine (COVISHIELD™) is most widely used in India. A large number of Indian people have been consuming various traditional medicines in the hope of better protection against COVID-19 infection. Several studies have reported immunological benefits of Ashwagandha and its potential as vaccine adjuvant. We plan to study co-administration of Ashwagandha with COVISHIELD™ vaccine on safety, immunogenicity and protection.

Methods and analysis We designed a prospective, randomized, double blind, parallel group, placebo controlled, two arm, exploratory study on healthy volunteers receiving the COVISHIELD™ vaccine. In addition to the two dose schedule of COVISHIELD vaccine as per national guidelines, participants will be administered 8gm Ashwagandha or placebo tablets respectively per day. Primary outcome measure is immunogenicity as measured by SARS-CoV-2 spike (S1) and RBD-specific IgG antibody titres. Secondary outcome measures are safety, protective immune response and quality of life measures. Adverse event following immunization will be monitored at each time throughout the study. Participants will be tracked on a daily basis with a user friendly mobile phone application. Following power calculation 600 participants will be recruited per arm to demonstrate superiority by a margin of 7% with 80% power. Study duration is 28 weeks with interim analysis at the end of 12 weeks.

Ethics and dissemination Ethical approval was obtained through the Central and institutional Ethics Committees. Participant recruitment is expected to commence by August 2021. Results will be presented in conferences and published in preprint followed by peer-reviewed medical journals.

Registration details

Clinical Trial Registry – India (CTRI) Registration Number: CTRI/2021/06/034496. Date of Registration June 30, 2021.

AYUSH-64 as an adjunct to Standard Care in mild to moderate COVID-19: An open-label randomized controlled trial in Chandigarh, India

ABSTRACT

Background

Interest in the use of traditional medicine systems such as Ayurveda to manage COVID-19 cases is increasing. However, there is limited evidence on the safety and efficacy of administering Ayurveda interventions as add-on to the standard care for COVID-19.

Objective

To explore the therapeutic efficacy and safety of AYUSH-64 as an add-on to standard care in the management of mild to moderate stage COVID-19.

Methods

An open-label randomized controlled trial was carried out at Dhanwantry Ayurvedic Medical College and Hospital, Chandigarh, India. Eighty participants with mild to moderate stage COVID-19 were randomly allocated into AYUSH-64 add-on group and control group in 1:1 ratio. Participants in the AYUSH-64 add-on group received two tablets (500 mg each) three times daily for 30 days along with conventional standard care that included Paracetamol, Cetirizine, Vitamin C, and Azithromycin. The control group received standard care alone. The primary outcome assessed was the proportion of participants with clinical recovery and negative RT-PCR test for COVID-19 at scheduled follow-up visits on day 7, 15, 23,and 30. Additionally, change in pro-inflammatory markers- IL-6, D-dimer, CRP, Serum Ferritin, Pro-calcitonin, change in metabolic functions- serum LDH, BNP, Creatine kinase, liver enzymes, renal function and HRCT chest and incidence of adverse drug reaction/serious adverse event were assessed.

Results

Of the 80 participants included in the study, 74 (37 participants in each group)contributed to the final analysis. Statistically significant difference was observed in the proportion of participants with clinical recovery in the AYUSH-64 add-on group ($p<0.001$) at each of the scheduled

follow-up visits. Further, all the participants in the AYUSH-64 add-on group clinically recovered by day 23 compared to 32.4 per cent in the control group. The mean duration for clinical recovery in the AYUSH-64 add-on group (5.8 ± 2.67 days) was less as compared to control group (10.0 ± 4.06 days). The proportion of participants who turned RT-PCR negative for COVID-19 on day 7, 15, and 23 were 81.8, 94.5, and 100 per cent in the AYUSH-64 add-on group, and 79.4, 94.5, and 97.2 per cent in the control group, however, the difference observed was statistically not significant ($p=0.314$). The proportion of participants with improvement in HRCT chest was statistically significant in the AYUSH-64 add-on group ($p=0.031$) unlike in the control group ($p=0.210$). Similar reductions in most inflammatory markers measured (IL-6, CRP, Serum ferritin, LDH, BNP, and Troponin T) on day 30($p<0.05$) were observed in both groups except that in the AYUSH-64 add-on group, significant reduction was also observed in the D-dimer level. None of the participants developed any complications nor were any significant study drug related Adverse Drug Reactions (ADR) and Adverse Events (AE) observed.

Conclusion

AYUSH-64 as adjunct to standard conventional care is safe and hastens clinical recovery in adult patients with mild to moderate COVID-19.

