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Evaluation of a homoeopathic therapeutic strategy involving tuberculinum, zincum metallicum, Chininum arsenicosum and calcarea phos in prophylaxis of COVID-19

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Abstract

Background: In March 2020, WHO declared the COVID-19 outbreak as a pandemic. Preventive strategies have been explored by a large number of researchers. Zincum Metallicum and China Ars are known to prevent replication of the virus. A use of nosodes Tuberculinum enhances the action of these components used in the formulation.

Methods: The study is an open-label randomized controlled trial evaluating the immune boosting ability of a Homoeopathic therapeutic strategy involving a nosodes Tuberculinum 1M, followed by Zincum Metallicum 6c, Chininum arsenicosum 6c and Calcarea Phos 6x in asymptomatic Novel coronavirus disease (COVID-19) in vulnerable risk group.

Results: A statistically significant effect was observed in the strata of age group of 21-30 in terms of completion of treatment ($p < 0.001$). Among the occupation, the health professionals group showed statistically significant results with respect to completion of the treatment ($p < 0.001$). There were no variation statistically significant results observed in terms of other factors.

Conclusions: Homoeopathic therapeutic strategy involving a nosodes Tuberculinum 1M, followed by Zincum Metallicum 6c, Chininum arsenicosum 6c and Calcarea Phos 6x is effective in age groups 21-30 years. A larger trial may be carried out based on the results of the current study.

Keywords: COVID-19, nosode tuberculinum, zincum metallicum 6c, Chininum arsenicosum 6c, calcarea phos

Introduction

Coronavirus disease (COVID-19) is an infectious disease caused by the SARS CoV-2 virus [1]. By May 2020 there were 34 lakh active cases in the world and 2.5 lakh deaths with mortality rate of 7.35%. In India, a similar scenario was evolving [2]. Homoeopathic strategies were used as preventive intervention earlier by its founder Dr. Samuel Hahnemann in epidemics [3].

A nosode Tuberculinum is used to enhance the action of other components used in the formulation. Nosodes are broad spectrum, widely used homoeopathic preparations sourced from biological materials such as clinical samples of microorganisms (bacteria, fungi, viruses) or from parasites, diseased tissues, or decomposition products from humans or animals. About 45 such nosodes have been used by homoeopathic practitioners since 1830 [4]. Dr. Herring experimented with nosodes and noted that such medicines could be used as curative medicines and intercurrent remedies in treating chronic diseases [5]. The use of nosodes is just like any conventional vaccination which administers the antigen in inactive state to gain immunity towards the disease and is given before the onset of the disease or disease symptoms in an individual as a prevention rather than cure [6]. Other components like Zincum Metallicum and China Ars prevent replication of the virus. For Zinc to be allowed entry in the body it needs an ionophore which is provided by China Ars (quinine compound) [7]. Zinc was demonstrated to cause a significant reduction in prevalence of pneumonia and has been shown to mediate antiviral effects against certain viruses. A concentration dependent inhibitory effect was observed with Zinc salt compared to control salts. Difference was significant even at the lowest zinc concentration tested (10 micrometer) [8]. Quinine significantly inhibited Dengue virus replication by reducing dengue virus RNA and viral

protein synthesis in a dose dependent manner. In addition, quinine ameliorated expression of genes related to innate immune response. These findings suggest the efficacy of quinine for stimulating antiviral genes to reduce Dengue virus replication^[9]. Calcarea Phos acts at cellular level and contributes to important metabolic and enzymatic reactions^[10]. Primary objective of this homoeopathic formulation was to act like immune booster. Homoeopathic formulation is easy to administer, safe and cost effective as well^[11].

The study was done in May 2020 when no other treatment or vaccines were available. HCQ and Zn album was tried on mass scales, however results were poor. In such a situation when vaccines were awaited and treatments were failing to control the increasing number of cases, it was essential to test every intervention which had a plausible mechanism to provide a solution for the prevention of spread of SARS-CoV-2 and reduce the morbidity and mortality. As most parts of the world were still under a lockdown with restrictions of movement, carrying out clinical studies on a population level also posed a serious challenge. Thus, it was decided to test this homeopathic formulation in two groups of population with similar possibility of exposure to the virus. A group of frontline workers and a group of matched participants residing in containment zones was selected initially. However, because of restriction of movements, it was difficult to follow-up with all the trial participants, especially from the second group.

