

Effect of a Yoga and Naturopathy-Based Lifestyle Intervention with 9-Month Follow-Up on Lipid Profile in Patients with Hypertension: A Two-Arm Parallel Group Randomized Controlled Trial

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Keywords

Diet therapy · Hypertension · Lipid profile · Naturopathy · Yoga

Abstract

Introduction: Hypertension is recognized as a modifiable risk factor for cardiovascular diseases, alongside dyslipidemia. Studies have revealed that between 15 and 31% of individuals have both hypertension and dyslipidemia. However, emerging evidence suggests that natural therapies and yoga can help manage mild increases in blood pressure. This study aimed to evaluate the impact of yogic and naturopathy treatments on lipid profiles in hypertensive patients, thereby contributing to the existing literature. **Materials and Methods:** A randomized controlled experiment was conducted, involving 262 hypertensive patients randomly assigned to either the study group (SG) or control group (CG). The SG, consisting of 131 individuals, received yoga and naturopathic treatments for 10 days, while the CG ($n = 131$) did not. The lipid profile was measured at the beginning and end of the 10 days, and they were followed up and reassessed after 9 months. **Results:** The study involved a total of 262 individuals, with 111 in the SG and 125 in the CG. After the 10-day intervention period, the SG

showed significant reductions in total cholesterol, triglycerides, high-density lipoprotein, low-density lipoprotein, very low-density lipoprotein, apolipoprotein-A (Apo-A), apolipoprotein-B (Apo-B), and lipoprotein-A (Lp-A) ($p < 0.001$) compared to the CG. Also, the change was observed after 9 months in Apo-A, Apo-B, and Lp-A significantly ($p < 0.001$). **Conclusion:** These findings underscore the potential of naturopathic and yogic interventions in improving lipid profiles in hypertensive patients, thereby contributing to the current literature. In conjunction with conventional management, these specific interventions could be considered as a safer form of complementary therapy in the treatment of dyslipidemia among hypertensive patients. Thus, these findings hold promise for the integration of naturopathic and yogic therapies in the standard care of hypertensive patients.

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Auswirkung einer auf Yoga und Naturheilkunde basierenden Lebensführungsintervention mit Nachbeobachtung nach neun Monaten auf das Lipidprofil bei Patienten mit Hypertonie: Eine zweiarmlige, randomisierte, kontrollierte Parallelgruppenstudie

Schlüsselwörter

Ernährungstherapie · Hypertonie · Lipidprofil · Naturheilkunde · Yoga

Zusammenfassung

Einleitung: Hypertonie ist ebenso wie Dyslipidämie als beeinflussbarer Risikofaktor für Herz-Kreislauf-Erkrankungen anerkannt. Studien zufolge liegen bei 15% bis 31% der Menschen sowohl Hypertonie als auch Dyslipidämie vor. Neueste Evidenz deutet jedoch darauf hin, dass naturheilkundliche Therapien und Yoga helfen können, einen leichten Anstieg des Blutdrucks zu beherrschen. Ziel dieser Studie ist es, die Auswirkung von yogischen und naturheilkundlichen Behandlungen auf das Lipidprofil von Patienten mit Hypertonie zu untersuchen und damit zur bereits vorhandenen Literatur weiter beizutragen.

Material und Methoden: Es wurde ein randomisierter, kontrollierter Versuch durchgeführt, bei dem 262 Hypertoniepatienten per Randomisierung entweder der Studiengruppe (SG) oder der Kontrollgruppe (CG) zugeteilt wurden. Bei der SG, die 131 Personen umfasste, wurden 10 Tage lang Yoga- und naturheilkundliche Behandlungen angewendet, bei der CG ($n = 131$) nicht. Das Lipidprofil wurde am Anfang und am Ende der 10 Tage sowie noch einmal nach einem Nachbeobachtungszeitraum von 9 Monaten gemessen. **Ergebnisse:** An der Studie nahmen insgesamt 262 Personen teil, 111 in der SG und 125 in der CG. Nach dem 10-tägigen Interventionszeitraum waren bei der SG im Vergleich zur CG die folgenden Werte signifikant niedriger: Gesamtcholesterin (TC), Triglyzeride (TG), an Lipoproteine hoher Dichte gebundenes (HDL-)Cholesterin, an Lipoproteine geringer Dichte gebundenes (LDL-)Cholesterin, an Lipoproteine sehr geringer Dichte gebundenes (VLDL-)Cholesterin, Apolipoprotein-A (Apo-A), Apolipoprotein-B (Apo-B) und Lipoprotein-A (Lp-A) ($p < 0.001$). Die signifikante Veränderung hatte beim Apo-A, Apo-B und Lp-A auch nach 9 Monaten Bestand ($p < 0.001$).

