



Original Article



Efficacy of a Customized Holistic Traditional Complementary Alternative Medicine Protocol for Improving Immunological, Metabolic, and Clinical Parameters in Mild to Moderate COVID-19 Patients: A Pilot Randomized Controlled Trial

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ABSTRACT

Background: The COVID-19 pandemic has necessitated exploring various treatment options, including Traditional Complementary and Alternative Medicine. This study aims to evaluate the efficacy of a customised Holistic Traditional Complementary Alternative Medicine (HTCAM) protocol in improving immunological, metabolic, and inflammatory outcomes in patients with mild to moderate COVID-19.

Methods: This pilot randomised controlled trial involved 100 patients, 50 in the HTCAM intervention group and 50 in the control group. Participants were adults diagnosed with mild to moderate COVID-19. Following 1:1 randomisation, baseline data were collected, including blood samples for interleukins, oxidative stress, and metabolic parameters. The HTCAM group received a detailed, customised protocol with daily supervision and clinical monitoring. Blood samples were collected at discharge or on the 7th day post-enrollment. Statistical analysis was performed using SPSS version 25.0, employing mean, standard deviation, chi-square tests, and independent t-tests, with significance set at $p < 0.05$.

Results: Sociodemographic and clinical variables showed no significant differences between groups. Significant improvements in the HTCAM group were observed in creatinine and triglyceride levels compared to the control group. Significant differences were also noted in serum albumin and TNF-alpha levels, enhancing inflammation management and overall health.

Conclusion: This pilot trial suggests combining the Holistic Traditional Complementary Alternative Medicine (HTCAM) protocol with conventional COVID-19 treatment may improve clinical and metabolic parameters. Significant benefits were observed in serum albumin levels and reductions in TNF-alpha, with HTCAM also maintaining stable ferritin levels and positively influencing triglycerides and creatinine. Further research must confirm these findings and clarify HTCAM's role in COVID-19 management.

KEYWORDS: Holistic medicine; Complementary therapies; Immunological; Metabolic; COVID-19

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INTRODUCTION

The COVID-19 pandemic, caused by the SARS-CoV-2 virus, has profoundly impacted global health systems, highlighting the need for effective treatment options. The disease's severe respiratory manifestations and variable progression have led to an extensive search for both conventional and alternative therapeutic approaches. Among these, Traditional Complementary and Alternative Medicine (TCAM) has garnered increasing attention for its potential role in managing COVID-19.^{1,2}

TCAM encompasses diverse practices, including herbal medicine, acupuncture, and dietary interventions, rooted in longstanding cultural traditions. Recent reviews suggest that TCAM approaches, with their holistic principles and multi-faceted mechanisms, may offer complementary benefits in treating COVID-19.^{3,4} For instance, herbal formulations used in traditional Chinese medicine have been shown to modulate inflammatory responses and enhance immune function, potentially addressing some of the pathological features of COVID-19.^{5,6} Similarly, dietary interventions and mind-body practices are recognised for supporting immune health and improving overall well-being, which could be beneficial in the context of a pandemic.^{7,8}

Despite these promising findings, rigorous clinical evaluations of TCAM in the context of COVID-19 are still limited. Most existing studies are observational or anecdotal, with insufficient data from randomised controlled trials to substantiate the efficacy of these approaches in COVID-19 management.^{9,10} The lack of robust evidence underscores the need for well-designed clinical trials to evaluate the safety and effectiveness of TCAM therapies.

This study aims to address this gap by investigating the impact of a Holistic Traditional Complementary Alternative Medicine (HTCAM) protocol in patients with mild to moderate COVID-19. By comparing the outcomes of patients receiving HTCAM with those receiving standard conventional care, this trial seeks to provide empirical data on the potential benefits of integrating TCAM approaches into traditional treatment regimens for COVID-19. The primary objectives are to assess improvements in immunological, while these secondary objectives are clinical and metabolic parameters and to evaluate any associated changes in patient outcomes.

