

VIRGIN COCONUT OIL INGESTION IN HEALTHY SUBJECTS AS PROPHYLACTIC AGAINST INFLAMMATORY DISEASES LIKE COVID-19**Dr. Sanjay Tamoli¹, Vaibhav Kaushik*², Kamini Gohil², Vaishali Gode² and Sudhakar Mhaskar²**¹Target Institute of Medical Education and Research Mumbai, Maharashtra, India.²Marico R&D Center, Marico Limited, Andheri (E), Mumbai, Maharashtra, India.***Corresponding Author: Vaibhav Kaushik**

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ABSTRACT

Inflammation related pathogenesis is on rise given the modern-day lifestyle and dietary choices. The present exploratory study is aimed at evaluating the effect of virgin coconut oil (VCO) ingestion by healthy subjects on inflammation related biomarkers and health conditions. 60-day pilot study was conducted on healthy Indian subjects with ingestion of 30 ml/day VCO (post meals) for a period of 2 months. Significant reduction in C-Reactive Protein levels from baseline and IL-6 levels from control group were recorded. The inflammation reduction effect was further substantiated with lower incidences for common infections (physician observation) & improvement in pain related conditions (self-assessment scale). In order to propose VCO as nutraceutical in controlling inflammation related pathogenesis, more elaborate studies – with larger sample size and diverse population set – need to be conducted.

KEYWORDS: Virgin Coconut Oil; Inflammation; C-Reactive Protein; Nutraceutical.**INTRODUCTION**

Coconut oil has been considered since ancient times as a superfood and source of nutrition to achieve multiple wellness goals. These health benefits of coconut oil do found mention in Ayurvedic Medicine (ancient literature) scriptures, dated centuries back.^[1] Ayurveda lists the qualities of coconut oil as nourishment to the body ('Bruhanam') and strength increase ('Balavardhana'). Scalp massage with Coconut oil helps deliver hair growth due to its 'Keshya' (good for hair) and 'Snigdha' (oily) properties. Coconut oil is attributed as 'Kushthahara' as it helps in wound healing, scars management, blemishes repair, anti-itching (against eczema, psoriasis conditions). It is also known to manage body heat & inflammation ('Pitta' Dosha pacifier) and a soothing agent.

Coconut Oil in the market is available in different types – broad categorization can be done as: 1) expelled copra oil from crushing, pressing of the dried coconut meat and 2) virgin coconut oil (VCO) produced by wet extraction process of the fresh coconut meat.^[1] Both the types have similar fatty acids and triglycerides profile, but differ in the content of phytoconstituent classes – sterols, polyphenols, alkaloids, tocopherols, tocotrienols etc.

Virgin Coconut Oil (VCO), its components and metabolites are studied extensively and known to have multifarious benefits. The underlying properties range

from being a natural immunity booster to antimicrobial protection to microbiome balance to satiety enhancement to improved metabolism to better absorption to oxidative stress management to anti-inflammatory to staving off dementia.^[2-4] VCO triglycerides on ingestion is broken down by lipases present in our body into various monoglycerides, diglycerides and free fatty acids – including Lauric Acid and Monolaurin.^[5] Monolaurin, Coconut Fatty Acids, Coconut Oil polyphenols and other components have been shown to exhibit anti-inflammatory response in various in-vitro and in-vivo studies.^[6-10] Mechanistically these components are shown to modulate the activities of enzymes involved in arachidonic acid metabolism (phospholipase A2, COX) and arginine metabolism (NOS), as well as the modulation of the production of other proinflammatory molecules.^[9-11]

Inflammation is the first line of defence in the wake of an injury or pathogenic infection in the body and is considered a normal immune response. Cytokines are essential part of the inflammation process and are produced by several immune cells. Over-production of cytokines in response to an external stimulus at a much higher rate than normal is referred to as a 'cytokine storm'.^[12] and if not attended to can lead to severe health complications resulting in organ damage. The reference to 'cytokine storm' in common parlance (Refer Figure 1a) has increased in the recent times due to emergence of

Coronavirus Disease 2019 (COVID-19). Inflammatory cytokines released during COVID-19 infection cause hyperinflammation prompting the immune cells to destroy healthy cells.^[13] Apart from the hyperinflammation, we have also witnessed a constant increase in the awareness about ‘lingering’ inflammation or chronic inflammation (Refer Figure 1b). Recent research work has suggested that the evolving lifestyle,

environmental and behavioral vectors cause Systemic Chronic Inflammation (SCI).^[14] SCI is known to be the precursor of several diseases that are the leading cause of disability and mortality disorders worldwide. Thus, strategies to control inflammation are extremely relevant both from the short-term and long-term perspective currently.

