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A prospective, multi center, single blind, randomized controlled study evaluating "AyurCoro3" as an adjuvant in the treatment of mild to moderate COVID-19 patients

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ABSTRACT

Background: There is so far no proven treatment for the unprecedented COVID-19 infections. Ayurveda holds promise in the treatment of this viral infection. We carried out a randomized controlled trial of 'AyurCoro-3', a combination of *Gomutra* (*Bos indicus* urine), hot water, turmeric, *Turati Churna* (potassium Alum), candy sugar (*Khadisakhar*), *Bos indicus* milk with two teaspoons of *Go Ghrut* (Ghee) as an adjuvant to standard care, in comparison to standard care alone in patients with mild-to-moderate COVID-19 infections. **Methods:** A randomized, blinded, controlled trial was carried out in adult patients diagnosed with mild-to-moderate COVID-19 infections confirmed by reverse transcriptase polymerase chain reaction (RT-PCR) test. Interventional group was administered single dose of 'AyurCoro-3' as an adjuvant with standard care, and the control group received only standard of care. Validated clinical improvement scale was used for evaluating the clinical improvement, time of resolution of presenting symptoms, duration of hospitalization, proportion of patients requiring mechanical ventilation, and functional status scale were the key outcomes. **Results:** One-hundred and seventy-four patients were recruited. Significantly more proportions of patients had resolution of all symptoms (cough, fever, breathlessness, weakness, and tastelessness) in the interventional group compared to control. Similarly, the interventional group also had shorter time for clinical improvement as well as shorter time of resolution for cough, breathlessness, and weakness. No significant differences were observed in the duration of hospitalization, proportion of patients requiring mechanical ventilation, functional status scale, and adverse events between the groups. **Conclusion:** The Ayurvedic medicine 'AyurCoro-3' was observed to significantly shorten the duration of COVID-19 infections and was well tolerated.

Key words: *Coronavirus infections, COVID-19, Ayurveda, Complementary and Alternative Medicine*

INTRODUCTION

The Coronavirus disease (COVID-19) has affected the world worst with over 158 million patients infected and 3.29 deaths worldwide as of May 10, 2021. The only drug in allopathic medicine approved by United States Food and Drug Administration for treating COVID-19 infections is remdesivir; approved only for use in adults and pediatric population ≥ 12 years (and weighing at least 88 pounds) and requiring hospitalization.[1] Since April 2021, there has been a second wave of COVID-19 infections in Indian sub-continent that has taken a huge surge of lives and shortage in the remdesivir supply was observed during this difficult time. Ayurveda is one of the world's oldest healing system and is one of the vital complementary and alternative systems of medicine. Ayurveda classifies an individual based on *Tridoshas* theory into one of the following types of *Prakriti*:

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Vata, *Pitta* and *Kapha*. *Vata* is related to motion, *pitta* to metabolism, and *Kapha* to lubrication.[2] Even several centuries ago, a holistic approach (physical, psychological, philosophical, ethical, and spiritual health) and personalized treatment based on their constitutional profile has been documented in Ayurveda.[3] Ayurveda has been shown to successfully cure many of the chronic diseases.[4] Although widely practiced, due to lack of documented scientific evidence, Ayurveda is still not accepted substantially.[5] There is documentation in Ayurveda related to deranged *Vayu* (air), *Jala* (water), *Desha* (habitat) and *Kala* (seasons) imbalance resulting in widespread air/water-borne infections killing mass population resembling the COVID-19 pandemic.[6]

Based on the preliminary documentation in standard Ayurvedic texts, we formulated 'AyurCoro-3' containing a combination of cow (*Bos Indicus*) urine, turmeric (Curcumin), potassium alum, candy sugar, *Bos indicus's* milk, and ghee. *Bos indicus* urine has been shown to possess broad-spectrum antimicrobial activity including multi-drug resistant *Escherichia coli* and *Klebsiella pneumonia*.[7] A preliminary data revealed that urine can enhance the recovery from COVID-19 infections.[8] Curcumin has been shown in several studies to effectively neutralize human immunodeficiency virus, Zika virus, Dengue virus, Chikungunya virus, and influenza virus.[9] Aluminum salts have been shown to possess antibacterial, antiviral, and immunogenic properties and alum is a common adjuvant used in several vaccines to boost the immunity.[10] Hence, the 'AyurCoro-3' combination has a potential to effectively treat patients with COVID-19 infections and hence the present study was envisaged.