Schlussfolgerung: Diese Ergebnisse unterstreichen das Potenzial naturheilkundlicher und yogischer Interventionen zur Verbesserung des Lipidprofils von Patienten mit Hypertonie und leisten so einen Beitrag zur aktuellen Literatur. In Kombination mit konventioneller Patientenversorgung könnten diese spezifischen Interventionen als sicherere Form der Komplementärtherapie zur Behandlung der Dyslipidämie bei Hypertoniepatienten in

Betracht gezogen werden. Diese Ergebnisse sind somit vielversprechend im Hinblick auf die Integration naturheilkundlicher und yogischer Therapien in die Standardversorgung von Patienten mit Hypertonie.

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Introduction

Hypertension is one of the main risk factors for the development of cardiovascular diseases (CVDs). It was described as having a systolic blood pressure (BP) of at least 140 mm Hg or a diastolic BP of at least 90 mm Hg, or as being currently using antihypertensive medication [1]. Hypertension is a pressing issue in public health that demands further research. In India, hypertension and cardiovascular mortality rates are alarmingly high [2]. Affecting nearly 30% of the population [3], high BP is responsible for approximately 9.4 million deaths worldwide annually, accounting for at least 45% of heart disease deaths and 51% of stroke deaths [4]. It is projected that by 2025, hypertension will have increased by 15%, reaching nearly 1.5 billion people [5]. In South Asia, high BP is the third most significant risk factor for disease burden was more in urban population of 33.82% [6].

Increased BP is prevalent in both urban and rural populations in India, with up to 37.6% of individuals affected in North Karnataka and 43.3% affected in coastal Karnataka [7]. Men have a higher prevalence of hypertension than women in both regions [8]. Epidemiological studies have shown that hypertension and dyslipidemia are linked [9], with common pathophysiological etiologies, such as obesity and the dysregulation of adipocytokine release from adipose tissue [10]. Therefore, lowering serum cholesterol levels is a primary strategy for preventing and treating CVDs [11].

Various lifestyle factors such as stress, smoking, alcohol consumption, excess weight, and dietary issues contribute to a significant portion of the worldwide disease burden, either directly or indirectly, through illnesses like high BP and raised blood cholesterol levels [12]. Promoting a healthy lifestyle and long-term BP control from a young age can have enormous cost-effective benefits, particularly in low- and middle-income countries like India [13]. Natural dyslipidemia therapies such as bodyweight reduction and regular exercise are vital in regulating BP and cholesterol levels, thus reducing the risk of high-risk cardiovascular illnesses [14], particularly coronary heart disease [15]. Therapeutic lifestyle changes should be the primary treatment for decreasing cholesterol levels, with conventional treatment reserved only for when lifestyle changes fail [16].

Complementary and alternative medicine is gaining greater awareness, with the potential to play a role in the

prevention and management of lifestyle disorders [17]. Naturopathy is a drugless system that believes in the body's self-healing capability through panchamahabhutas, which are earth (Prithvi), water (Ap), fire (Tej), air (Vayu), and space (Akash) and primarily focuses on the restoration and prevention of various illnesses through lifestyle modifications [18]. It consists of various therapeutic modalities such as hydrotherapy, mud therapy, manipulative therapy, chromotherapy, magnetotherapy, diet and fasting therapy, and physical therapy [19].

Studies have shown that naturopathy and yogic lifestyle modifications can effectively treat hypertension, and benefits can be sustained by following the same principles and various therapies used in naturopathy and yoga [20]. Physical activity [21], salt reduction [22], and yoga are also effective in preventing and controlling hypertension in young adults [23]. Regular physical activity, lowering sodium intake, potassium supplementation, a balanced diet, and dietary fiber are effective in treating CVDs [24]. Integrated naturopathy and yoga treatments have a considerable impact on BP control in hypertensive patients [25] and have lowered the total demand for antihypertensive drugs in a relatively short period [26, 27]. However, a literature search and review revealed that there is currently no evidence of the effect of combined naturopathy and yogic interventions on lipid profile among hypertensive individuals. This is a secondary analysis of a previous randomized controlled trial assessing the effect of yoga and naturopathy interventions on heart rate variability in people with hypertension [28]. So, the present study was planned to assess the effect of integrated naturopathy and yogic interventions on lipid profile on hypertensive individuals with long-term follow-up.

