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Clinical efficacy of *Gojihvadi Kwath, Shirishadi Kwath, Sanjeevani Vati, Panchagavya Ghrita* Granules & *Shunthi Churna* for COVID-19 management, a randomized controlled trial

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The obscure disease pattern of COVID -19 have to be evaluated with Ayurvedic interventions and the present clinical trial was a randomized open label parallel three-arm control trial on the major and minor symptomatic patients with the recent pandemic. The patients were recruited from the Super specialty building of Sir Sunderlal hospital, COVID- 19 ward and home isolated ones. The Ayurvedic intervention includes the 15 days oral administration (Group A) –*Gojihvadi Kwath*, *Sanjeevani Vati*; *Panchagavya Ghrit* Granules; *Shunthi* (Dry ginger powder) plus conventional treatment, in (Group B) – *Shirishadi Kwath, Sanjeevani Vati*; *Panchagavya Ghrit* Granules; *Shunthi* (Dry ginger powder) plus conventional treatment and in Group C (control group) only the conventional medicines. Assessment was done based on the RT-PCR reports, signs and symptoms. The results point out the efficacy of trial medicine (that is group A and B) to discharge the patients earlier than those from the control group. The early reduction in the signs and symptoms noted were also observed. Group B showed a faster recovery from dry cough and shortness of breath and improvement in appetite. Home-isolation patients showed faster recovery of clinical symptoms than the hospitalized patients. *Ayurvedic* interventions can accelerate viral load clearance associated with quicker recovery and concurrently decrease the risk of viral dissemination. Additionally, there were no adverse reactions observed with these trial medicines.

Keywords: *Ayurveda*, COVID-19, *Gojihvadi Kwath*, *Panchagavya Ghrit* Granules, *Shirishadi Kwath*, *Sanjeevani Vati*

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The SARS-CoV-2 (Severe Acute Respiratory Syndrome Corona Virus 2), designated with the COVID-19 (Corona Virus Disease 2019) title presented the peculiar medical emergency where world saw the measures like “lockdowns”, “mask mandates”, and “social distancing” complementing the therapeutic protocols. The records till July, 2020 of Indian sub-continent represented 10,77,618 contracted cases, among which 3,73,379 where active ones. Even with death tolls of 26,816 and 543 new fatalities, 6,77,422 people have recovered so far in the country as per the Health Ministry's bulletin[1]. The synthesized vaccines so far reduced the wildness of communicability but the degree of mortality and morbidity was greater with the existing therapeutic approaches. This was even more vulnerable in patients with co-morbidities like diabetes

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mellitus, hypertension, cardiovascular disease, chronic kidney disease[2]. The compounds from Traditional medicine which are a compendium of different phytochemicals synergistically was evidenced in many clinical studies with profound effect on mild to moderate COVID-19 cases[3].

Ayurveda categorizes this disease under *Aupasargika Roga* (Communicable disease) like *Rajayakshma, Krimiroga* (*Raktaja Krimi*), *Bhootopasarga, Rakshogna & Janapadodhwamsa* that is pandemic in nature, with treatment protocols based on the pathogenetic components (*Samprapti Ghataka*). The alignment of concepts regarding the presentation of etiology, symptomatology, system involvement, pathophysiology, and treatment concluded the above classification[4-6]. The absence of effective therapeutic framework paved way to adopt the drug repurposing strategy. Here the holistic *Ayurveda* interventions chosen for the compliance of the COVID 19 patients comprises *Gojihvadi Kwath, Shirishadi Kwath, Sanjeevani Vati, Panchagavya Ghrita* Granules *& Shunthi Churna*. These medicines are already known for remedial interventions in the management of gastrointestinal tract disorders, URTI (Upper respiratory tract infection), etc. These possess target molecules for the antibacterial, anti-viral, immune regulation, free radical scavenging, antioxidant, anti-inflammatory, antimicrobial, anti-cancer, hepato-protective, anti-allergic, antihistaminic and mast cell stabilizing properties. The mentioned properties along with the chosen treatment protocol for the present clinical study also includes the antipyretic components. Three arm clinical trial designed constituted *Gojihvadi Kwath, Shirishadi Kwath, Sanjeevani Vati, Panchagavya Ghrita* Granules *& Shunthi Churna*, and *Shunthi Churna* in group A while group B comprises of *Shirishadi Kwath* in place of *Gojihwadi Kwath* and remaining three medicines were kept same as Group A, The key objective of this clinical trial is to determine the influence of Ayurvedic medicine on the proportion of recovery from SARS-CoV-2 using RT-PCR. The further objective was to assess the efficacy of Ayurvedic medications in the treatment of signs and symptoms.

Materials and Methods

Medicine procurement

The medications were provided by following pharmacies.

Gojihvadi Kwath, Panchagavya *Ghrita* Granules and ***Shunthi Churna***

Manufactured by Shree Kamdhenu Divya Ausadhi Mahila Sahakari Mandli (GMP certified Unit License number-#GA/1913).