METHODOLOGY

Study design and participants: This pilot randomised controlled trial included 100 participants, with 50 in the intervention group and 50 in the control group. All participants were diagnosed with mild to moderate SARS-CoV-2 infection (As per guidelines of 'clinical management protocol: COVID-19' laid by the Government of India - Ministry of Health and Family Welfare Directorate General of Health Services (EMR Division)) and were receiving treatment at the tertiary care centre during 2020-21.¹¹

Inclusion and exclusion criteria: The inclusion criteria were mild to moderate COVID-19 participants aged 18 years, able and willing to participate, and had not taken any herbs or complementary therapies in the past 8 weeks. Exclusion criteria included enrollment in other COVID-19 prevention or treatment trials, allergies or sensitivities to food items, comorbidities such as metabolic, psychiatric, neurological, or autoimmune disorders, secondary malignancy, steroid therapy, significant physical debility, and pregnancy.

Randomisation and group allocation: Participants were randomised using a block randomisation technique, with a 1:1 allocation ratio using a computer-generated number using the SNOOSE method between the intervention and control groups.

Control group: The control group comprised 50 participants. Baseline data were collected through interviews, and blood samples were drawn, labelled, transported, and analysed on the same day for COVID-19. Samples were also stored for later analysis of interleukins, oxidative stress, and antioxidant parameters.

Intervention group: The intervention group, consisting of 50 participants, received Holistic Traditional Complementary Alternative Medicine (HTCAM) treatment (details of which are attached in [Supplementary file 1](#)). These participants followed a customised HTCAM protocol under daily supervision, with clinical signs, symptoms, and blood samples monitored at discharge or on the 7th-day post-enrollment.

Outcomes: The primary outcomes of the study are (kidney function, liver function, lipid, and other

metabolic indices), and the secondary outcomes are Inflammatory and oxidative stress markers.

Statistical Analysis: Statistical analyses were conducted using SPSS version 25.0. Descriptive statistics (mean and SD) were used, and inferential statistics (independent sample t-tests) were employed to assess group differences. A p-value of <0.05 was considered statistically significant.

Ethical Considerations: Ethical approval was obtained from the Institute Ethical Committee. Written informed consent was obtained from each participant before inclusion in the study.

RESULTS

Baseline characteristics: The study included 100 participants, 50 in the intervention group and 50 in the control group (Figure 1). The mean age in both groups was comparable. Gender distribution showed more males in the control group, but this was not statistically significant. Educational and occupational statuses, as well as marital status, were similar across both groups. The detailed baseline characteristics are summarised in Table 1.

Figure 1: CONSORT Flow.

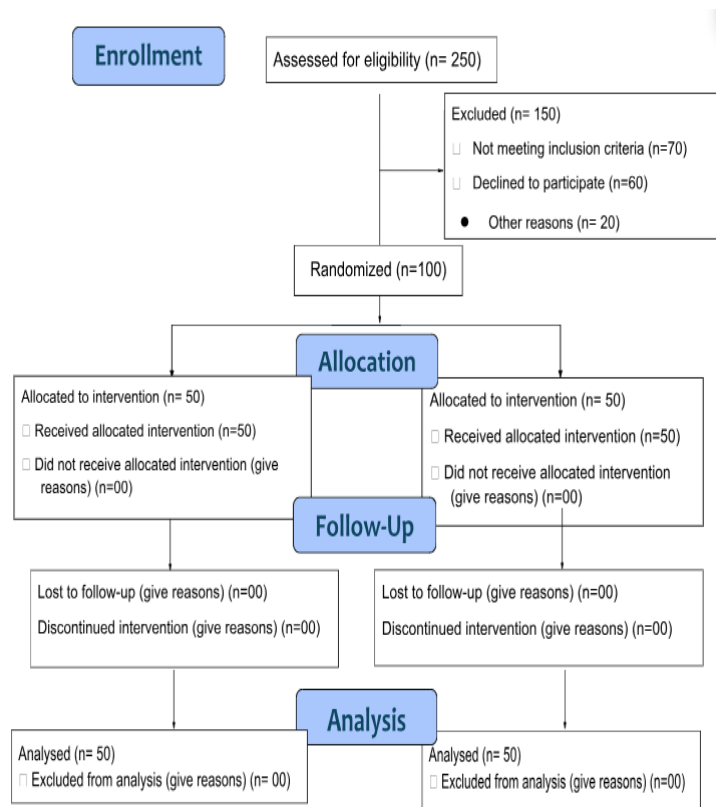


Table 1: Socio-demographic and clinical characteristics among two groups.