Materials and Methods

Study Design and Setting

The present study used parallel groups and was prospectively randomized. The study participants were recruited from the SDM Yoga and Nature Cure Hospital from the southern part of India between February 2020 and March 2022, as depicted in Fig. 1.

Participants

After participants were screened for eligibility, those who met the requirements were provided with an information sheet outlining the purpose and nature of the study. Each participant signed an informed consent form indicating their desire to take part in the study. The objective of this study was to evaluate the effectiveness of an integrated approach using naturopathy and yoga treatments on lipid profiles among hypertensive individuals. Among the 1,500 patients screened, 400 were

recruited for the study as they met the eligibility criteria. From the 262 participants, two groups were formed by randomization, the SIG with 131 individuals and the CG with 131 individuals. However, 20 participants from the SG and 6 from the CG were excluded from the final analysis due to noncompliance with the treatment and follow-up. The study was conducted between February 2020 and February 2022. All the participants of this present study were the same with the previous study of yoga and naturopathy interventions on hypertensive individuals [28].

Inclusion and Exclusion Criteria

If a participant satisfied the following inclusion requirements, they were eligible: male and female hypertension patients between the ages of 25 and 60 who have BP that is at least 130/90 mm Hg or who are receiving antihypertensive medication. Among the exclusion standards were individuals with thyroid abnormalities and documented acute illness, patients with uncontrolled hypertension, and those reporting secondary hypertension.

Sample Size

The sample size is calculated by using G*power 3.19 for assumption of repeated measures analysis of variance for within- and between-group interactions, considering a 1:1 allotment ratio for a parallel arm design at 80% power ($1 - \beta$), with 5% level of significance (α), and expecting mild magnitude of change to effect size $f(\nu) = 0.25$ with 2 tailed hypothesis, the total sample size was found to be 196. For a 25% anticipated attrition rate, the total sample size was multiplied by a factor value of 1.33, and the obtained number is 261 which is rounded to 262 (131 per group).

Randomization

A block randomization procedure with different block lengths was used to achieve randomization. Randomization was done using computed generated random numbers. The study coordinator will inform the study statistician when the subsequent group is prepared for randomization, provided that each participant in a possible treatment group has finished the baseline evaluation. The treatment coordinator will then be informed by the statistician of the group's randomization.

Blinding

In this study, we implemented a partially blinded design where the statistician, assessors, and therapists were blinded to the treatment allocation to minimize bias. However, patients were informed about the treatment they were receiving, allowing us to evaluate outcomes, while maintaining rigor in data analysis and assessment procedures.