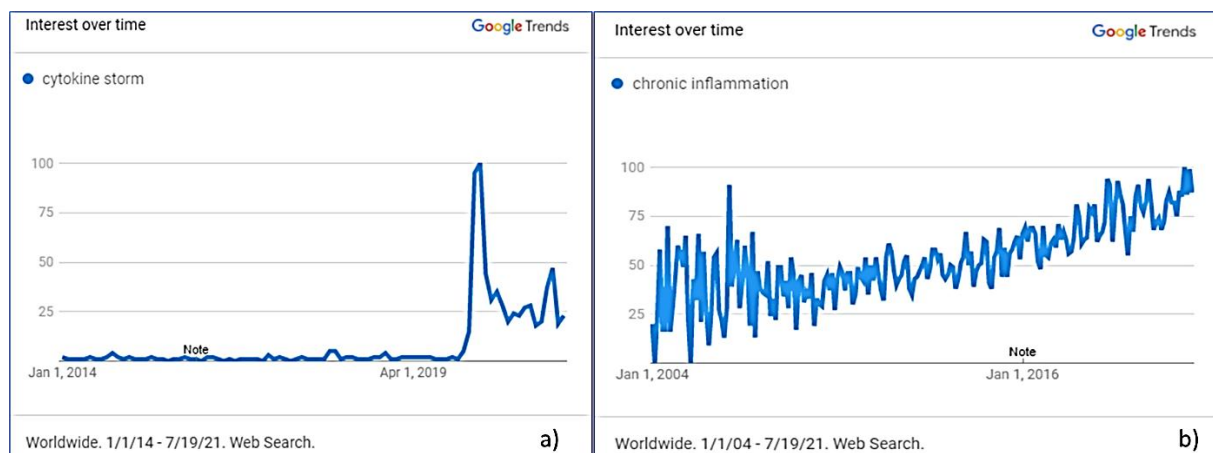


Fig. 2: Google Search Trends as depiction of interest for terms – a) ‘Cytokine Storm’ b) ‘Chronic Inflammation’ (<https://trends.google.com/>).

Even though coconut oil – components and metabolites – are shown to be effective anti-inflammatory agents in both cell lines as well as in-vivo studies,^[1] there is lack of scientifically reported work on the anti-inflammatory efficacy of the VCO in human trials. In the present study, we evaluated on healthy individuals the daily ingestion of VCO as protection against inflammatory biomarkers and related conditions. We employed randomized, comparative, open-labelled, in-home usage study to evaluate different parameters of inflammation, immunity, and general health.

MATERIALS AND METHODS

Materials

Commercially available VCO under the brandname of Coco Soul™ was procured and used for the studies.

Volunteer Recruitment

In-home usage study (60-day intervention period) was done with 20 volunteers per group (40% males, 60% females; All Asian) aged 30–55 years. Healthy subjects not suffering from any medical condition were included in the study. Healthy individuals were considered as those who did not have any underlying medical condition for which they are required to take regular medications or medical intervention. Care was taken to exclude the subjects who are having coconut intake as a regular part of their diet – either coconut oil or even raw coconut meat. Informed consent was obtained, and a participant information leaflet was supplied to all the volunteers prior to the studies. The protocol was approved by the expert clinician and carried out under their supervision for the period of Dec 2020 to Feb 2021. There were no

dropouts in the study and all subjects completed the study intervention.

Study Design

The study was a randomized, controlled trial wherein all the subjects were randomly assigned (as per computer generated randomization list) to either one of the two treatment arms in 1:1 ratio. Test Group (Group A) was suggested with VCO oral intake of 1 tablespoon (15ml) two times a day after meal. The inclusion of VCO in the diet was suggested to be done gradually with 1 tablespoon only for initial 7 days and then increase to 2 tablespoons every day. Control Group (Group B) was suggested to continue with their normal food intake. They were advised to refrain from bringing any significant changes to their regular eating habits.

Demographic information from study participants was collected on enrollment in the study. Weight, height, BMI, waist circumference and waist-to-hip ratio were measured at baseline (day 1), and endpoint (day 60). Study schematic (refer Figure 2) summarizes the design of the in-home usage study. The assessment markers of VCO consumption can be divided into below categories:

1. Inflammation Markers – C-Reactive Protein (CRP) and Interleukin-6 (IL-6).
2. Bio-Markers for evaluating impact on Lipid profile and specific cardiac health risk markers like Total Cholesterol (TC), Triglycerides (TGs), High-Density Lipoprotein (HDL), Low-Density Lipoprotein (LDL) and their ratios.