METHODOLOGY

Study ethics and study design

The study was initiated after obtaining approval from the Institutional Ethics Committee and approval from the Ministry of Health (EC/NEW/INST/2019/245). Written informed consent was obtained from each of the study participants. The study was randomized, blinded, controlled trial comparing 'AyurCoro-3' as and adjuvant to the standard of care with standard of care in patients with mild-to-moderate COVID-19 infections. The study was carried out in hospitals dedicated for treating COVID-19 patients approved by Government of India, between October 2020 and March 2021 in compliance to the latest update of Declaration of Helsinki guidelines. The study procedure details are stated in (Electronic supplementary Table 1)

Study participants

Adult patients (≥18 years) of either sex presenting with symptoms and signs of mild-to-moderate COVID-19 infections confirmed by reverse transcriptase polymerase chain reaction (RT-PCR) test were recruited. Mild-to-moderate infections were characterized by the presence of symptoms of mild pneumonia, with respiratory rate less than 30/minute, blood oxygen saturation (SpO2) > 90%, ratio of partial pressure of oxygen in the blood to fractional inspired oxygen concentration (PaO2/FiO2) ratio < 300, and absence of any altered mental state/multiple organ failure.[11] Those who were pregnant or breastfeeding, requiring mechanical ventilation, history of allergies/hypersensitivity reactions were excluded. Patients with uncomplicated upper respiratory tract infections, with mild symptoms such as fever, cough sore throat, nasal congestion, malaise, and headache were classified as 'mild COVID-19 disease'. Presence of symptoms mimicking pneumonia (without signs of severe disease) was considered as 'moderate COVID-19 disease'.

Treatment arms

Standard of care (common to both the treatment groups)

Mild COVID-19 infections

- Symptomatic management with paracetamol orally 500 milligram every six hours for fever/pain.
- Adequate nutrition/rehydration.
- In the presence of risk factors such as age > 60 years, hypertension, diabetes, chronic lung/kidney/liver disease, cerebrovascular disease

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and obesity, hydroxychloroquine orally (day 1: 400 mg twice on the first day and 200 mg twice a day for another four days) was administered.

Moderate COVID-19 infections

- Oxygen was administered using nasal prongs/mask/masks with breathing/non-rebreathing reservoir bag.
- Hydroxychloroquine at the above-mentioned dosing regimen was administered to all patients.
- Methylprednisolone at 0.5 to 1 mg/kg/day intravenously for 3 days in case of increased requirement of oxygen or elevated erythrocyte sedimentation rate and/or C-reactive protein.
- In case of anticoagulation requirement, unfractionated/enoxaparin (low molecular weight heparin) was administered.

Interventional arm

In addition to the standard of care, this group received 'AyurCoro-3' administered three times on their baseline visit. 'AyurCoro-3' consists of:

- *Bos Indicus* urine/hot water/turmeric to be gargled twice a day. First gargle one hour prior to lunch around 12 PM and second gargle around 9 PM.
- *Turati Churna* (potassium Alum) with candy sugar (*Khadisakhar*) in half a glass of warm water mixed with *bos indicus* urine 10 ml, orally. The first dose of this intervention was started one hour post lunch, the second dose was administered two hours post first dose, and the third dose after two hours following the second dose.
- One glass (200 ml) of pure *Bos indicus* milk with two teaspoons of *Go Ghrut* (Ghee) was administered post one hour of the third oral dose.

For each patient, a fresh preparation of the above complex was carried out just before administration.

Outcomes

- Proportion of patients with clinical improvement: Clinical assessments were carried out on days 3, 5, and 7 following initiation of treatment. Resolution of clinical symptoms/signs was considered as clinical improvement. Ordinal scale for Clinical improvement scale (Electronic supplementary Table 2) was used.
- Time of resolution of baseline symptoms.
- Duration of hospitalization.
- Proportion of participants requiring mechanical ventilation any time during the hospitalization.
- Proportion of patients with 2-point improvement in 8-point ordinal scale for clinical improvement.
- Functional status scale (Electronic Supplementary Table 3) assessed after 7 and 14 days, following hospital discharge.
- Adverse event and serious adverse events (during their hospital stay and days 7 and 14 after discharge).