This study may provide useful insights of effective homoeopathic preventive strategies. Understanding the limitations due to pandemic, further well-planned Randomized control trial is needed to explore potential of homoeopathic formulation.

Aims and Objectives

To verify the immune boosting ability of the Homoeopathic therapeutic strategy in preventing development of symptoms related to COVID-19 illnesses.

End-point

The ability of the test drug to reduce the COVID positivity rate was studied using test to positivity ratio as an indicative parameter. RT-PCR testing was done in all participants who developed symptoms of COVID-like illness.

Materials and Methods

The study is an open-label randomized controlled trial. The location of the study was Father Muller Homoeopathic Hospital at Mangalore. The study protocol was approved by institutional ethics committee (FMIEC/CCM/180/2020) and registered with CTRI (CTRI/2020/06/026045). The study was conducted over a period of 2 months.

The primary objective of the study was to verify the immune boosting ability of the Homoeopathic therapeutic strategy in preventing development of symptoms related to COVID-19 illness. The Homeopathic formulation contained

Calceria phos, Zincum metallicum and China ARS. The individual entities have been listed in the Homeopathy Pharmacopoeia of India^[12]. SARS-CoV-2 infects a human cell, and the spike protein nudges Zn molecule out of cell as it inhibits spike proteins from multiplying^[13]. The rationale for use of this medicine was, if this process is stopped and reverted, which means infusing the cells with Zn in molecular form could prevent viral replication^[14, 15]. Homoeopathic medicines even if potentised retain original substance in form of nanoparticle^[16]. Process of potentisation charges the nanoparticles in electronics volts and facilitates entry by ionophoresis^[17]. The Cinchona and all its compounds have natural ionophore for Zn^[7]. Biochemical Ca²⁺, charged due to trituration shall act as ionophore carrying Zn⁺² inside the infected cell by its capacity to reverse polarity. Entry of Zinc will regulate multiplication of virus. If Ca⁺² alone is not able to open the gates for Zinc, Cinchona as backup will do the same^[7].

The intervention group i.e., Group A participants were healthcare workers and their family members from Father Muller Hospital. The control group i.e., Group B participants were matched by their demographic characteristics and were from containment zone in Mangalore. The containment zone was selected as the control group as an attempt to match the levels of exposure to the SARS-COV2 virus with that of the front-line workers recruited in the intervention group. Inclusion criteria consisted of asymptomatic, vulnerable risk group between the ages of 14 and 60 years, all genders, those with comorbidities and high-risk frontline workers. Patients with severe comorbidities including end stage renal disease and progressive liver dysfunction, pregnant and lactating females and patients on any other prophylaxis such as Ars ALB 30 and Hydroxychloroquine were excluded. After screening, participants were randomized using stratified randomization according to age to either of the groups.

Group A: Participants were administered Tuberculinum 1M on day 0. They were then administered China Ars 6C, Zincum Metallicum 6C and Cal Phos 6x on days 1 through 14. Group A: Participants were followed-up every 15 days for development of symptoms of COVID-19. Control group data recovered from Government records. Individuals who developed symptoms of COVID-19 were referred to appropriate COVID centers and fever clinics, tested using RTPCR testing and treated as per ICMR protocol if results were positive for COVID-19.

Sample size was calculated as 800 with 400 participants in each arm assuming 95% confidence interval and power of 80%. Chi square test was used to analyze the data using IBM SPSS Statistics for Windows, Version 23.0. Armonk, NY: IBM Corp.

Results

A total of 1336 participants were recruited in Group A and data for 1549 cases was available for Group B (Figure 1).