3. Bio-Markers for Thyroid functions include Total Tri-Iodothyronine (T3), Total Thyroxine (T4) and Thyroid Stimulating Hormone (TSH).
4. Assessment by physicians for infections and medical conditions.
5. Self-assessment ratings by Study Participants on questionnaire related to parameters like Energy & Stamina, Stress & Anxiety, Digestion and Holistic Health.

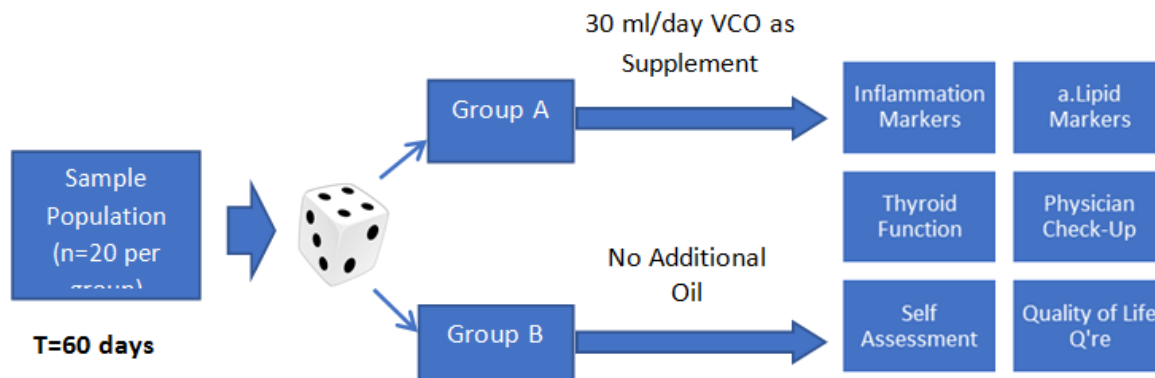


Fig. 3: Study Design Schematic for VCO as dietary supplement in Healthy Subjects.

RESULTS

All the enrolled subjects completed the study. The average age for the study participants in VCO group and Control group were 44.2 and 42.5 years, respectively. The average weight of the study participants in the VCO and Control groups at baseline were 78.4 and 74.8 kg, respectively. After the intervention, there was a non-

significant increase of about 0.9 and 0.7 kg in the weight of the participants enrolled in the VCO group and Control group, respectively. BMI, Waist Circumference and Waist to Hip Ratio also deviated non-significantly during the study duration. Analysed data is captured in Table I.

Table I. Average anthropometric measures of study participants for two groups over study duration.

Anthropometric Parameters	VCO Group			Control Group		
	Baseline	Day 60	p-Value	Baseline	Day 60	p-Value
BODY WT (kg)	78.5±20.0	79.4±19.8	0.132	70.8±14.7	71.5±14.1	0.146
BMI (kg/m²)	29.0±6.7	28.9±11.0	0.245	29.5±6.1	31.5±6.0	0.120
Waist Circumference (inches)	39.0±6.3	39.1±5.8	0.771	36.9±2.9	37.6±3.3	0.356
Waist Hip Ratio	0.919±0.08	0.933±0.09	0.574	0.875±0.07	0.905±0.04	0.302

Lipid Profile was evaluated at the start and end of the study to look for any positive impact on the Dyslipidemia related biomarkers due to intervention. Results are captured in Table II. TGs, TC, LDL and HDL Cholesterol levels remain similar at the start and the end of the study, with non-significant deviations. Even the ratio of TC to HDL as well as LDL to HDL remain

within the non-significant zone before and after the study. Two-Sample T-Test comparison for Lipid Markers between the two groups at Baseline as well as Day 60 also showed parity results (p-value >0.05; data not shown). No Changes in the Lipid Profile indicates no adverse effect or complications on the lipid markers due to the study intervention of ingesting VCO regularly.

Table II. Lipid Profile of study participants for two groups over the study duration.