Study procedure

Eligible patients were randomized to either control or interventional arm and were hospitalized until their recovery. Outcomes of interest were evaluated at baseline, days 3, 5, and 7 after randomization. The following symptoms were evaluated for assessing the clinical improvement: fever, cough, breathlessness, weakness, and tastelessness. Following their discharge from the hospital, patients were followed-up for assessment of any adverse events on days 7 and 14. The clinical improvement and functional status scales were validated for their reliability in an initial cohort of 10 patients who were not included in the main study (*kappa* value of 0.85 was observed).

Statistical analysis

With a power of 80% and type 1 error rate of 5%, a clinically significant difference of 10% and 10% lost to follow-up, 87 patients were estimated per each group. Computer-generated random number sequence was used for randomization, and the generated randomization list was concealed using opaque and sealed envelope until the evaluation of eligible patients. The study members involved in evaluating the response to treatment and statisticians involved in data analysis were blinded to the treatment

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allocation. Descriptive statistics was used for representing the demographic variables. Intention to-treat analysis was carried out. Numerical data was evaluated for normal distribution using Kolmogorov-Smirnov test and accordingly either parametric or non-parametric test was used. Statistical analyses were done using 'R version 4.0.2', Python 3 and 'SPSS version 20'. A p-value $\leq$ 0.05 was considered significant. We adhered to the Consolidated Standards of Reporting Trials (CONSORT) statement in reporting this clinical trial.[12]

RESULTS

Demographics

Two-hundred and twelve patients were screened of which 38 were excluded and 174 were finally recruited. The study flow diagram is represented in Figure 1. Eighty-seven were recruited in each of the arms and four died in the control arm. A summary of demographic characteristics of the study participants are represented in Table 1. Nearly half-of the study participants in each arm presented with cough and breathlessness.

Proportion of patients with clinical improvement

Proportions of patients experiencing various symptoms at baseline, and at each follow-up day until discharge are depicted in Figure 2 and Electronic Supplementary Figure 1. Significantly more proportions of patients had resolution of all the symptoms on day 3 in the interventional group compared to control arm (p<0.05). Odds ratios for symptom resolution are represented in Table 2 comparing each of the symptoms on days 3, 5, and 7 compared to baseline. Significantly fewer patients had cough, breathlessness, weakness, and fever on day 3 in the interventional group compared to control arm. Similarly, on day 5, significantly fewer patients had cough, taste disturbances, and weakness in the interventional group compared to control arm. On day 7, significantly fewer patients had cough in the interventional arm compared to control group. Median (range) values of the ordinal scale for clinical improvement scale in the interventional compared to control groups were as follows: Day 1: [3 (3), 4 (3); p=0.7]; day 3: [2 (2), 3 (3); p<0.0001]; and day 5: [2 (2), 3 (3); p<0.0001]; day 7: [2 (2), 2 (4); p<0.0001]; discharge: [1 (0), 1 (8); p=0.001]

Time of resolution of symptoms

Significantly shorter time of resolution [mean (SD)] were observed for cough [9.3 (4.1), 11.9 (3.6) days; p < 0.0001], breathlessness [9.2 (6.1), 11 (6.7) days; p = 0.0009], and weakness [9.5 (2.9), 11.5 (3.7) days; p < 0.0001] with the interventional arm compared to the control group. We did not observe any significant (p>0.05) differences in the time taken for resolution of other symptoms [taste disturbance: 8.9 (3.4), 7.2 (3.3) days; and fever: 9.8 (6), 9.7 (3.6) days].

Duration of hospitalization

Median (range) of duration of stay in the hospital in the interventional group was 9 (39) days and in the control group 10 (31) days and was not statistically significant (p=0.4).

Proportion of participants requiring mechanical ventilation any time during the hospitalization

In the interventional arm, 1(1.14%) required mechanical ventilation while 4 (4.5%) in the control arm needed and it was not statistically significant (p=0.4).

Proportion of patients with 2-points improvement in the clinical improvement scale

Thirty-four (39.08%), 44 (50.57%), 58 (66.66%), 85(97.70%) on days 3, 5, 7, and on the day of discharge respectively in patients in the interventional group showed 2-points improvement in the scale compared to 13 (14.94%), 19(21.83), 27(31.03%), 71(81.60%) in the control group and it was significantly different (p < 0.001). The odds ratios for 2-points improvement in the scores in the interventional group compared to control were as follows: Days 3, 5, 7, and on the day of discharge compared to baseline were 2.85 [1.4, 5.7], 3.02 [1.6, 5.7], 3.8 [2, 7.1], and 9.6 [2.1, 43] respectively.