Shirishadi Kwath

Manufactured by Ravi Pharma, Varanasi (GMP certified Unit License number 1994/85, U P).

Sanjeevani Vati

Manufactured by Narayan Pharmaceuticals (P) Ltd (Mfg. License number-#GA/331).

Trial design

A treatment protocol evaluated the efficacy of trial medicine in reducing viral load and symptomatic improvement along with standard treatment protocol. The clinical study was designed to be a randomized open label parallel three-arm control single blind trial on 240 patients of SARS-CoV-2 coronavirus. The place of conduct was in the Super specialty building of Sir Sunderlal hospital, COVID- 19 ward. The trial was also registered with Clinical Trial Registry-India (The registration number for this trial is CTRI/2020/08/026980). The ethical clearance was obtained from the Institutional ethics committee (NO.SSH/F.Ps to MS/2020-21/680). All the COVID-19 on RT-PCR positive patients were enrolled with their written consents. The RT-PCR analysis was done with the ICMR approved laboratory-Multi disciplinary research unit lab, IMS, BHU, Varanasi and Virology Research and Diagnostic lab, IMS, BHU, Varanasi with aseptic condition from nasopharyngeal and oropharyngeal swab and investigation was done on 0, 7 and 15 days to assess the secondary outcome. The Study Plan and Follow-up details are mentioned in the Figure 1 & 2. The particularities of patients, gender distribution and comparative analysis of RT-PCR are diagrammatically represented in the Figure 3, 4 & 5, respectively.

Procedure

Subject selection and registration

Patients who fulfill the diagnostic features of COVID – 19 mild and moderate diseases as per WHO definitions associated with laboratory test positive for COVID – 19 between 10 to 90 years of age of either sex were registered for the study. Patient's clinical history was recorded in the specially designed performa for the study. All the patients enrolled in

this study were documented with subsequent medical history of past disease and its management.

Randomization

Consented patients who fulfilled the diagnostic criteria were registered and randomization was done by computer based software and concealment was done by opaque envelopes. All the patients registered in the trial were assessed clinically for the symptoms of the disease, such as, fever, dry cough, shortness of breath, tiredness, sore throat , loss of smell , loss of appetite, disturbed sleep, irregular bowel habit, burning micturition, rashes, conjunctivitis, diarrhoea & aches and pains. Duration of the study was 15 days or until the recovery from the patients with 7 days interval follow ups. The patients presenting with above clinical symptoms were recorded on day 0, 7 and 15 days. Nasopharyngeal swab samples were collected and subjected to RT-PCR analysis for SARS-CoV-2.