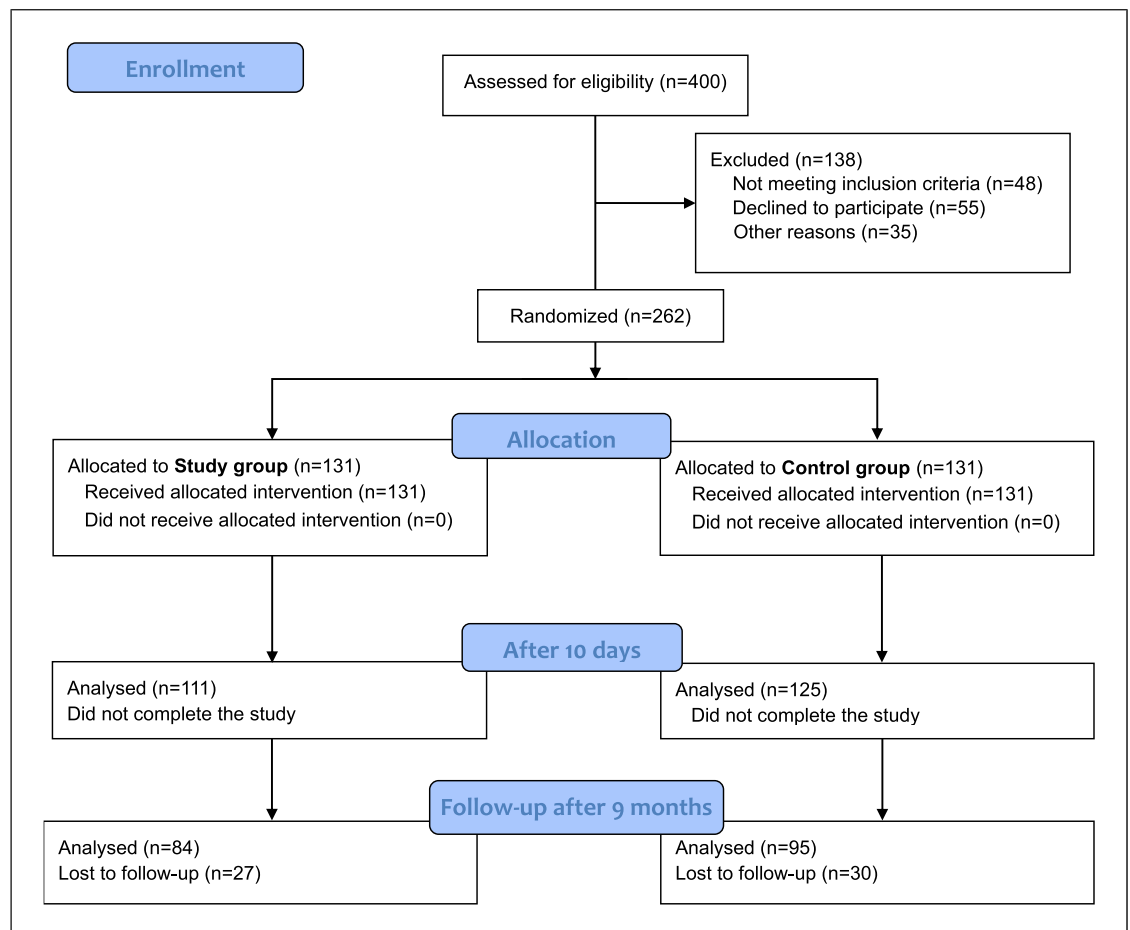


Fig. 1. CONSORT flowchart of the study.

Interventions

Upon admittance, a licensed medical professional evaluated each patient, and a treatment card was used to record the specifics of their clinical care. Given the predicted considerable changes in lifestyle, BP was measured twice a day. Three years were spent doing the study.

SG

From 5:30 am to 9:00 pm, patients underwent various yoga and naturopathy procedures. The frequency of each treatment is detailed in online supplementary Table 1 (for all online suppl. material, see <https://doi.org/10.1159/000543024>), which shows that all participants had received 10 days of integrated yoga and naturopathy treatments. All patients will find mild yoga regimens comfortable, as they were created with age differences in mind. By taking into account the DASH diet's guidelines, 2,000 calories of food were provided [29]. Once the 10-day intervention was over, the patients were instructed to incorporate yoga and naturopathy into their daily routines.

Online supplementary Table 2 displays the follow-up instructions that were provided at the time of discharge.

Control Group

For 10 days, there were no yoga or naturopathic treatments given to any of the subjects; they were only given their regular prescription medication.

Assessments

Extended Lipid Profile

The serum total lipid profile, including total cholesterol (TC), triglycerides (TG), high-density cholesterol (HDL-C) by enzymatic method, low-density lipoprotein cholesterol (LDL-C), very low-density lipoprotein (VLDL) by direct method, apolipoproteins-A1 (Apo-A1), apolipoprotein-B (Apo-B), and lipoprotein(a) by immunoturbidimetry, were estimated. Under aseptic conditions, 4 mL blood sample was collected 8 h after last meal in a sterile vacutainer by venepuncture and were calculated at the Mediquest healthcare facility, which holds National Accreditation Board for Testing and Calibration Laboratories accreditation.