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Functional status scale

Median (range) of functional status scores in the interventional group was 1(3) for each of the groups on days 7 and 15, and it was not statistically significant (p=0.99).

Adverse event and serious adverse events

The number of patients reporting various adverse events during their stay in the hospital, on days 7 and 15 after discharge are represented in Table 3. No serious adverse events other than death of four patients in the control arm were observed.

Discussion

In the light of several controversies revolving around the treatment options for COVID-19 infections, the present study carries significant importance as we have evaluated the clinical utility of 'AyurCoro-3' as an adjuvant to the standard of care in mild-to-moderate infections. We observed that significantly high proportion of patients receiving this Ayurvedic treatment had most of their presenting symptoms resolved, as well as their time of resolution were much shorter compared to the control group. No significant differences were observed in the functional status after discharge, proportion of patients requiring mechanical ventilation, and adverse events between the groups. To the best of our knowledge, this is the first randomized, blinded clinical trial on this Ayurvedic combination for treating COVID-19 infections. As the COVID-19 pandemic was sudden, inadvertent, and unanticipated, it was impossible to discover new drugs to clear the viral infections. Hence, many investigators were involved in identifying the potential repurposing of the existing drugs as possible treatment options for COVID-19 infections. Various initiatives were taken from the Government of India to evaluate and establish any effective therapy for prevention/treatment from Ayurveda, Yoga and Naturopathy, Unani, Siddha, and Homoeopathy; clinical trials evaluating the efficacy and safety of *Withania somnifera*, *Tinospora cordifolia* (Thunb.) and *Glycyrrhiza glabra* are ongoing.[13] We observed that our 'AyurCoro-3' as adjuvant provides more rapid relief of COVID-19 related symptoms compared to standard of care alone. Like most of the complementary and alternative treatment options, since the present study has provided preliminary evidence for 'AyurCoro-3' in ameliorating COVID-19 symptoms, it is the need of the hour to do 'reverse pharmacology' exploring the exact mechanism of anti-viral activity. *In vitro* studies evaluating the dose-response relationship on the cytopathic effect of the ingredients used in 'AyurCoro-3' needs to be explored. *Bos Indicus* urine contains various nutrients such as iron, calcium, phosphorus, salts, carbonic acid, potash, nitrogen, ammonia, manganese, sulphur, phosphate, potassium, urea, uric acid, amino acids, enzymes, cytokines, lactose that may act as immune boosters.[14] Curcumin has been observed to exert antiviral activity against coronavirus through multiple modes: inhibiting the entry of viral proteins; inhibits viral protease activity, reduces interleukin - 6 and nuclear factor-kappa β activity.[15] The ingredients used in 'AyurCoro-3' are easily available in India (and in several developing countries) that it is relatively easier to cater the needs of the pandemic than synthetic/allopathic drugs. We did not observe any significant adverse events associated with this Ayurvedic combination. We have empirically used single dose of this Ayurvedic preparation and future studies shall explore the therapeutic benefit of prolonged administration. Further, future studies should focus on 'AyurCoro-3' as adjuvant for patients with more severe COVID-19 infections. Also, cost-effective studies are also needed to understand its utility in resource-limited nations/healthcare set-ups. The strengths of the study are as follows: the design of the study was randomized, and triple blinded; a strict definition of mild-to-moderate coronavirus infection was adhered with evidence of infection based on RT-PCR test; and objective, validated scales were used for evaluating the response of the interventions. The study is limited in not evaluating the viral loads in the respiratory secretions/antiviral titer; genotyping of the virus causing infections was not carried out; and RT-PCR test was not repeated daily.