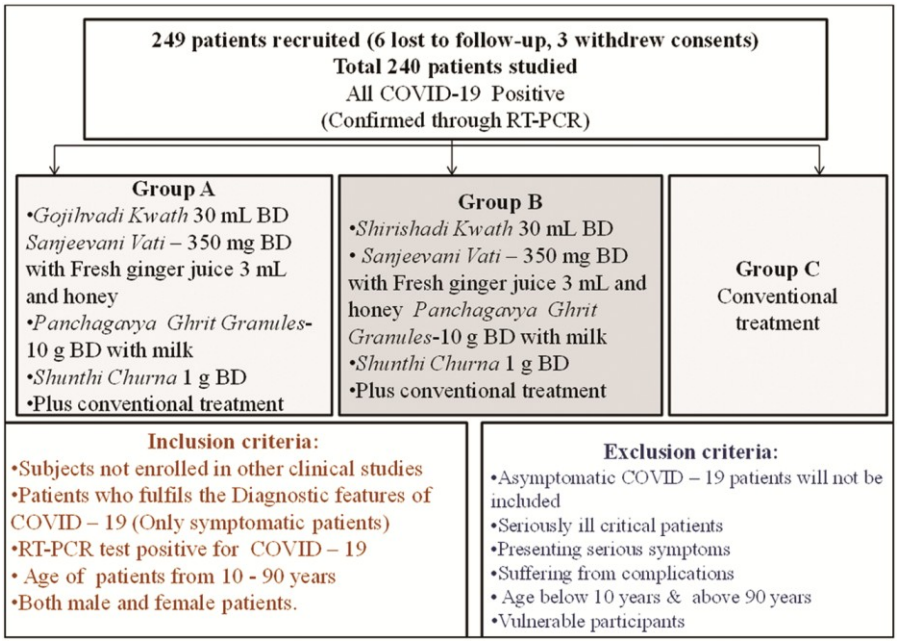

Fig. 1 — Study plan details

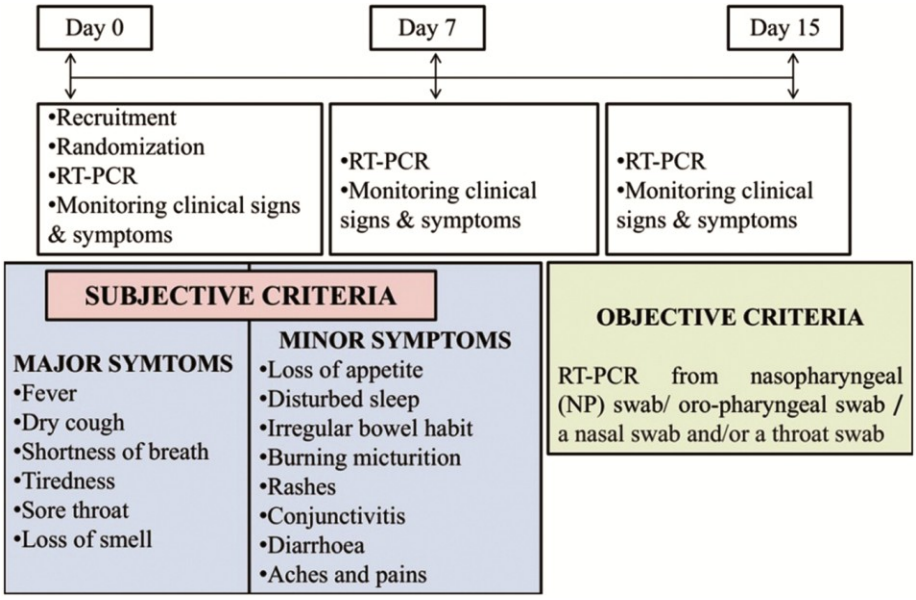

Fig. 2 — Follow up and assessment criteria

Management and administration of oral *Ayurvedic* treatment

The trial group A received *Gojihvadi Kwath*, *Sanjeevani Vati*; *Panchagavya Ghrit* Granules; Shunthi (Dry ginger powder) along with conventional treatment while in Group B patients received – *Shirishadi Kwath* in place of *Gojihvadi Kwath* and remaining Ayurveda medicines like Group A with conventional treatment. Group C served as control with conventional medicines. Drug administration is depicted in Figure 2. The "sachets" containing the medicines were given to the patients and the respective decoction was provided to admitted patients and home isolated patients with the proper instructions about the preparation of the decoctions. The hospitalized patients were admitted for the entire length of the trial, and all the medications were delivered to them. No other interference was given to the patients apart from the aforementioned treatment.

Follow up monitoring and investigations

Duration of the study was 15 days or until the recovery from the patients with 7 days interval follow ups. Patient presenting with clinical symptoms like fever, dry cough , shortness of breath, tiredness, sore throat, loss of smell , loss of appetite, disturbed sleep, irregular bowel habit, burning micturition, rashes, conjunctivitis, diarrhoea & aches and pains were recorded on day 0, 7 and 15 days.

Data collection

Data was collected from IPD of S. S. Hospital, Super specialty building, Varanasi and Home isolation patients from Varanasi district & Mirjapurmandal in the designed performa for the current clinical study.