S. No	Variable	Sub-categories	Groups f (%)		p-value
			Experimental group (n=50)	Control group (n=50)	
1	Age	Mean (±SD)	35.04 ± 11.79	36.19 ± 9.52	0.001 *
2	Gender	Male	26 (52)	35 (70)	0.065
3	Educational status	Graduate and Higher	44 (88)	45 (90)	0.842
4	Occupational status	Service	35 (70)	35 (70)	0.442
		Student	09 (18)	13 (26)	
		Others	06 (12)	02 (04)	
5	Marital status	Married	29 (58)	26 (52)	0.546
6	Body Mass Index	Mean ±SD	21.47± 3.33	21.79± 1.75	0.555
7	Dietary pattern	Vegetarian	22 (44)	20 (40)	0.685
8	Alcohol intake	NO	47 (94)	47 (94)	1.000
9	Fever	Yes	42 (84)	41 (82)	0.790
10	Cough	Yes	36 (72)	35 (70)	0.826
11	Body Pain	Yes	36 (72)	35 (70)	0.826
12	Nausea	Yes	9 (18)	9 (18)	1.000
13	Diarrhea	Yes	18 (36)	18 (36)	1.000

*p value <0.05 represents significance; Chi-square is used to assess the significance of categorical data; for continuous data (Mean ± SD), an independent sample t-test is used.

Primary outcomes:

The primary outcomes focused on kidney function, lipid profile, liver function, and inflammatory markers. Creatinine levels and triglycerides showed significant differences, favouring the intervention group. Serum albumin was also significantly higher in the intervention group, while TNF-alpha levels were reduced compared to the control group. Other markers, such as sodium, potassium, and cholesterol, did not differ significantly. Table 2 presents the detailed primary outcomes.

Table 2: Comparison of primary outcomes (kidney function, liver function, lipid, and other metabolic indices) from baseline to end of the trial between experimental and control groups

S. No.	Variables	Difference in Experimental group (n= 50)	Difference in Control group (n=50)	p-value
1	Sodium	-1.15 (-35 to 34)	-0.35 (-100.4 to 16)	0.393
2	Potassium	-0.125 (-1.97 to 3.02)	-0.16 (-1.79 to 1.16)	0.962
3	Urea	-1.85(-38.3 to 32.5)	1.0 (-61.5 to 26.3)	0.279
4	Creatinine	-0.09 (-0.8 to 3.89)	0.015 (-6.73 to 1.97)	0.003*
5	Chloride	-0.15 (-49 to 24.10)	0.15 (-94.47 to 13)	0.398
6	GGT	-0.1 (-28.5 to 66)	-4.8 (-273.8 to 224.1)	0.122
7	Total Bilirubin	-0.05(-0.45 to 0.71)	-0.02 (-0.8 to 1.34)	0.586
8	Direct Bilirubin	-0.04(-0.44 to 0.17)	-0.05 (-0.54 to 0.84)	0.929
9	Total protein	0.0(-3.46 to 2.88)	0.16(-2.02 to 3.14)	0.145
10	Albumin	-0.02(-0.87 to 1.0)	0.26(-0.87 to 3.78)	0.01*
11	ALP	-5.25(-20.2 to 155.2)	-7.2(-196.9 to 474)	0.877
12	AST	-1.05(-51.8 to 29.5)	3.65(-196.5 to 80)	0.486
13	Triglycerides	-13.4 (-418.80 to 128)	7.2 (-509.5 to 154.2)	0.020*
14	Total Cholesterol	-4.00 (-182 to 59)	-12.15 (-124.5 to 98.3)	0.484
15	LDL-C	-8.35 (-131.2 to 72)	-11.15 (-125 to 55)	0.697
16	HDL-C	-4.525 (-46 to 76.4)	0.90 (-36.2 to 41.4)	0.372
17	Calcium	0.145 (-3.26 to 4.69)	0.155 (-6.7 to 2.94)	0.866
18	Phosphorus	0.19(-3.49 to 5.78)	0.60 (-7.52 to 9.15)	0.151
19	Amylase	-1.05(-62.4 to 267)	-1.1 (102 to 109.8)	0.699
20	T3	0.19 (-1.02 to 1.92)	0.19 (-1.31 to 2.68)	0.515
21	T4	0.01 (-0.27 to 0.72)	0.06 (-1.28 to 1.13)	0.296
22	TSH	0.34 (-6.14 to 7.26)	0.00 (-9.23 to 83.07)	0.145