Lipid Parameters	VCO Group			Control Group		
	Baseline	Day 60	p-Value	Baseline	Day 60	p-Value
Total Cholesterol (mg/dL)	184.2±27.9	171.2±63.4	0.45	195.8±22.6	208.89±26.8	0.083
HDL Cholesterol (mg/dL)	46.55±10.4	48.45±10.6	0.111	44.11±10.2	45.67±8.2	0.202
LDL Cholesterol (mg/dL)	114.82±33.4	123.18±31.2	0.078	133.22±21.5	136.11±24.5	0.63
Triglycerides (mg/dL)	143.91±44.4	141.82±34.9	0.413	167.00±59.3	163.89±63.3	0.814
TC/ HDL Cholesterol ratio	4.08±0.8	4.10±1.0	0.854	4.68±1.1	4.71±0.9	0.876
LDL / HDL Ratio	2.55±0.8	2.69±0.9	0.119	3.26±0.7	3.06±0.7	0.354
VLDL Cholesterol (mg/dL)	28.79±8.9	27.36±7.0	0.213	33.32±11.9	35.07±14.0	0.484
NON-HDL Cholesterol (mg/dL)	137.81±27.0	141.45±33.1	0.359	164.31±48.6	164.71±26.2	0.98

Inflammation markers' changes over the study duration for the VCO and control interventions is captured in

Table III. At baseline, the CRP levels and IL-6 content are found to be similar across the groups (p-value of

0.643 and 0.998 respectively; Table IV). A significant decrease (-25%) in CRP levels was observed in the VCO group while, the control group showed a non-significant increase (+21%) in CRP levels during the same period. In case of IL-6, VCO group showed a non-significant

decrease (-15%) while the control group exhibited a significant increase (+17%) over the study period. Figure 3 captures the changes in Inflammation Markers for the two groups over the study duration.

Table III. Inflammation Biomarkers of study participants for two groups over the study duration.

Inflammation Markers	VCO Group				Control Group			
	Baseline	Day 60	p-Value	% Change	Baseline	Day 60	p-Value	% Change
CRP (mg/l)	2.9±0.9	2.1±0.9	0.011	-25%	2.5±0.6	3.1±0.8	0.096	21%
IL-6 (pg/ml)	3.6±1.0	3.1±0.3	0.482	-15%	3.6±0.3	4.2±0.8	0.035	17%

Table IV. Two-Sample T-Test for significance evaluation across the groups for Inflammation markers.

		Control Baseline	Control Day60
IL-6	VCO Baseline	0.998	0.382
	VCO Day60	0.073	0.003
CRP	VCO Baseline	0.643	0.824
	VCO Day60	0.581	0.281

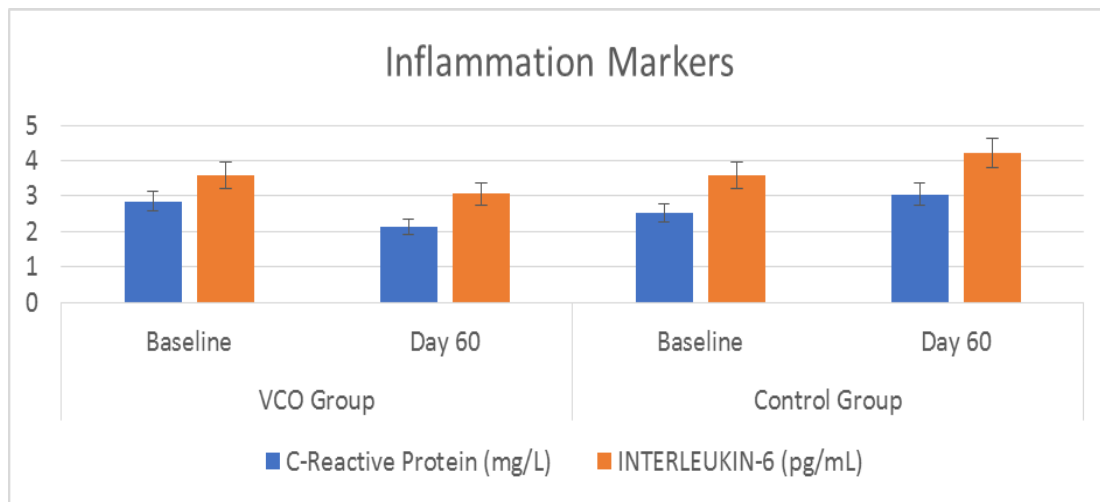


Fig. 4: Inflammation Markers of the study participants for the two groups over the study duration.

Thyroid Functions in the body controls the metabolism activity and hence, directly influence the energy generation. Thyroid function markers evaluated over the study duration showed non-significant deviations

(captured in Table V). TSH values for intervention groups showed 16% decrease with p-value of 0.063. Reduction in TSH indicates an improved metabolism activity in the VCO intervention group.