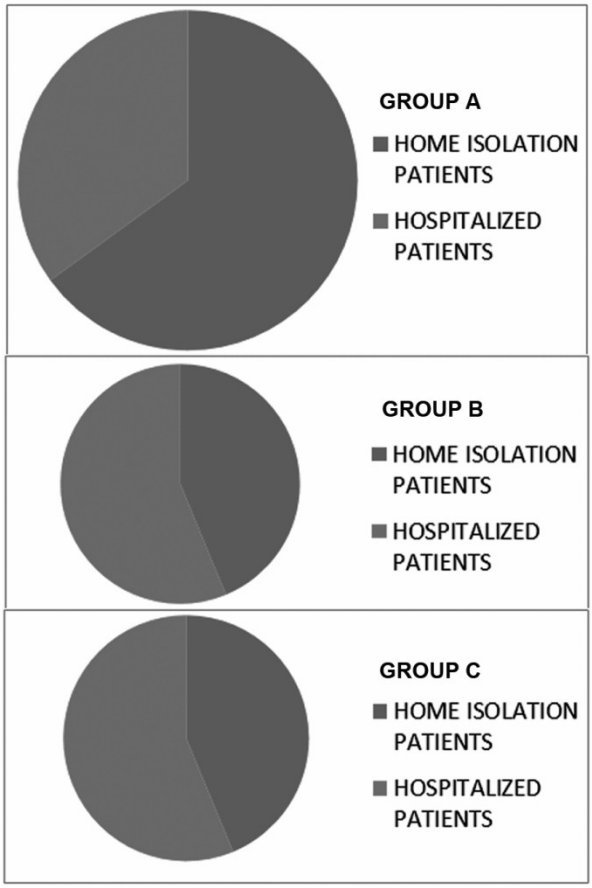

Fig. 3 — Proportion in patient distribution among groups

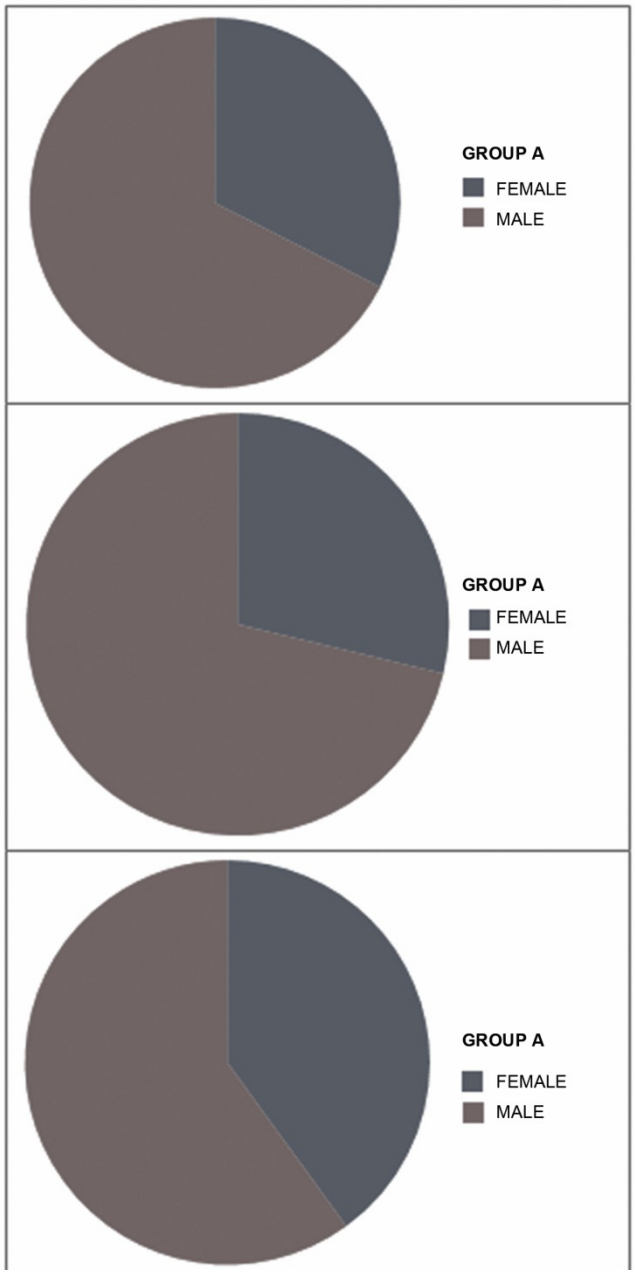

Fig. 4 — Distribution of gender in the control and treatment arms

Primary outcomes

Patient testing negative for SARS-CoV-2 in the RT-PCR analysis was done with the ICMR approved laboratory-Multi disciplinary research unit lab, IMS, BHU, Varanasi and Virology Research and Diagnostic lab, IMS, BHU, Varanasi with the aseptic condition from nasopharyngeal and oropharyngeal swab and investigation was done on 0, 7 and 15 days to assess the secondary outcome.

Secondary outcomes

Patients presenting with reduction in the signs and symptoms of the SARS-CoV-2.

Statistics

The statistical analysis was done using SPSS windows version 23.0. For categorical data, Chi-square and Fischer's exact test were used. For comparing two groups, student t test was applied and for paired samples, paired t test was used. The critical value of $p<0.05$ was used for clinical significance. Statistical significance of the treatment was observed between the groups were determined using two-way ANOVA

Results

249 patients were screened and enrolled for this study during the month of August, 2020 to January, 2021. Out of 249 patients, 6 lost to follow-up and 3 withdrew their consents. Hence, the observations reported in this study are from 240 patients. Patients receiving group A medicines showed improvement in appetite as compare to group B. Patients receiving group B showed a faster recovery from dry cough and shortness of breath. Rest of the clinical symptoms were releaved early in comparison to control group. While patients who were receiving medicines on home-isolation showed faster recovery of clinical symptoms than the patients admitted in the hospital.

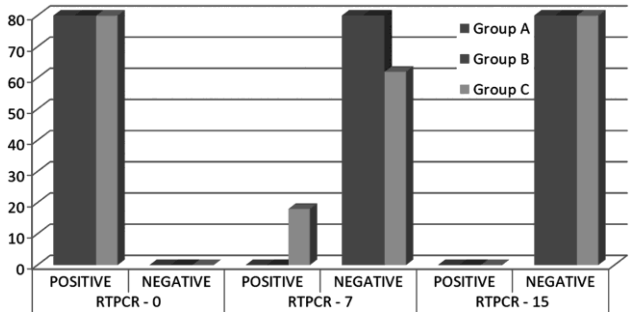

Fig. 5 — Depicting RT-PCR test comparative analysis of treated and control group

Baseline characteristics

Relevant baseline characteristics are recapitulated in Table 1. Table 2 depicts the hospital and home isolation patients enrolled in the study. The majority of the cases were in the age group of 40-45 years. More number of male patients were enrolled for the present study. Among the three arms patients were comparably distributed in terms of age, clinical characteristics and gender. (Fig. 1; Table 1). Out of 80 patients in the control group, 4 patients were with history of Diabetes mellitus. In the *Ayurveda* treated groups out of 160, 6 patients were having Diabetes mellitus, 8 patients with hypertension history, 4 patients were IHD patients, 2 patients were having asthma. The vitals were in median range and also in the acceptable limits for both treatment and control groups. From these observations, it is deducible that the administered treatment did not exert any observable adverse side effects.