***p value <0.05 represents significance; Values in Median (IQR), Mann-Whitney U test used for assessing difference;**

Abbreviations: GGT: Gamma-Glutamyl Transferase ALP: Alkaline Phosphatase AST: Aspartate Aminotransferase LDL-C: Low-Density Lipoprotein Cholesterol HDL-C: High-Density Lipoprotein Cholesterol T3: Triiodothyronine T4: Thyroxine TSH: Thyroid-Stimulating Hormone

Secondary outcomes: The secondary outcomes included oxidative stress markers, bone-related markers, and thyroid profiles. No significant differences were found between the groups in these areas. Table 3 provides the details of the secondary outcomes.

Table 3: Changes in Inflammatory and oxidative stress markers from baseline to end of the trial between the Experimental group and Control group.

S. N.	Variables	Differences in Experimental group (n= 50)	Differences in Control group (n=50)	p-value
1	IL-6	-4.5800 (-5499.99 to 4899.00)	-.0150 (-5499.99 to 4898.50)	0.728
2	IL-10	0.0 (-234.85 to 15.0)	0.0 (-234.85 to 15.00)	0.653
3	TNF alpha	-0.05 (-411.00 to 123.20)	-31.45 (-558.30 to 123.2)	0.05*

4	CRP	-11.015 (-158.50 to 4.79)	-21.555 (-148.50 to 4.79)	0.519
5	Pro-calcitonin	0 (-5.69 to 0.04)	0 (-0.19 to 0.51)	0.466
6	Iron	-0.35 (-121.1 to 132.7)	-7.3 (-204.2 to 176.9)	0.254
7	Ferritin	-0.46 (-378.05 to 790.24)	-15.63 (-320.66 to 219.9)	0.106
8	MDA	-0.0327 (-.32 to 0.32)	-0.03(-0.12 to -0.02)	0.842
9	TAS	-129.165 (-2123.16 to 678.27)	-133.7873 (-954.54 to 392.65)	0.901
10	SOD	5.05(-98.7 to 78.4)	9.75 (-58 to 89.9)	0.340

***p value <0.05 represent significance; Values in Median (IQR), Mann-Whitney U test used for assessing difference; Abbreviations:** IL-6: Interleukin 6 IL-10: Interleukin 10 TNF- α : Tumor Necrosis Factor-alpha CRP: C-Reactive Protein MDA: Malondialdehyde TAS: Total Antioxidant Status SOD: Superoxide Dismutase.

DISCUSSION

The COVID-19 pandemic has highlighted the necessity for diverse and effective treatment strategies. As SARS-CoV-2 continues to impact global health, integrating complementary approaches such as Holistic Traditional Complementary Alternative Medicine (HTCAM) into conventional treatment regimens has garnered interest. This study's findings highlight the potential benefits of HTCAM in managing COVID-19, particularly in improving serum albumin levels and modulating inflammatory markers.

Our study observed significant changes in serum albumin and TNF-alpha levels among patients receiving HTCAM compared to those on standard allopathic treatments. Elevated serum albumin levels have been associated with better clinical outcomes in COVID-19 patients, as low levels often indicate poor prognosis and increased mortality. Improving serum albumin among patients receiving HTCAM supports its potential role in enhancing patient recovery and managing inflammation. This finding is consistent with recent research suggesting that maintaining or increasing serum albumin levels can improve immune function and reduce the risk of severe outcomes in COVID-19 patients.¹²

The observed reduction in TNF-alpha levels is noteworthy, as this pro-inflammatory cytokine is known to contribute to disease severity in COVID-19. Elevated TNF-alpha levels have been linked to hyperinflammation and severe clinical outcomes, making its modulation a critical aspect of effective treatment. HTCAM's impact on TNF-alpha suggests it may help reduce inflammation and associated complications. This finding aligns with studies showing the anti-inflammatory effects of various complementary therapies, including herbal medicines and dietary supplements, in managing cytokine storm and systemic inflammation in COVID-19 patients.^{13,14}