Trial Registration: Clinical Trial Registry of India - CTRI/2020/05/025214

Keywords: Ayurveda, COVID-19, Pandemic, Complementary medicine, Viral disease

Effect of an Ayurvedic intervention (Ayush-64) in mild to moderate COVID-19: An exploratory prospective single arm clinical trial

Abstract

Background: Ayush-64 is an Ayurvedic formulation, developed and patented by Central Council of Research in Ayurvedic Sciences (CCRAS). In the present study, we repurposed it for use in mild to moderate COVID-19 cases based on a pilot study against Influenza like illness (ILI) and molecular docking study which revealed that several compounds isolated from Ayush-64 demostrated antiviral activity.
Purpose: To evaluate the role of Ayush-64 in clinical recovery of mild to moderate COVID-19 pattients

Study Design: A single arm, pilot study in mild to moderate COVID-19 patients

Methods: The study was conducted from 20th June, 2020 to 11th August, 2020 at Chaudhary Brahm Prakash Ayurved Charak Sansthan (CBPACS), New Delhi, India involving 37 confirmed COVID-19 participants. Ayush 64 tablets in the dose of two tablets (500 mg each) thrice daily was given to the participants for a duration of either 8 or 14 days. Number of participants showing 'clinical recovery' was set as primary outcome. Percentage of participants with negative SARS-CoV-2 on nasal or throat swab in a 2-day consecutive real time RT-PCR test was evaluated as secondary outcome.

Result: In the study 86.1% participants have shown clinical recovery after 14 days intervention of Ayush-64, out of which 75% clinically recovered within 7 days. Finding of RT-PCR test has shown that 69.4% participants turned negative till 15th day, out of which 50% became negative on 8th day. No AE/ ADR was observed during the course of the study.

Conclusion: Ayush-64 is a safe treatment option in mild to moderate COVID-19 cases and is likely to significantly facilitate clinical improvement in terms of duration for clinical recovery and attaining negative conversion, without any ADR/AE.

Keywords:- Ayush-64, SARS-CoV 2, Ayurveda, Drug Repurposing, ILI

Ayurveda formulation AYUSH 64 in asymptomatic and mild COVID 19 infection- A prospective, open label Clinical Study

Abstract

Background

COVID 19 pandemic has evolved as a unique unprecedented global health crisis that has affected severely the economies and daily lives of people. Despite the diligent worldwide efforts to contain it, there is an exponential rise in cases. Associated serious morbidity and mortality has continued the efforts towards a clinically proven prophylaxis and therapeutic strategy. In the absence of any effective approved treatment, drug repurposing of available drugs are underway across the globe for treating COVID 19 patients. AYUSH 64 is an antimalarial Ayurveda formulation repurposed in COVID 19 management due to its proven efficacy in malaria and influenza like illness.

Trial Design: This was a prospective, open-label, single-arm, pilot study conducted at Ayurveda and Unani Tibbia College(A&U Tibbia) and Hospital, Designated COVID-19 Health Center under Govt. of NCT of Delhi.

Objective: The primary objective of the study was to assess the efficacy of AYUSH 64 in the management of asymptomatic, mild to moderate COVID-19 cases .However the secondary objectives were to assess clinical safety and to describe the clinical profile of COVID-19 with special reference to early symptoms, severity of disease, complications, course of disease, diagnostic investigations, biochemical & imaging abnormalities and patterns of clinical recovery.

Methods:

The study was conducted on 40 patients out of which maximum were asymptomatic and mild COVID-19 cases of either sex aged above 18 years admitted in the hospital with positive naso-pharyngeal swab test for SARS-CoV-2 (RT-PCR) or Rapid antigen test. Ayush- 64 tablets in the dose of two tablets (500 mg) thrice a day after food with warm water was given to the participants for the period of 7 to 14 days but once the patient got RtPCR negative ,medicine was discontinued. The primary outcome of the

study was negative status of SARS-CoV-2 on nasal or throat swab after 07 days or 14 days of intervention in a 2-day continuous real time RT-PCR test and changes in liver enzymes & renal functions. The secondary outcome of the study included the mean time (days) for clinical recovery as per clinical recovery criteria defined, number of symptomatic patients showing clinical recovery and improvement in selected laboratory parameters:, differential and total leukocyte counts, acute phase reactants, serum IL-6, Serological Protective Antibody Assay (IgE ,IgM and IgG).

Results

Out of 40 participants who were enrolled in the study, 36 (90%) completed the trial. Out of 36 participants, 69.44% participants after 07 days of AYUSH 64 intervention in the study became RT-PCR negative until 8th day and the rest 30.55 % participants completed the study in 14 days and they turned RT-PCR negative on 15th day. Out of 36 participants, 28 participants were symptomatic. 39.28% participants clinically recovered in 7 days of AYUSH-64 intervention and 53.5% participants clinically recovered in 14 days. Mean time for clinical recovery was 7.04 days (± 2.88 days standard deviation). No adverse drug reaction was found in any of the participants. Serious adverse event (SAE) was reported in two participants (5%) just another day after enrolment in the study, which was not related, to the trial drug and the same was informed to the sponsor.