Outcome of the study

Primary outcome

The primary outcome of the present clinical trial was reduction in the time taken by the patients treated with *Ayurvedic* medicines to be negative in the RT-PCR analysis, indicating accelerated improvement in the trial groups. By day 7, 100% patients in the treatment group tested negative for RT-PCR compared to 77.5% patients exhibiting same outcome

Table 1 — The comparison of demographic, anthropometric and hemodynamic parameters

Basic Parameters	Group A (N =80)	Group B (N =80)	Group C (N =80)	p-value
Age (in years)	44.04±18.16	42.32±16.61	42.56±1.45	p = 0.804
Sex				0.309
Female	26 (10.8)	23 (9.6)	32 (13.3)	
Male	54 (22.5)	57 (23.8)	48 (20.0)	
Height (in cm)	165.84±10.04	166.20±10.40	164.05±11.23	p = 0.389
Weight (in kg)	65.84±10.68	69.12±8.98	63.19±10.45	p = 0.001
Pulse Rate	74±8.50	77.55±10.41	77.28±9.79	p = 0.139
Systolic BP	118.52±9.68	119.70±9.91	121.62±9.71	p = 0.130
Diastolic BP	76.98±7.94	77.58±9.94	77.42±8.34	p = 0.904
Respiratory Rate	20.85±2.81	21.02±3.10	20.35±2.81	p = 0.315

in the control group. However the remaining 22.5% control group patients exhibited negative for RT-PCR on day 15th.

Secondary outcome

The impact of *Ayurvedic* treatment on the signs and symptoms were the secondary outcomes of this study. The signs and symptoms were noted on day 0. This was done following the randomization and the start of the treatment, on days 7 and 15. In this study we had observed that patients on trial medicine (that is group A and B) discharged earlier than those from the control group and early reduction in the signs and symptoms noted in comparison to control group.

About the clinical symptoms- Both group A and B patients showed similar improvement in fever. Patients receiving *Shrishadi Kwath* (that is group B) showed a faster recovery from dry cough and shortness of breath. Also we had observed that group B patients were having evident improvement in appetite as compared to group A. Patients who were at home-isolation showed faster recovery of clinical symptoms than in hospital stay. The comparison within Group A, B and C on 0, 7 and 15 days with grading of major symptoms of COVID-19 is shown in Table 3 and comparison within Group A, B and C on 0, 7 and 15 days with grading of minor symptoms of COVID-19 is shown in Table 4. 1 patient from the trial in group A showed no specific improvement in dry cough even after 25 days. 2 Patients from the trial groups reported complain of sore throat after 7 days. Both the patients were not having this on day 1.

Patients treated with *Ayurveda* interventions in Group A & Group B trial witnessed early recovery by day 7, while it was delayed in the control group. Patient's improvement details of the observations for the calculations of the percent recovery after day 7 and day 15 are provided in Table 3, 4 & 5. Number(s) needed to treat (NNT), particularly, with the small size of the given sample, indicates that this medical intervention is effective compared to the control group. Statistical calculation done to check the likeliness of the reduction in time to recovery in the treatment group and the same is mentioned in the Table 3, 4 & 5 and it also indicates that lesser chance of delayed recuperation in the trial group is a more likely occurrence.

Table 2 — Type of isolation in Group A, B and C

	Group A (N %)	Group B (N %)	Group C (N %)	Total	p-value
Home-Isolation Patients	52 (21.7%)	35 (14.6%)	35 (14.6%)	122 (50.8%)	0.008
Hospitalized Patients	28 (11.7%)	45 (18.8%)	45 (18.8%)	118 (49.2%)	

Table 3 — comparative statistical analysis showing the RT-PCR results

RTPCR RESULT		Group 1	Group 2	Group 3	Total	p-value
RT-PCR - 0	Positive	80	80	80	240	
	Negative	00	00	00	00	
RT-PCR - 7	Positive	0	0	18	18	0.000
	Negative	80	80	62	222	
RT-PCR - 15	Positive	00	00	00	00	
	Negative	80	80	80	240	

Discussion

A randomised three-arm research was undertaken on major and minor symptomatic patients who tested positive for SARS-CoV-2 using RT-PCR. The primary outcomes showed a reduction in the time it took for patients treated with Ayurvedic medicines to test negative in the RT-PCR analysis and so indicating the rapid improvement in the study groups. The secondary outcomes revealed a reduction in the time to recovery in signs and symptoms. Although the patients in the control group recovered, they did so at a slower rate than those in the therapy group.

Many *Ayurveda* formulations showed better results in treating COVID 19 patients[7-9]. *In silico* studies demonstrated that phyto-constituents of commonly used *Ayurvedic* herbal formulations have potential to inhibit SARS-CoV-2 infection and COVID-19 disease[10]. The present trial with the three groups- out of which two groups treated with *Ayurveda* interventions and the conventional care group, were analogous in clinical characteristics and disease severity, which removed the confounding at baseline itself.