In contrast, the study found that serum ferritin levels were adversely affected by standard treatments, whereas HTCAM showed no significant change. Elevated ferritin levels are often associated with inflammation and liver dysfunction in COVID-19. The ability of HTCAM to maintain stable ferritin levels could indicate its role in managing systemic inflammation and preventing complications related to ferritin dysregulation. This is consistent with research suggesting that specific complementary therapies can modulate ferritin levels and improve disease management.^{15,16}

Additionally, the study's findings on lipid profiles and creatinine levels further underscore the potential benefits of HTCAM. Hypertriglyceridemia and elevated

creatinine levels have been observed in COVID-19 patients, and managing these parameters is crucial for comprehensive care.^{17,18} HTCAM's positive effect on these markers suggests its utility in addressing metabolic and renal concerns associated with the disease. Previous studies have highlighted the role of dietary and herbal interventions in improving lipid metabolism and kidney function, which could contribute to better overall outcomes in COVID-19 patients.¹⁹

Moreover, integrating HTCAM with conventional therapies might enhance overall patient well-being and reduce the burden on healthcare systems. The holistic nature of HTCAM, which often includes dietary advice, lifestyle modifications, and stress management techniques, could be supportive in managing long-term COVID-19 symptoms and recovery. This approach aligns with the growing recognition of the importance of holistic and patient-centred care in managing chronic and complex diseases.

In our study, we recognise several limitations that impact the findings. Firstly, the statistically significant age difference between the two groups constitutes a known confounder, potentially influencing the outcomes. Furthermore, conducting a comprehensive baseline comparison of primary outcomes—such as kidney function, liver function, lipid levels, and other metabolic indices—would have enhanced our understanding of the initial comparability between the groups.

Overall, our findings contribute to the evolving evidence on the potential benefits of incorporating complementary approaches into conventional COVID-19 treatment regimens. While our study provides promising insights, further research with larger sample sizes and rigorous methodologies is essential to validate these results and establish comprehensive guidelines for integrating HTCAM into standard treatment protocols. Future studies should also explore the mechanisms underlying the observed effects and assess the long-term outcomes of HTCAM interventions in diverse patient populations. Despite these promising findings, integrating HTCAM into standard treatment regimens requires further investigation to establish its efficacy and safety comprehensively.

CONCLUSIONS

This pilot randomised controlled trial demonstrates that the Holistic Traditional Complementary Alternative Medicine (HTCAM) protocol may offer benefits when combined with conventional treatment for COVID-19. The study observed significant improvements in serum

albumin levels and reductions in inflammatory markers like TNF-alpha among patients receiving HTCAM. Additionally, HTCAM did not adversely affect ferritin levels, negatively impacted by standard treatments. The protocol also showed potential in managing metabolic markers, such as triglycerides and creatinine. While these findings are promising, further research with larger sample sizes is needed to validate these results and fully understand the role of HTCAM in COVID-19 management.

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CONFLICTS OF INTEREST STATEMENT

The authors declare no conflict of interest

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ETHICS STATEMENT INCLUDING PATIENT CONSENT

Not applicable

AUTHOR'S CONTRIBUTION

AAM: Conceptualization; Data curation; Resources; Methodology; Analysis; Writing the draft; Review & Editing

NG: Conceptualization; Supervision

CVK: Conceptualization; Supervision

KKR: Conceptualization; Supervision

BG: Conceptualization; Supervision

MJ: Conceptualization; Supervision

ASB: Conceptualization; Data curation; Supervision

PKP: Conceptualization; Supervision

SRY: Conceptualization; Data curation; Supervision

RG: Conceptualization; Supervision

SM: Conceptualization; Data curation; Methodology; Supervision

AI DECLARATION

No AI tool was used to generate research data, perform data analysis, interpret findings, formulate scientific conclusions, or make editorial decisions. All AI-assisted content was critically reviewed, verified, and revised by the authors. The authors take full responsibility for the accuracy, originality, integrity, and final content of the manuscript.

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