Conclusion

Among asymptomatic and mild COVID-19 cases, the repurposing of AYUSH 64 was found effecatious and quite safe to alleviate infection with significant clinical improvement within 14 days. Subsequent research on larger scale is warranted for statistically robust evidences in the treatment of COVID-19.

Trial Registration: CTRI/2020/05/025338- Clinical Trials Registry-India

Key words: Ayurveda, AYUSH 64, COVID-19, SARS-CoV-2

STUDY PROTOCOL

Impact of AYUSH interventions on COVID-19: a protocol for a living systematic review and meta-analysis [version 1; peer review: awaiting peer review]

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v1 **First published:** 28 Jul 2021, **10**:674
https://doi.org/10.12688/f1000research.55109.1
Latest published: 28 Jul 2021, **10**:674
https://doi.org/10.12688/f1000research.55109.1

Abstract

Background: The coronavirus disease 2019 (COVID-19) pandemic has created a great burden on governments and the medical fraternity globally. Many clinical studies from the Indian system of Traditional Medicines [Ayurveda, Yoga and Naturopathy, Unani, Siddha, and Homoeopathy (AYUSH)] have been carried out to find appropriate solutions. Through a living systematic review and meta-analysis, this study aims to determine the effectiveness of the Traditional System of Indian Medicine (AYUSH system) in lowering the incidence, duration, and severity of COVID-19.

Methods: We will search the following databases: Pubmed; the Cochrane central register of controlled trials (CENTRAL); the Clinical Trials Registry - India (CTRI); Digital Helpline for Ayurveda Research Articles (DHARA): AYUSH research portal; and World Health Organization (WHO) COVID-19 database. Clinical improvement, WHO ordinal scale, viral clearance, incidences of COVID-19 infection, and mortality will be considered as primary outcomes. Secondary outcomes will be use of O2 therapy or mechanical ventilator, admission to high dependency unit or emergency unit, duration of hospitalization, the time to symptom resolution, and adverse events. Two authors will independently search the articles, extract the data and disagreements will be resolved by the involvement of a third reviewer. Data will be synthesized, and the risk of bias will be assessed with RevMan 5.4 tool. Certainty of evidence will be assessed through the GRADE (Grading of Recommendations, Assessment, Development and Evaluations) tool. The review will be updated bi-monthly with two updates.

Conclusion: This living systematic review will be the first to address AYUSH interventions in COVID-19, synthesizing the full spectrum of Indian Traditional System of Medicine against COVID-19. It will facilitate professionals, guideline developers, and authorities with up

Open Peer Review

Reviewer Status *AWAITING PEER REVIEW*

Any reports and responses or comments on the article can be found at the end of the article.

A safer option to hydroxychloroquine in the chemoprophylaxis of COVID-19 in high-risk health-care workers: A randomized controlled, non-inferiority trial

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Word count: Abstract 377 and Main manuscript: 4365

Abstract

Objectives: Comparative study of Ashwagandha (*Withania somnifera*; WS) and hydroxychloroquine (HCQ) for chemoprophylaxis against COVID-19 in actively engaged high-risk health-care workers.

Design: Randomized, multicentric, open label, active control, two arm parallel efficacy study of 16 weeks. Sample size was based on pre-set 15% non-inferiority margin to HCQ for prophylaxis against COVID-19 with 80% power and alpha < 0.05.

Participants: 400 health-care workers from three sites who were asymptomatic and tested negative for a quantitative Reverse Transcription Polymerase Chain Reaction test (RT-PCR) for COVID-19 and SARS-CoV-2 antibodies (IgG) were randomized in a 1:1 ratio. Participants observed physical protection measures as per the national policy. All incident confirmed COVID-19 were withdrawn.

Interventions: Two tablets of 250 mg standardized aqueous extract of WS, twice daily after meal or HCQ 800 mg loading followed by 400 mg weekly for 16 weeks as per the national guidelines.

Main outcome measures: The primary efficacy measure was "failure of prophylaxis" as confirmed by RT-PCR at any time during the study. Both intention-to-treat (ITT) and per-protocol (PP) efficacy analyses were performed.