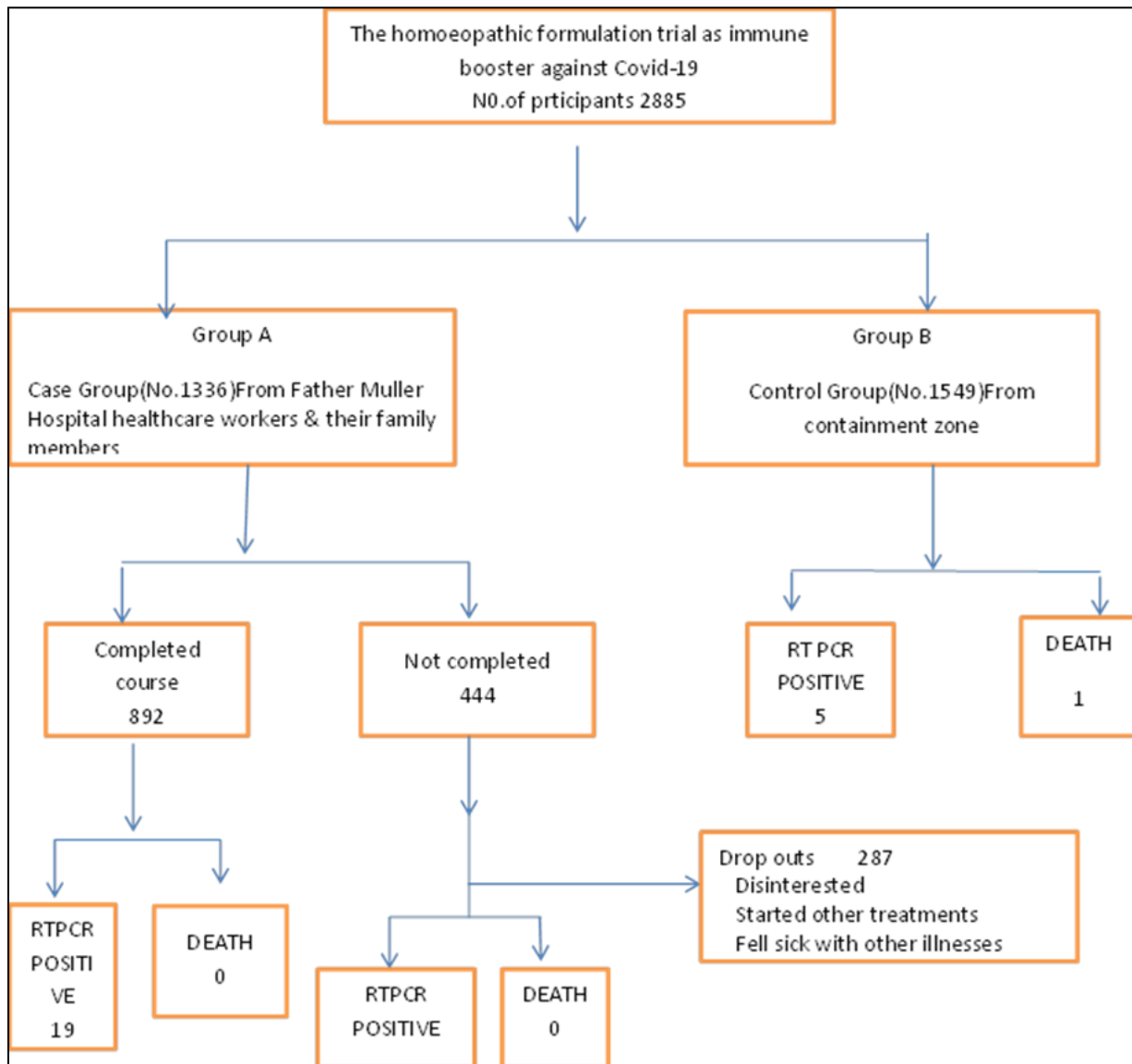


Fig 1: Consort chart with reported outcomes

The group A, which was the interventional group, has 1336 subjects out of which 122(9.1%) belonged to 14-20 age group, 500 (37.4%) were in 21-30 age group, 218 (16.3%) were in 31-40 age group, 286 (21.4%) were in 41-50 age group and 210 (15.7%) were in 51-60 age group. Majority

of the subjects belonged to the 21-30 age group. Male to female ratio was 0.49:1. An 11.8% dropout rate was observed. 66 participants underwent RTPCR testing of which 26 (39.4%) tested positive for COVID-19 (Table 1 & 2).