Table V: Thyroid Function Markers of study participants for two groups over the study duration.

Thyroid Function Markers	VCO Group			Control Group		
	Baseline	Day 60	p-Value	Baseline	Day 60	p-Value
Total Triiodothyronine (T3)	109.7±24.6	99.8±17.3	0.23	112.4±28.0	109.7±26.9	0.62
Total Thyroxine (T4)	7.7±1.9	7.4±2.1	0.59	8.4±1.5	7.8±3.3	0.54
Thyroid Stimulating Hormone (TSH)	3.4±1.7	2.9±1.0	0.06	3.6±2.8	3.5±2.2	0.35

Physicians interviewed the study participants for incidence of infection and medical conditions in last 60 days at the start and end of the study duration (Table VI). All the incidences deviation observed were only directional, statistically non-significant changes. The incidences for conditions of body ache, joint & muscle pain, headache, and upper respiratory tract infection (RTI) were found to be reduced with VCO intervention, while the opposite trend was seen for the Control Group.

Table VI: Incidences of Infections and Medical Conditions for two groups over the study duration.

Infections and Medical Conditions	VCO Group		Control Group	
	Day0	Day60	Day0	Day60
ALLERGY	0.45±0.48	0.64±0.50	0.89±.43	0.56±0.42
HEADACHE	2.55±0.62	2.18±0.69	2.78±0.61	3.44±0.39
JOINT AND MUSCLE PAIN	3.40±0.98	2.09±0.57	1.44±0.53	2.00±0.61
FEVER	0.64±0.29	0.27±0.20	0.56±0.23	0.33±0.22
BODY ACHE	3.82±0.96	2.55±0.70	2.00±0.52	2.44±0.45
SKIN PROBLEMS	0.91±0.67	0.80±0.53	1.22±0.69	1.11±0.70
UPPER RTI	1.73±0.75	0.91±0.54	1.78±0.54	2.11±0.66
URINARY INFECTION	0.27±0.20	0.55±0.57	0.89±0.62	0.67±0.63

Study participants' perception-based ratings were recorded for changes experienced during the study for different parameters. (Table VII) The parameters were categorised under Digestion, Energy & Stamina, Stress & Anxiety and Hair & Skin health. The changes recorded were not significantly different and only directional in nature. Increased appetite, better bowel movements and improved digestion ratings were seen for

VCO group. Higher ratings of Stamina, Energy and Physical Strength were recorded for VCO group. In addition to the same, better sleep quality and reduced stress levels over the duration of study for VCO group was observed. The study participants in VCO group also perceived an improvement in skin health and reduction in hairfall.

Table VII. Self-perceived Ratings (scale of 0 to 10) for different parameters by the subjects in the two groups captured over the study duration.

Categories	Parameters	VCO Group		Control Group	
		Day0	Day60	Day0	Day60
Digestive System	Appetite ↑	6.82±0.58	7.18±0.66	7.00±0.59	6.11±0.56
	Bowel Habits ↓	1.82±0.47	1.18±0.13	2.00±0.42	2.00±0.35
	Digestion ↑	6.09±0.64	6.82±0.68	5.00±0.88	5.22±0.49
Energy	Energy ↑	6.73±0.60	7.09±0.75	6.44±0.61	6.33±0.47
	Stamina ↑	6.36±0.65	6.82±0.78	5.78±0.74	6.11±0.60
	Physical Strength ↑	6.55±0.75	6.91±0.62	5.67±0.59	5.78±0.47
Stress	Sleep ↑	6.14±0.68	6.77±0.91	6.00±0.63	6.00±0.42
	Stress ↓	6.14±0.69	5.04±0.95	5.44±0.63	5.89±0.42
Hair & Skin	Skin Health ↑	3.73±0.35	4.00±0.28	3.11±0.29	3.33±0.39
	Hair Loss ↓	2.45±0.38	1.55±0.30	2.89±0.33	2.33±0.39

↑ - Higher the better; ↓ - Lower the better

Key outcomes from the study data analysis are summarized below:

- No significant change in Lipid Markers observed for VCO 60-day intervention. This indicates that the consumption of VCO did not increase the risk of coronary heart disease.
- Significantly higher reduction in Low-Grade Inflammation Markers with average CRP levels reduced from baseline and average IL-6 levels lowered on comparison with the Control group. This was further substantiated with lower incidences for common Infections & Pain related conditions which relate to inflammatory conditions in the body.