Gojihwadi Kwath is used in the treatment of URTI (Upper respiratory tract infection) in day to day clinical practice and it has been found effective against URTI (Upper respiratory tract infection) causing pathogenic microorganism[11]. Fortunellin supports protective immunity while inhibiting pro-inflammatory cytokines and apoptosis pathways and protecting against tissue damage. Fortunellin is a phytochemical found in *Gojihwadi Kwath*, an Indian traditional *Ayurvedic* formulation with an antiviral activity that is effective in COVID-19 patients. Authors discovered that fortunellin reliably binds to key targets that are necessary for viral replication, growth, invasion, and infectivity[12].

Shirish is a well known *Vishaghna dravya*[13] and *Shirishadi Kwath,* containing *Shirish* has proven *Vishaghna* (*antitoxin*)*,* antiallergic, antihistaminic and mast cell stabilizing properties along with the anti-inflammatory and antioxidant activity[14,15]. *Panchgavya* therapy is advocated for the management of various diseases like *Apasmara* (epilepsy), *Jvara* (fever), *Kamala* (jaundice), asthma, flu, allergies, cardiovascular diseases, gastrointestinal tract disorders, tuberculosis, and other bacterial, fungal and

Table 4 — Comparison within Group A, B and C on 0, 7 and 15 days with grading of major symptoms of COVID-19

Symptoms	Follow UP	Grading	Group A (N %)	Group B (N %)	Group C (N %)	p-value
Fever	0 Days	0	34 (42.5%)	7 (33.8%)	49 (61.2%)	0.001
		1	7 (8%8)	16 (20.0%)	5 (6.2%)	
		2	39 (48.8%)	28 (35.0%)	26 (32.5%)	
		3	0 (0.0%)	9 (11.2%)	0 (0.0%)	
	7 Days	0	77 (96.2%)	78 (97.5%)	73 (91.2%)	0.158
		1	3 (3.8%)	2 (2.5%)	7 (8.8%)	
	15 Days	0	80 (100.0%)	80 (100%)	80(100.0%)	χ^2 -
						p -
Dry cough	0 Days	0	39 (48.8%)	51 (63.8%)	49 (61.2%)	< 0.001
		1	8 (10.0%)	11 (13.8%)	0 (0.0%)	
		2	33 (41.2%)	15 (18.8%)	31 (38.8%)	
		3	0 (0.0%)	3 (3.8%)	0 (0.0%)	
	7 Days	0	62 (32.3%)	74 (92.5%)	56 (70.0%)	0.003
		1	18 (22.5%)	6 (7.5%)	22 (27.5%)	
		2	0 (0.0%)	0 (0.0%)	2 (2.5%)	
	15 Days	0	77 (96.2%)	79 (98.8%)	76 (95.0%)	0.524
		1	3 (3.8%)	1 (1.2%)	3 (3.8%)	
		2	0 (0.0%)	0 (0.0%)	1 (1.2%)	
Shortness of breath	0 Days	0	61 (76.2%)	53 (66.2%)	65 (81.2%)	0.099
		1	1 (1.2%)	3 (3.8%)	0 (0.0%)	
		2	1 (1.2%)	4 (1.7%)	0 (0.0%)	
		3	17 (7.1%)	20 (25.0%)	15 (18.8%)	
	7 Days	0	74 (92.5%)	73 (91.2%)	70 (87.5%)	0.394
		1	4 (5.0%)	5 (6.2%)	5 (6.2%	
		2	0 (0.0%)	2 (2.5%)	4 (5.0%)	
		3	2 (2.5%)	0 (0.0%)	1 (1.2%)	
	15 Days	0	78 (97.5%)	80 (100.0%)	75 (93.8%)	0.061
		1	2 (2.5%)	0 (0.0%)	5 (6.2%)	
Sore throat	0 Days	0	60 (75.0%)	48 (60.0%)	54 67.5%)	0.030
		1	5 (6.2%)	3 (3.8%)	0 (0.0%)	
		2	15 (18.8%)	29 (36.2%)	26 (32.5%)	
	7 Days	0	72 (90.0%)	68 (85.0%)	66 (82.5%)	0.027
		1	4 (5.0%)	11 (13.8%)	14 (17.5%)	
		2	4 (5.0%)	1 (1.2%)	0 (0.0%)	
	15 Days	0	80 (100.0%)	79 (98.8%)	80 (100.0%)	0.366
		1	0 (0.0%)	1 (1.2%)	0 (0.0%)	
Loss of smell	0 Days	0	61 (76.2%)	52 (65.0%)	69 (86.2%)	0.005
		1	17 (21.2%)	17 (21.2%)	11 (13.8%)	
		2	0 (0.0%)	5 (6.2%)	0 (0.0%)	
		3	0 (0.0%)	2 (2.5%)	0 (0.0%)	
		4	2 (2.5%)	4 (5.0%)	0 (0.0%)	
	7 Days	0	74 (92.5%)	75 (93.8%)	76 (95.0%)	0.808
		4	6 (7.5%)	5 (6.2%)	4 (5.0%)	
	15 Days	0	80 (100.0%)	80 (100.0%)	80 (100.0%)	
Tiredness	0 Days	0	27 (33.8%)	26 (32.5%)	32 (40.0%)	0.009
		1	14 (17.5%)	3 (3.8%)	11 (13.8%)	
		2	37 (46.2%)	44 (55.0%)	37 (46.2%)	
		3	2 (2.5%)	7 (8.8%)	0 (0.0%)	
	7 Days	0	36 (45.0%)	39 (48.8%)	39 (50.0%)	0.695
		1	19 (23.8%)	20 (25.0%)	18 (22.5%)	
		2	22 (27.5%)	21 (26.2%)	21 (226.2%)	
		3	3 (3.8%)	0 (0.0%)	1 (1.2%)	
	15 Days	0	50 (62.5%)	53 (66.2%)	48 (60.0%)	0.274
		1	26 (32.5%)	17 (21.2%)	22 (27.5%)	
		2	4 (5.0%)	10 (12.5%)	10 (12.5%)	