Table 1. Change in lipid profile before (baseline), after (post), and follow-up of yoga and naturopathy interventions with control and study groups

Variables	Study group		Control group		Between-group (post)		Between-group (follow-up)	
	baseline (n = 111)	post (10th day) (n = 111)	follow-up (9 months) (n = 84)	baseline (n = 125)	post (10th day) (n = 125)	follow-up (9 months) (n = 95)	z or F	p value
TC, mg/dL	200.17±34.84	173.31±34.4***	200.96±33.66	213.9±45.2	215.73±47.06	210.96±52.63	z = 7.09	<0.001
TG, mg/dL	155.24±79.78	88.09±26.78***	162.1±80.13	182.67±111.4	175.8±110.45	195.04±108.29	F = 86.22	<0.001 ^c
LDL, mg/dL	131.9±29.48	117.62±31.55***	130.79±29.63	139.45±42.15	141.6±42.21	133.41±45.92*	z = 4.52	<0.001
HDL, mg/dL	43.62±10.99	39±9.61***	42.88±11.88	48.92±22.77	45.22±11.89	42.15±10.81**	z = 4.56	<0.001
VLDL, mg/dL	31.05±15.96	17.62±5.36***	32.33±16.17	36.36±22.41	29.35±21.94***	37.21±22.35	F = 29.6	<0.001 ^c
TC/HDL	4.8±1.24	4.67±1.3	5.21±2.96	5±1.6	5.05±1.53	5.23±1.48*	z = 1.69	0.09
LDL/HDL	3.17±0.91	3.19±1.13	3.18±0.8	3.23±1.2	3.3±1.16	3.27±1.14	z = 0.56	0.57
Non-HDL, mg/dL	156.55±34.79	134.31±35.75***	158.07±29.87	164.98±49.58	170.51±47.03*	168.81±50.12	z = 6	<0.001
Apo-A	124.09±20.14	103.49±16.17***	113.85±20.56***	120.44±23.68	120.23±22.16	118.57±21.5	z = 6.58	<0.001
Apo-B	95.6±21.65	86.03±22.19***	110.41±22.2***	109.74±30.59	114.75±30.98*	111.88±35.82	F = 58.61	<0.001 ^c
Apo B/A	0.79±0.2	0.87±0.29**	0.98±0.26***	0.94±0.33	0.98±0.32*	0.97±0.35	F = 0.65	0.41 ^c
Lp-A mg/dL	26.4±23.96	30.85±22.77***	27.71±28.33***	19.75±16.02	20.01±17.3	21.21±23.16	z = 3.86	<0.001
TC, total cholesterol; TG, triglycerides; LDL, low-density lipoprotein; HDL, high-density lipoprotein; VLDL, very low-density lipoprotein; Apo-A, apolipoprotein-A; Apo-B, apolipoprotein-B; Lp-A, lipoprotein-a. *p < 0.05, **p < 0.01, ***p < 0.001. ^c Analysis of covariance.								

Data Analysis

The Statistical Package for the Social Sciences (SPSS) version 21 was used for all statistical analysis. The Shapiro-Wilk test was used to assess the normality of the distribution for all data that were reported as mean standard deviation. Since the data were not regularly distributed, non-parametric tests were used. The analysis of covariance model was used to analyze due to the baseline difference, and descriptive characteristics were provided as numbers and percentages. The demographics were compared using the chi-square test, between-group data were compared using the Mann-Whitney U test, and within-group comparisons were compared using the Wilcoxon signed-ranked test. Statistical significance was defined as a *p* value of <0.05.

Results

In the yoga and naturopathy intervention group, the mean age was 50.09 ± 8.57 , while in the control group, it was 51.63 ± 7.83 . Additionally, 57.5% of subjects in the intervention group were male, and 42.4% were female, whereas in the control group, it was 58.8% male and 41.13% female.

The results showed a significant reduction in TC, TG, HDL-C, LDL-C, VLDL, non-HDL, Apo-A1, Apo-B, Lp-A, TC/HDL, and Apo-B/A ratio with a *p* value <0.001 in the SG compared to the CG after 10 days, as presented in Table 1. After 9 months of follow-up, a significant reduction (*p* < 0.001) was observed in Apo-A1, Apo-B, and Lp-A, with no significant difference was noted in rest of the parameters in the SG compared to the control group as shown in Table 1.

Discussion

The aim of the study was to assess the combined approach of naturopathy and yoga treatments in managing lipid profiles in hypertensive patients. Lipid metabolism disorders may result from either the overproduction or deficiency of lipoproteins, and they may be primary or secondary. These conditions are collectively known as dyslipidemia, and they are frequently observed in patients with a variety of environmental and genetic factors, including dietary habits, lifestyle, health problems, and medication use [30]. The present study shows a significant decrease in lipid parameters after 10 days of yoga and naturopathy interventions compared to the control group, which with notable change even after 9 months of follow-up after the intervention.