Results: 95 participants in the Ashwagandha (WS) arm and 101 participants in the HCQ arm completed the study. Both groups were well matched at the baseline. 91 participants from the Ashwagandha arm and 84 from the HCQ arm were withdrawn because they received the COVID-19 vaccination. Four participants (2%; 95% CI 2.8 to 3.9%) in the Ashwagandha and 5 (2.5%; 95% CI 5.4 to 8%) in the HCQ arm developed confirmed COVID-19. This was within the prefixed non-inferiority margin and the 95% CI of the absolute risk reduction (ARR) was -2.9 to 3.8% intention to treat (ITT) and -5.9 to 7.5% per protocol (PP). The 95% CI of ARR for the total COVID-19 cases was -2.8 to 11.9% ITT and -5.7 to 20.3% PP. Several health measures, particularly anxiety and stress, improved significantly in the Ashwagandha arm. Seven out of 117 in the Ashwagandha and 59 out of 178 in the HCQ groups were reported to be possible drug-related adverse events (AE); there were significantly less gut-related AE in

the Ashwagandha group. AE were mostly mild and did not cause withdrawal. All incident COVID-19 cases recovered without complications.

Conclusions: Ashwagandha was non-inferior to HCQ in the chemoprophylaxis against COVID-19 in high risk health-care workers. It was significantly safer, well tolerated and improved quality of life measures. Ashwagandha as COVID-19 prophylaxis seems appropriate in high-risk populations.

Trial registration: The Clinical Trials Registry India Number CTRI/2020/08/027163 dated August 14, 2020.

Keywords: COVID-19, Prophylaxis, *Withania somnifera*, Ashwagandha, Hydroxychloroquine, Ayurveda, Herbal drugs.

What is already known

- No specific therapies for COVID-19 are available.
- In addition to vaccines, safer chemoprophylaxis agents are needed.
- Use of HCQ based on empirical data is controversial.

What this study adds

- Ashwagandha, a known immunomodulator is non-inferior to HCQ.
- Ashwagandha can be used for effective chemoprophylaxis of COVID-19 with safety and health benefits.

EVALUATION OF EFFECTIVENESS OF *AROGYA KASHAYAM*-20 IN COVID-19 CASES - A RANDOMIZED CONTROLLED STUDY

Abstract

Introduction: The characteristic clinical features of Covid-19 disease range between asymptomatic to mild-moderate symptoms. Studies suggest that a large population (80%) presents its asymptomatic or milder form. Remaining 20 percent, owing to severity of the diseases, need hospital-based care. Many treatment protocols and strategies have been promoted and recommended by authorities including WHO, but nothing has actually been finalized till date. The present study was planned to evaluate the effectiveness of an *Ayurvedic* formulation viz. *Arogya Kashayam-20* in the hospitalized cases of Covid-19.

Aim: To evaluate the effectiveness of *Arogya Kashayam*-20 in the cases of COVID-19 particularly the negative conversion of RTPCR in 10 days duration.

Material and Methods: This was a randomized controlled trial conducted at COVID-19 Care Center, Pt. Khushilal Sharma Government Ayurveda College & Institute, Bhopal, Madhya Pradesh with a sample size of 112 participants, aged between 16 to 60 years of either sex. Participants were divided in two groups viz. group A and B. Both the groups received Hydroxychloroquine (HCQ), vitamin C and Zinc as per the prevailing ICMR guidelines and group 'A' received additionally *Arogya Kashayam*-20 for 10 days. Outcome measure of the study was to see the negative conversion RT-PCR test after intervention period of 10 days.

CTRI Registration: CTRI/2020/06/026221.

Results: Among the 60 cases registered in study group (group A), 51 cases (85.00%) were reported with negative RTPCR on 10^{th} day. Out of 52 cases registered in control group (group B); 39 cases (75.00%) were tested negative RTPCR on 10^{th} day. In both the groups all the cases were discharged asymptomatically on 10^{th} day as per the prevailing ICMR guidelines. No ADR/AE observed during the intervention period.

Conclusion: The study observes that the add on intervention group has a better outcome in terms of RT-PCR negative reports after 10 days comparing to the control group.

Key words: Arogya Kashayam, Coronavirus disease-19, Herbal drugs, Immunomodulator, Randomized Control Study, Severe Acute Respiratory Syndrome Coronavirus-2.

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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Research Article

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

Posted Date: December 7th, 2021

DOI: https://doi.org/10.21203/rs.3.rs-1143938/v1

Abstract

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, 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 its wider

implementation 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.

Declarations

Funding: This systematic review is not funded by any organization.

Study registration: Registered with PROSPERO (CRD42021267844) dated 14.07.2021

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.

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.

Authors' contributions

Review question, search strategy and first draft of the protocol was designed by AKR, AA, KK and PM, protocol was refined by BY and SK and approved by BCR and NS. AKR, PM, AA wrote the first draft of this manuscript and further refined by BY, SK, BCR 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.

Availability of data and materials

Not applicable

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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Supplementary Files

This is a list of supplementary files associated with this preprint. Click to download.

- ProtocolPRISMAP.docx
- PRISMAPchecklistAyurvedaforCOVID19.docx
- SearchStrategy.docx

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