Table 1: Demographic and baseline characteristics

		Count	Column N %
Age	14 – 20	122	9.1
	21 – 30	500	37.4
	31 – 40	218	16.3
	41 – 50	286	21.4
	51 – 60	210	15.7
	Total	1336	
Sex	Male	442	0.33
	Female	894	0.67
Occupation	Health care workers	715	0.54
	Common man	621	0.47
Course completed/ not completed	Not completed	157	0.12
	Completed	892	0.67
	Dropouts	287	0.22
RT PCR test	Not done	1270	0.95
	Done	66	0.05
Test result	Negative	40	0.61
	Positive	26	0.39

Table 2: Age and sex distribution in Group A and Group B and Statistical analysis of COVID positive and negative cases in both groups

Age Group	Group A - Case		Group B - Control		Control		Cases		Fishers exact test p value
	Count	Percentage	Count	Percentage	Total No.	Positive	Count	Percentage	
14-20	122	9.1	268	17.2	260	0	122	2	0.000, HS
21-30	500	37.4	247	15.9	247	1	500	11	
31-40	218	16.3	260	16.7	260	1	218	4	
41-50	286	21.4	407	26.2	415	0	286	5	
51-60	210	15.7	367	23.6	367	1	210	4	
Male	442	33.1	770	49.5	770	3	442	9	0.000, HS
Female	894	66.9	779	50	779	0	894	17	

A statistically significant effect was observed in the strata of age group of 21-30 in terms of completion of treatment ($p < 0.001$). Among the occupation, the health professionals group showed statistically significant results with respect to

completion of the treatment ($p < 0.001$). There were no variation statistically significant results observed in terms of other factors (Table 3).

Table 3: Statistical analysis as per completion of course of prophylaxis

	Course completed / not completed						Chi square test p value	
	Not Completed		Completed		Dropouts			
	Count	Row N %	Count	Row N %	Count	Row N %		
Age	20 and below	14	11.50%	88	72.10%	20	16.40%	.036, sig
	21 – 30	77	15.40%	306	61.20%	117	23.40%	
	31 – 40	18	8.30%	151	69.30%	49	22.50%	
	41 – 50	29	10.10%	198	69.20%	59	20.60%	
	51 – 60	19	9.00%	149	71.00%	42	20.00%	
Sex	Male	44	10.00%	309	69.90%	89	20.10%	0.187
	Female	113	12.60%	583	65.20%	198	22.10%	
Occupation	1	100	14.00%	466	65.20%	149	20.80%	.025, sig*
	2	57	9.20%	426	68.60%	138	22.20%	

The results of the studies show a statistically significant difference in terms of completion of treatment in age group of 21 to 30. No statistically significant difference was found

in terms of age, gender and other factors. The results of this study show a significant reduction in the test to positivity ratio between the two groups (Table 4).

Table 4: Analysis of the RTPCR test results with respect to age, sex, occupation and completion of course

		Test results				Chi square test p value
		Negative		Positive		
		Count	Row N %	Count	Row N %	
Age	20 and below	1	33.30%	2	66.70%	0.72
	21 – 30	16	59.30%	11	40.70%	
	31 – 40	7	63.60%	4	36.40%	
	41 – 50	12	70.60%	5	29.40%	
	51 – 60	4	50.00%	4	50.00%	
Sex	Male	10	52.60%	9	47.40%	0.399
	Female	30	63.80%	17	36.20%	
Occupation	1	32	64.00%	18	36.00%	0.319
	2	8	50.00%	8	50.00%	
Course completion	Not completed	3	30.00%	7	70.00%	.032, sig
	Completed	37	66.10%	19	33.90%	
	Dropouts	0	0.00%	0	0.00%	

The RT PCR results were significant in the patients who had not completed the course of treatment than the ones who

had completed the course of treatment ($p < 0.001$).