viral infections. It is also having hepato-protective and immunostimulant properties. Cow's urine has been established to have antioxidant property. Milk, ghee, and curd are used as diet in *Ayurveda* texts[16,17].

Table 5 — Comparison within Group A,B and C on 0, 7 and 15 days with grading of minor symptoms of COVID-19

Symptoms	Follow UP	Grading	Group A (N =80)	Group B (N =80)	Group C (N =80)	p-value
Loss of appetite	0 Days	0	54 (37.5%)	34 (42.5%)	56 (70.0%)	<0.001
		1	26 (32.5%)	46 (57.5%)	24 (30.0%)	
	7 Days	0	64 (80.0%)	54 967.5%)	67 (83.8%)	0.009
		1	0 (0.0%)	3 (3.8%)	5 (6.2%)	
		2	12 (15.0%)	11 (13.8%)	5 (6.2%)	
		3	4 (5.0%)	12 (15.0%)	3 (3.8%)	
	15 Days	0	69 (86.2%)	63 (78.8%)	80 (100.0%)	< 0.001
		2	11 (13.8%)	17 (21.2%)	0 (0.0%)	
Disturbed sleep	0 Days	0	66 (82.5%)	61 (76.2%)	68 (85.0%)	0.344
		1	14 (17.5%)	19 (23.8%)	12 (15.0%)	
	7 Days	0	69 (86.2%)	70 (87.5%)	69 (86.2%)	0.030
		1	1 (1.2%)	2 (2.5%)	5 (6.2%)	
		2	5 (6.2%)	0 (0.0%)	0 (0.0%)	
		3	5 (6.2%)	8 (10.2%)	6 (7.5%)	
	15 Days	0	79 (98.8%)	80 (100.0%)	80 (100.0%)	0.366
		2	1 (1.2%)	0 (0.0%)	0 (0.0%)	
Irregular bowel habit	0 Days	0	75 (93.8%)	69 (86.2%)	76 (95.0%)	0.096
		1	5 (6.2%)	11 (13.8%)	4 (5.0%)	
	7 Days	0	80 (100.0%)	80 (100.0%)	78 (97.5%)	0.133
		1	0 (0.0%)	0 (0.0%)	2 (2.5%)	
	15 Days	0	80 (100.0%)	80 (100.0%)	80 (100.0%)	
Burning micturition	0 Days	0	80 (100.0%)	80 (100.0%)	78 (97.5%)	0.133
		1	0 (0.0%)	0 (0.0%)	2 (2.5%)	
	7 Days	0	80 (100.0%)	80 (100.0%)	78 (97.5%)	0.133
		1	0 (0.0%)	0 (0.0%)	2 (2.5%)	
	15 Days	0	80 (100.0%)	80 (100.0%)	80 (100.0%)	
Rashes	0 Days	0	80 (100.0%)	80 (100.0%)	80 (100.0%)	
	7 Days	0	80 (100.0%)	80 (100.0%)	80 (100.0%)	
	15 Days	0	80 (100.0%)	80 (100.0%)	78 (97.5%)	0.133
		1	0 (0.0%)	0 (0.0%)	2 (2.5%)	
Conjunctivitis	0 Days	0	80 (100.0%)	80 (100.0%)	79 (98.8%)	0.366
		1	0 (0.0%)	0 (0.0%)	1 (1.2%)	
	7 Days	0	80 (100.0%)	80 (100.0%)	80 (100.0%)	
	15 Days	0	80 (100.0%)	80 (100.0%)	78 (97.5%)	0.133
		1	0 (0.0%)	0 (0.0%)	2 (2.5%)	
Diarrhoea	0 Days	0	72(90.0%)	68 (85.0%)	77 (96.2%)	0.081
		1	3 (3.8%)	1 (1.2%)	0 (0.0%)	
		2	1 (1.2%)	3 (3.8%)	0 (0.0%)	
		3	1 (1.2%)	2 (2.5%)	0 (0.0%)	
		4	0 (0.0%)	2 (2.5%)	0 (0.0%)	
		5	1 (1.2%)	4 (5.0%)	3 (3.8%)	
		6	2 (2.5%)	0 (0.0%)	0 (0.0%)	
	7 Days	0	80 (100.0%)	80 (100.0%)	80 (100.0%)	
	15 Days	0	80 (100.0%)	80 (100.0%)	80 (100.0%)	
Aches and pain	0 Days	0	60 (75.0%)	41 (51.2%)	47 (58.8%)	< 0.001
		1	9 (11.2%)	18 (22.5%)	27 (33.8%)	
		2	6 (7.5%)	11 (13.8%)	6 (7.5%)	
		3	0 (0.0%)	6 (7.5%)	0 (0.0%)	
		4	5 (6.2%)	4 (5.0%)	0 (0.0%)	
	7 Days	0	75 (93.8%)	71 (88.8%)	67 (83.8%)	0.271
		1	3 (3.8%)	8 (10.0%)	10 (12.5%)	
		2	2 (2.5%)	1 (1.2%)	3 (3.8%)	
	15 Days	0	77 (96.2%)	77 (96.2%)	63 (78.8%)	0.001
		1	3 (3.8%)	3 (3.8%)	15 (18.8%)	
		2	0 (0.0%)	0 (0.0%)	2 (2.5%)	