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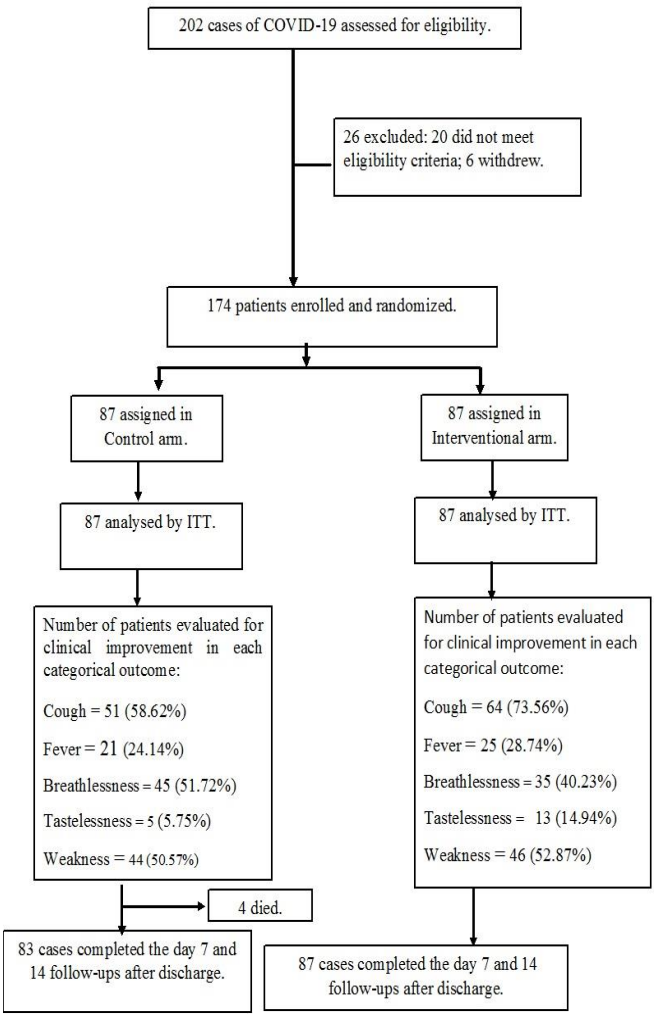
CONCLUSION

We observed that our Ayurvedic medicine 'AyurCoro-3' was associated with significantly shorter time of resolution of symptoms in patients with mild-to-moderate COVID-19 infections. This Ayurvedic medicine was also well tolerated.

FUNDING

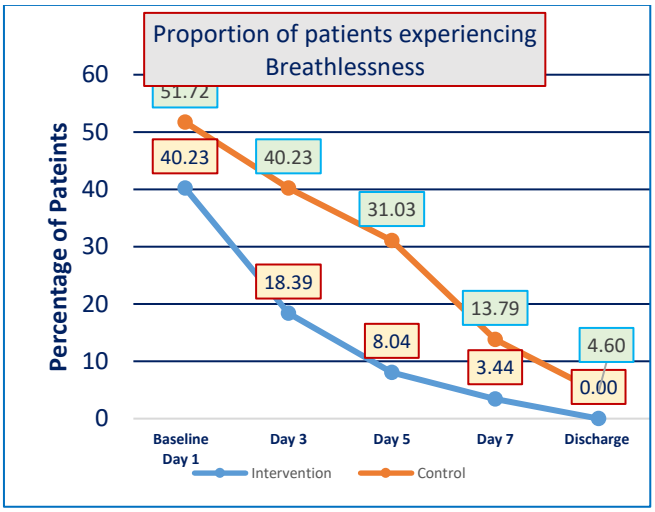
The funder of the study had no role in the study design, data collection, data analysis, data interpretation or writing of the report. The corresponding author had full access to all the data in the study and had final responsibility for the decision to submit for publication.