DISCUSSION

Coconut Oil is an important part of the diet in some tropical and sub-tropical countries of the world from a long time. In the last two decades, the popularity of edible coconut oil has increased across the world with endorsements from digital influencers & celebrities promoting various health benefits like cholesterol reduction, weight loss, improved cognition,

antimicrobial, immunity enhancer etc. This has been supplemented with a spurt in scientific studies reported in peer-reviewed literature investigating various health benefits of edible coconut oil. Most of the scientific studies with human ingestible intervention or epidemiological studies have revolved around evaluating the cardio-protective benefits of coconut oil. There have been contrasting suggestions from the reported studies and a consensus has not been reached yet. Couple of points which needs more deliberation have been 1) Identifying the nature of saturated fats originating from coconut oil triglycerides in terms of their metabolism and absorption pathways and 2) Conducting large scale, long duration human intervention studies on Cardiovascular health. There have been very few intervention studies related to body inflammation and by extension to the immunomodulatory benefits of coconut oil ingestion.

The present study evaluated the effects of VCO ingestion on healthy subjects in terms of a mix of biomarkers as well as subjective assessments. Intake of meals with VCO seem to have no significant change in the lipid

parameters at the end of 60 days. There is an ongoing debate in the scientific community regarding the impact of Coconut Oil consumption on cholesterol levels.^[15-17] The results we obtained are inline with those reported by Allan *et al.*^[18] in a 3-week intervention study of coconut oil consumption in pigs. They reported 1) no significant difference in LDL levels, 2) Increase in HDL levels, and 3) Decrease in Triglycerides. Further support to our data is from a VCO intervention study by Nevin *et al.*^[19] on Sprague–Dawley rats where they observe a reduction in triglycerides, total cholesterol, LDL and VLDL cholesterol; while increase in HDL. They attributed the effect to the polyphenol and minor constituents' composition of VCO.

CRP is an acute inflammatory protein and at sites of inflammation it goes up by 1000-fold. Normal levels of CRP in human are <5mg/L. In the present study, the baseline CRP levels are well below the threshold (VCO group: 2.9 ± 0.89 mg/L and Control Group: 2.5 ± 1.6 mg/L). A significant reduction of 25% was observed in VCO group suggesting the anti-inflammatory action of VCO on healthy subjects. The CRP-reducing benefit of VCO ingestion has been studied recently in Philippines.^[20] on suspected COVID patients.^[20] Comparatively lower reduction of CRP levels in our study can be explained basis the subject recruitment criteria – the present study is done on healthy subjects.

IL-6 is a cytokine which induces synthesis of acute phase proteins such as CRP. Serum IL-6 concentration normal level is <7pg/ml.^[21] Average IL-6 levels for the two groups at the start and end of the study is in the normal range and the IL-6 contents at the start of the study are similar for VCO and Control group (3.6 ± 0.30 and 3.6 ± 0.27 pg/ml, respectively). At the end of the study, the VCO group showed non-significant decrease (-15% from baseline) while the Control group showed a significant increase (17% from baseline). IL-6 Levels for the two groups at the end of the study are also significantly different (p-Value for 2-Sample T-Test = 0.03). Inflammatory cytokines (including IL-6) were reported to reduce in the presence of VCO in multiple in-vitro studies.^[1,22] IL-6 concentrations were also reported to decrease in mice fed with Coconut Oil rich diet for 5 weeks; as compared to other fat diets.^[23] The current study demonstrated the IL-6 lowering effect of VCO ingestion in normal, healthy subjects.

Immune-nutritive benefits of Coconut Oil and its metabolites have been researched and reviewed in recent literature.^[1] One of the underlying mechanisms for immunity enhancement has been to reign in the inflammatory damage. With the presented data, intake of moderate amount of VCO can serve as a cost-effective, natural strategy for immunity building via imparting anti-inflammatory benefits.

CONCLUSION

The presented exploratory, pilot clinical study concludes that consumption of VCO in healthy subjects is safe without causing any adverse effects on various clinical and laboratory parameters more importantly on the lipid levels. Significantly higher reduction in Inflammatory Markers like CRP and IL6 supported by the lower clinical incidences for common Infections & Pain related conditions provide evidence of potential immunity boosting effect of VCO. The study paves way for further randomized comparative studies with larger sample size to establish the efficacy of VCO for daily routine use as an adjunct therapy against inflammatory conditions.

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