Naturopathy and yoga therapies are two effective non-pharmacological methods for correcting serum

lipid profiles, curing dyslipidemia, and preventing further complications, such as stroke. They are drug-free and have no adverse side effects. Naturopathic approaches include hydrotherapy, diet therapy, and yoga practice [31]. These therapies not only aim to treat the pathological condition but also seek to eliminate the underlying cause and cure the individual.

There was a notable decrease in LDL after 10 days of intervention, which was substantiated with the literature showing that a 90-day hydrotherapy intervention, the subjects' whole bodies were immersed in water, gradually cooled from 22 to 14°C, for a duration that increased from 5 to 20 min. After this period, a decrease in plasma catecholamines was observed, which regulate lipid and lipoprotein metabolism in humans [32]. Increased sympathetic outflow leads to an increase in catecholamine-induced caloric utilization, which influences serum cholesterol concentrations. Cold exposure and initial catecholamine increase are thought to shift substrate utilization towards fatty acid metabolism. The studies have also shown that thyroid hormone signaling elevates LDL receptors, leading to the elimination of LDL particles [33].

Total cholesterol and TGs were collectively decreased after 10 days may be due to the diet given during the 10 days. Dietary interventions in naturopathy play a significant role in regulating metabolism. A high-fiber, low-carbohydrate diet helps to improve serum lipid profiles and lower blood cholesterol levels [34]. Higher fiber diets, which contain less fat and cholesterol, indirectly lower serum lipid levels [35]. Reducing carbohydrates during diet therapy results in weight loss, which lowers TGs and LDL cholesterol. However, restricting carbohydrates can increase the production of VLDL, leading to an increase in LDL cholesterol [36]. Additionally, a low-fat diet may cause a reduction in HDL levels [37]. There was also a significant decrease in VLDL and increase in non-HDL noted in the control group and the reason is unknown; it may be due to more distributed data with high standard deviation.

Also, the mind-body intervention called yoga was advised and properly trained for the participants during the 10 days for the correct practice during the follow-up period by a professional yoga and naturopathy doctor had helped in managing the lipid metabolism. Yoga interventions at the cellular level increase hepatic lipase and lipoprotein lipase, which affect the metabolism of lipoprotein and consequently increase the uptake of triglycerides by adipose tissues [38]. The improvement in lipid profiles after yoga may be due to the hydrolysis of TG-rich lipoproteins, which are replaced by intramuscular fat utilized during yoga and pranayama exercises.

In our recent study, those who have undergone yoga and naturopathy interventions showed improvements sympathovagal balance toward parasympathetic activity [28], and in the present study, yoga and naturopathy have shown to improve lipid profile, and it suggests that yoga and naturopathy will not only improve lipid profile but also improves autonomic function in people with hypertension.

More dropouts were noted because of the data collection was affected during the COVID-19 pandemic was considered as one of the potential limitations of the study, sample size was not calculated using any previous study. As the results here have shown that integrated naturopathic and yogic interventions given were effective in treating dyslipidemia among hypertensive individuals, we can conclude that this alternative therapy is considered as one of the modalities to regulate lipid profile and prevent complications from altered lipid profile in hypertensive individuals.

Conclusion

It can be concluded that a combination of naturopathy and yoga modality is beneficial and hence can be used as an efficient complementary approach to improve lipid profile values in hypertensive patients. The results of the study showed that it is a safe, easier, and effective method to reduce cholesterol levels without any side effects on hypertension, but further study needs to be conducted with longer duration.

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Statement of Ethics

The SDM College of Naturopathy and Yogic Sciences Institutional Review Board in Ujire, India, gave its approval to the procedure Approval No. [EC-214]. A document describing the study's purpose and intervention was distributed to participants who met the qualifying requirements. Every participant's written informed consent to participate in the study was obtained from the participant's desire to take part in the study in accordance with the World Medical Association Declaration of Helsinki.

Conflict of Interest Statement

The authors have no conflicts of interest to declare.

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Author Contributions

Conceptualization: P.S.; methodology, software, validation, formal analysis: S.K.J. and M.A.; writing – original draft preparation: S.K.J., N.N.S., and M.A.; writing – review and editing: J.K.J., A.V.P., and S.K.J.; and supervision and project administration: P.S. All authors have read and agreed to the published version of the manuscript.

Data Availability Statement

Some or all datasets generated during and/or analyzed during the current study are not publicly available but are available from the corresponding author on reasonable request.

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