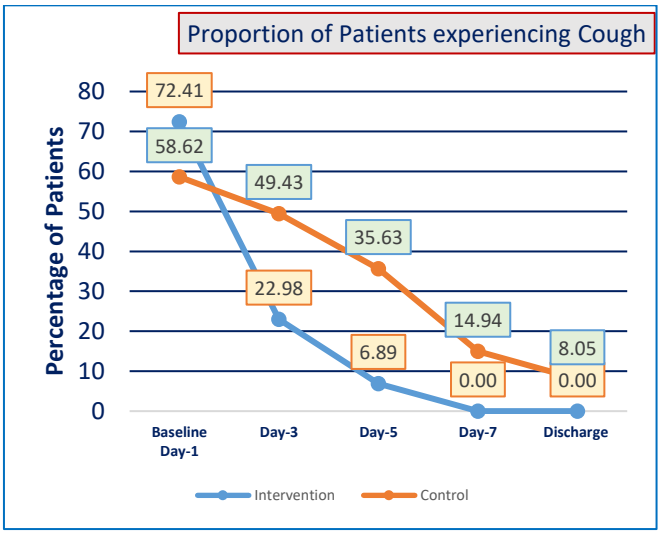
Figure 1: Study flow diagram

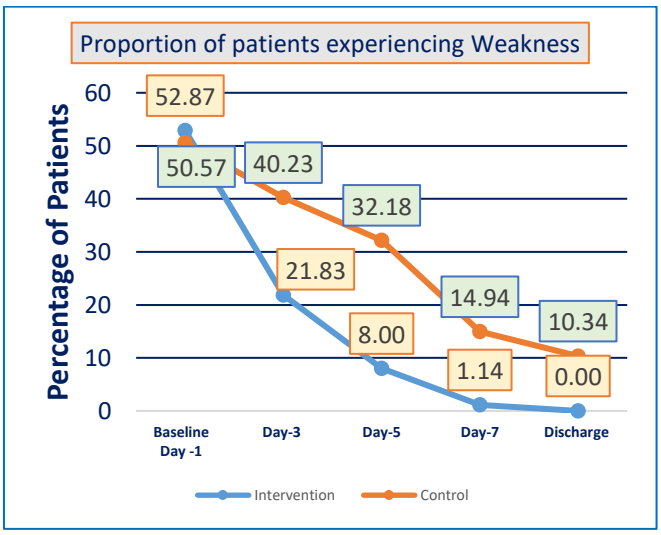


This diagram depicts the flow of study participants from screening until the final follow-up days.

Figure 2. Proportion of patients with improvement in each of the COVID-19 related symptoms.







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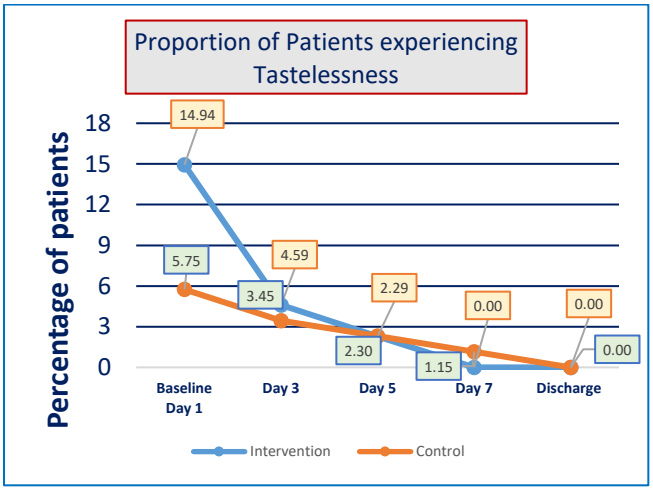

The diagram represents the proportion of patients with each of the COVID-19 related symptoms at each follow-up days in both the groups.

Table 1: Demographic characteristics of the study participants (N=174)

Variables	Control arm (n= 87)	Interventional arm (n=87)
Age (years)α	55.48 (48.27)	52.70 (45.48)
Sex (male)	58 (66.66 %)	65 (74.71 %)
Coexisting diseases		
Hypertension	16 (18.39 %)	20 (22.98 %)
Ischemic heart disease	3 (3.45%)	2 (2.30%)
Diabetes mellitus	11 (12.64%)	11 (12.64%)
Proportion of Symptoms		
Cough	51 (58.62%)	64 (73.56%)
Breathlessness	45 (51.72%)	35 (40.23%)
Tastelessness	5 (5.75%)	13 (14.94%)
Fever	21 (24.14%)	25 (28.74%)
Weakness	44 (50.57%)	46 (52.87%)
Deaths	4 (4.5%)	0 (0%)
Duration of oxygen requirement (days)α	5.8 (6.38)	3.2 (1.50)

α – represented in mean (SD). All others are represented in n (%).

Table 2: Odds ratios [95% confidence intervals] of COVID-19 symptoms on each follow-up days compared to baseline in the interventional groups.