Table 5: Overall outcomes in Group A

		Group A (Total: 1336)			
		Completed		Not Completed	
		Number	Percentage	Number	Percentage
	Total	892	67%	444	33%
	Symptomatic	53	6%	10	2%
	RTPCR done	53		10	
	Positive	19		7	
	Test to positivity		36%		70%
	Positivity % in Group		2%		2%

	Death	0		0	
Occupation	Healthcare	466	52%	249	56%
	Others	426	48%	195	44%
Healthcare	RTPCR Positive	13	3%	5	2%
	RTPCR Negative	28	6%	3	1%
Others	RTPCR Positive	6	1%	0	0%
	RTPCR Negative	6	1%	2	1%

Table 6: Overall outcomes in Group B

Group B (Total: 1549)		
	Number	Percentage
Total	1549	
Symptomatic	5	
RTPCR Done	5	
Total positive	5	
Test to positivity%		100%
Positivity % in group		0.32%
Death	1	0.06%

In totality, it was observed that the RTPCR positivity rates had lowered to a significant percentage among the participants who completed the course of study intervention i.e., the test to positivity ratio among the participants had significantly reduced indicating the effectiveness of the intervention (Table 5 & 6).

Discussion

Test to positivity rate has been recommended as one of the important parameters to monitor the testing efficacy and determine the status of disease activity in the given population by CDC [18]. The reduced test to positivity ratio in participants who completed the treatment as per protocol is an indicator that the treatment is likely to be helpful.

Previous research has shown that homeopathic remedies can be used to treat flu-like symptoms. During the 2009 H1N1 virus, Arsenicum album and Bryonia were found to be useful in treating symptoms like fever, cough, running nose, and headache. Other authors observed and reported similar results [19, 20].

Similarly, according to a report from Pune, India, [21] COVID-19 positive individuals who were treated with a combination of hydroxychloroquine and homeopathic medicine reported a shortened recovery time with this combination. However, the identity of the homeopathic drug was not made public. In Gujarat, India, 3,174 and 2,000 quarantined individuals, respectively, received Ayurvedic preparation and homeopathic medicine to increase their immunity as a prophylactic step against COVID-19. None of the patients who took the medication in accordance with the instructions displayed any COVID-19 symptoms or signs during the 14-day quarantine period, and all of them tested negative for coronavirus infection [22]. Such findings in accordance with the current study highlight the utility of homeopathy therapy in the prophylaxis of COVID-19.

There were few limitations to the study. The dropout rate was not taken into consideration while calculating the sample size. A double blinding could have been used which was not possible in our scenario given the study being conducted in era of pandemic and pandemic-related social constraints. Monitoring of the control group was challenging as the control group selected was located in containment zones. Population from containment zones was selected as the control group to match the exposure levels

with front line workers. However, monitoring this population posed a logistic challenge. Future studies may try to perform double blinding and improve on the current study itself.

A few studies have used a randomized open label design to evaluate effectiveness of the interventions [19-21]. The current study uses a similar design with specific homeopathic endpoints.

Despite the limitations, the current study was first of a kind in homeopathy. The significant results in 21-30 years age group give a hope that with well-designed future studies, the immunological boosting capabilities of the study compounds can be demonstrated.

Conclusion

In literature, there have been no studies done so far for prevention of Coronavirus Disease 2019 (COVID-19) using homeopathic remedies. This is the first study of this kind to be done in two separate groups and using randomization.

The study showed a significant impact on completion of treatment in specific age groups by using the homeopathic strategy involving a nosode Tuberculinum 1M, followed by Zincum Metallicum 6c, Chininum Arsenicosum 6c and Calcarea Phos 6x. This study supports the feasibility of a larger randomized, double-blind, placebo-controlled trial. The preparation should be fully explored for prevention of COVID-19 disease in future studies. The data from this study can be used on pilot basis for designing of further well-designed clinical trials to check efficacy of the given intervention.

Highlights

- Very few Homeopathic therapeutic strategies have studied prophylaxis of COVID-19.
- The novel homeopathic strategy involving a nosode Tuberculinum 1M, followed by Zincum Metallicum 6c, Chininum arsenicosum 6c and Calcarea Phos 6x increases compliance to treatment significantly.
- It is feasible to carry out larger randomized, double-blind, placebo-controlled trial in this therapeutic area for prevention of COVID-19.

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Conflict of Interest: None

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