Traditionally *Sanjeevani Vati* is used for the management of fever, indigestion, microbial infections, vomiting, pain related to indigestion, productive cough, abdominal mass, snake bite etc[18]. Besides, *in silico* comparison *Sanjeevani Vati* exhibited better anti-COVID-19 potential in comparison to commonly used *Ayurvedic* formulations used for the same clinical condition[7].

Ginger (*Zingiber officinale* Roscoe) root is used to alleviate and treat headaches, cold, nausea, and emesis. Many phenolic and terpene compounds in ginger have been identified. The phenolic compounds are mainly gingerols, shogaols, and paradols, which account for the various bioactivities of ginger and these compounds possess biological activities & variety of pharmacological functions including antibacterial, anti-viral, immune regulation, scavenging free radicals, antioxidant, anti-inflammatory, antimicrobial, and anticancer activities.

The sample size calculation along with the variables were convenient even in the absence of a previous substantiated data. In our study cohort, we had middle aged patients (mean age 42 to 44), with male predominance (Male/Female-159/81). Our study showed that majority of the patients who received *Ayurvedic* treatment, were negative for RT-PCR test of nasopharyngeal swab samples collected on day 7, whereas the percentage wise proportion of of the negative result for RT-PCR test in the control group was less. Therefore, we can infer that the *Ayurvedic* treatment regime tested in this study potentially offers long-term benefits to healthy lung tissue. The present clinical trial revealed that the *Ayurveda* interventions might be associated with early virus clearance. The holistic approaches of health interventions have been found to decrease the disease causing micro-organisms and so effectively lessening the viral load in community transmission[19]. Though, this clinical study was conducted upon the patients having major and minor symptoms, the extrapolation of results cannot be imposed with severe category or those with life threatening co morbidities. However this study does not signify whether the *Ayurveda* treatment regime can surmount the vaccine associated limitations. This study has the potential to pave the path for developing *Ayurvedic* regimes to assist the treatment of COVID 19 infections with better clinical outcomes associated with less adverse reactions.

Limitations of the study

A complete disease resolution cannot be generalised with the sample peculiarity, and as previously indicated, wild deviation and catastrophic seriousness cannot be combined. However, this observations are in accordance with the statistical outcomes in our trial.

Conclusion

The SARS-CoV-2 has diverse mutations and the observed variants analyzed were not responding properly towards any of the conventional treatment. The most difficult factor of widespread community transmission were so to be limited with any of the available anti-viral mechanisms. The primary endpoint of this study is an early reduction in signs and symptoms in response to treatment, as well as the reduced time required by patients intervened with these specific Ayurvedic medications. The hasty approach to negative RT-PCR shows faster progress in the trial groups. The subjects have also shown no adverse reactions to the procedures. As a result, this study demonstrated the efficacy of using Ayurvedic therapies to treat COVID-19 patients.

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Conflict of Interest

Authors declare no conflict of interests with regards to the submitted work.

Author Contributions

P S B- Principal investigator & study design and execution of the work from various COVID19 treating centres and co-ordination with that team and analysis, MK- Compilation of patient data and analysis and writing. V S, NJ, RNC, SKM, AKD, RKM: Planning and framing the proposal of the study S K D- Study design and execution of the work from various COVID19 treating centres and

co-ordination with that team N J- R. N C- S K M- A K D- A K C- Compilation of patient data and analysis, H J- Planning and framing the proposal of the study and supply of study materials R K M- T B S- Statistical analysis and study design and its outcomes and data analysis, A P S- data analysis R J- Editing.

Data Availability

The data would be made available from the concerned authors on request.

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