Day	Baseline Vs Day 7		Baseline Vs Day 5		Baseline Vs Day 3	
Symptom	**Control**	**Intervention**	**Control**	**Intervention**	**Control**	**Intervention**
Cough	0.12 (0.06, 0.26)	0.0022α (0.0001, 0.036)	0.39 (0.21, 0.72)	0.03α (0.01, 0.07)	0.69 (0.38, 1.26)	0.11α (0.06, 0.23)
Breathlessness	0.15 (0.07, 0.31)	0.05 (0.02, 0.18)	0.42 (0.23, 0.78)	0.13α (0.05, 0.31)	0.63 (0.34, 1.15)	0.33α (0.17, 0.67)
Taste disturbance	0.19 (0.02, 1.67)	0.03 (0.002,0.53)	0.39 (0.07, 2.05)	0.13α (0.03, 0.61)	0.59 (0.14, 2.53)	0.61α (0.25, 1.53)
Weakness	0.17 (0.08, 0.35)	0.01 (0.001, 0.078)	0.46 (0.25, 0.86)	0.08α (0.03,0.19)	0.66 (0.36, 1.2)	0.25α (0.13,0.48)
Fever	0.07 (0.02, 0.33)	0.03 (0.004,0.22)	0.15 (0.05, 0.46)	0.12 (0.04,0.36)	0.45 (0.2,1.01)	0.25α (0.11,0.6)

α – Statistically significant.

Table 3: Adverse events reported in the study participants.

Variable	Hospital Stay		Post Discharge at Day-7 follow-up		Post Discharge at Day-15 follow-up	
	Intervention	**Control**	**Intervention**	**Control**	**Intervention**	**Control**
Nausea	1	3	0	1	0	0
Acidity	1	3	1	2	1	1

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Loss of appetite	0	2	0	1	0	1
Disturbed sleep	0	2	0	2	0	1
Loose Motion	1	2	0	1	0	1
Headache	1	1	0	4	0	1
Skin Dryness	0	1	0	1	0	0
Burning micturition	0	0	0	2	0	0

Table 4: Clinical trial study procedure

SN	Procedure	D-1	D-3	D-5 & D-7	Discharge	7, 14 Day Follow up
1	Signed Informed Consent Form	X				
2	Medical History	X				
3	Clinical Examination	X	X	X	X	
4	Review of eligibility criteria[1]	X				
5	Vital signs and Demography[2,3]	X				
6	Randomization	X				
7	Study Medication administration[4]	X				
8	Clinical Improvement Scale		X	X	X	
9	Functional status scale[5]					X
10	AE/SAE	X	X	X	X	X
	recording[6]					
11	Comorbid Conditions	X				
12	Concomitant Medications	X				
13	Safety Follow Up Visit					X

AE= Adverse Event, SAE=Serious Adverse Event

Footnotes:

1 - Eligibility Criteria confirmed at D1 after informed consent procedure

2 - Vital Signs Included: Pulse, BP, SPO2

3 - Demography features captured in the case record form included age, gender.

4 - AyurCoro-3 medication compliance sheet was maintained to assess compliance with the study medicine.

5 - Blinded Study team member conducted telephonic follow up

6 - Adverse events (AE) were defined as any new symptoms or worsening of pre-existing symptoms and were followed until complete resolution of symptoms. Serious adverse events (SAE) were defined as per the New Drug Clinical Trials - 2019 guidelines and ICMR 2017 guidelines. SAEs were reported to the "Bhaktivedanta Hospital Ethics Committee for Biomedical and Health Research" for independent adjudication of relatedness. SAEs were graded for causality. Investigators reviewed SAE's for medical management and compensation.

Table 5: Clinical improvement scale

1. Discharge
2. Hospital admission no symptoms for consecutive 2 days
3. Hospital admission with symptoms
4. Hospital admission symptoms with experimental drugs like remdesivir.
5. Hospital admission symptoms with requiring supplemental oxygen
6. Hospital admission symptoms requiring high flow nasal cannula or non-invasive mechanical ventilation
7. Hospital admission symptoms requiring invasive mechanical ventilation

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8. Death

Table 6: Functional status scale

1. I have no limitations in my daily routine activities and no symptoms, pain, depression, or anxiety related to the infection.
2. I have no limitations in my daily routine activities and no symptoms, but I have anxiety related to the infection.
3. I have negligible limitations in my daily routine activities, and no symptoms, pain, depression, or anxiety related to the infection.
4. I have negligible limitations in my daily routine activities, but I still have persistent symptoms, pain, depression, or anxiety.
5. limitations in my everyday life disturbs my routine activities due to which I am unable to perform most of the activities, but I do not need nursing help as I can still do activities independently
6. limitations in my everyday life disturbs my routine activities due to which I am unable to perform most of the activities. I need nursing help however I do not think hospital admission is required.
7. limitations in my everyday life disturbs my routine activities due to which I am unable to perform most of the activities. I need nursing help. I strongly feel that I need hospital admission.

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