ISSN No: 0976-5921

Research Article

Efficacy of Add-on *Ayurveda* Treatment Protocol in the Management of Subclinical Hypothyroidism: A Pilot Randomized Controlled Clinical Trial

Anamika[1], Suketha Kumari[2*], Bawadkar Prasad[3], Dhulappa Mehatre[4]

1. Department of Kayachikitsa, Sanskriti Ayurvedic Medical College & Hospital, Chhata, Mathura (281401), Uttar Pradesh, India.
2. Department of Kayachikitsa, KAHER's Shri BM Kankanawadi Ayurveda Mahavidyalaya, Belagavi (590003), Karnataka, India.
3. Department of Kayachikitsa, KAHER's Shri BM Kankanawadi Ayurveda Mahavidyalaya, Belagavi (590003), Karnataka, India.
4. Professor and HOD Dept of Dravya Guna, N K Jabshetty Ayurvedic Medical College and PG Center Bidar Karnataka. India.

Received: 18-03–2025 Accepted: 07-09-2025 Published: 30-09-2025

Abstract

Background: Subclinical hypothyroidism, a common endocrine disorder characterised by elevated serum thyroid-stimulating hormone (TSH) levels while maintaining normal free thyroid hormone levels. While levothyroxine remains the standard treatment, it can sometimes lead to adverse effects. This randomized controlled trial evaluated the efficacy of Integrative Ayurveda Treatment Protocol (IATP), including dietary modifications, *yoga* and the polyherbal formulation *Shiva gutika*, alongside conventional therapy in managing Subclinical Hypothyroidism. Methods: Thirty patients of subclinical hypothyroidism (TSH: 5 to 50 mIU/L) aged 18–60 years were randomly assigned to the Standard Treatment Protocol for Subclinical Hypothyroidism (STP) and IATP groups. The STP received standard levothyroxine treatment along with dietary and lifestyle guidance, while the IATP group followed an add-on protocol including *Ayurveda* protocol, which includes polyherbal combination *shiva gutika*, *ayurveda* diet and *yoga* along with add-on conventional medicine. Outcomes were assessed using serum TSH, T3 and T4 levels on 0th and 60th day and anthropometric measures, ZULEWSKI score and WHO quality of life BREF on 0th , 30th and 60th day. Statistical analyses were performed using SPSS v25, with $p<0.05$ considered significant. Results: The IATP group exhibited significant reductions in serum TSH levels ($p<0.0001$) compared to the STP group. Improvements were also observed in IATP group in ZULEWSKI scores ($p<0.0001$). Anthropometric measures, weight, BMI and WHOQOL-BREF scores showed favorable trends within the IATP group, with marked quality-of-life improvements by day 60 ($p<0.007$). No adverse events were reported. Conclusion: The Integrative *Ayurveda* treatment protocol demonstrated enhanced efficacy in managing subclinical hypothyroidism when compared to conventional therapy alone, highlighting its potential as a safe and effective adjunct. Larger studies are recommended to validate these findings.

Keywords: Subclinical Hypothyroidism, *Shiva Gutika, Yoga*, Dietary Intervention, Serum TSH, Integrative Medicine

Access this article online

Website: https://ijam.co.in

DOI: https://doi.org/10.47552/ijam.v16i3.5957

Introduction

Hypothyroidism refers to insufficient production of thyroid hormones by the thyroid gland and can be categorised as either primary, due to dysfunction within the gland itself, or secondary/ central, resulting from disorders that affect the hypothalamus or pituitary gland. The term "Subclinical Hypothyroidism" describes a mild form of primary hypothyroidism, characterised by elevated thyroid-stimulating hormone (TSH) levels while serum free thyroxine (T4) and triiodothyronine (T3) levels remain in the normal range (1). Subclinical hypothyroidism is usually asymptomatic. However in some cases it may present with symptoms of hypothyroidism which include fatigue, weight gain, lethargy and cold intolerance, though these symptoms are non-specific (2,3). The prevalence of subclinical hypothyroidism ranges between 3% and 15%, depending on the characteristics of the study population (3). Epidemiological studies stated that subclinical hypothyroidism is more prevalent among older adults and women, affecting 8% of the women's population compared to 3% of men's (4,5). Though subclinical hypothyroidism is more prevalent in females, it is well established that the prevalence of hypothyroidism increases after pregnancy and during the postpartum period, as stated by the American Thyroid Association. The annual progression rate of subclinical hypothyroidism to overt hypothyroidism ranges from 2% to 6% (3). Hypothyroidism can lead to a wide range of cardiovascular complications, including reduced cardiac output, increased systemic vascular resistance, diminished arterial compliance, and the development of atherosclerosis. Furthermore, additional factors such as impaired relaxation of cardiac muscle, a lower heart rate, and

*** Corresponding Author:**
Suketha Kumari
Department of Kayachikitsa,
KAHER's Shri BM Kankanawadi Ayurveda Mahavidyalaya,
Belagavi (590003), Karnataka, India
Email Id: sukethashetty411@gmail.com

decreased stroke volume may collectively contribute to an increased risk of heart failure in individuals affected by hypothyroidism (6). Furthermore, subclinical hypothyroidism has been linked to ischemic heart disease and a higher risk of cardiovascular mortality (7). The standard course of treatment for thyroid hormone replacement is levothyroxine-based (8). Long-term use and excessive dosing of levothyroxine can lead to various symptoms and conditions including angina pectoris, tachycardia, arrhythmia, myocardial infarction, anxiety, insomnia, weight loss, fatigue, diarrhea, vomiting, skin rashes, menstrual irregularities and decreased bone mineral density (osteoporosis) (9,10). Hence, a safer alternative medical system or the supplementary effect of other therapeutic methods alongside conventional medicine is necessary for effectively managing the condition. So, this study is carried out which include polyherbal medication, i.e., dietary modification, yogic intervention and *Shiva gutika* along with conventional medication. *Shiva gutika i*s an esteemed herbal-mineral preparation described as a beneficial *Rasayana* (immunomodulatory) in the classical *Ayurvedic* texts and is a rich source of antioxidants, which can help reduce oxidative stress in the body. This can lead to improved health of organs and tissues and subsequently enhance metabolic processes (11). A previous study shows that *yoga* has a good impact on hypothyroidism (12). Dietary intervention shows potential in reversing this hypometabolism at the tissue level, consequently leading to the normalization of thyroid stimulating hormone (TSH) through feedback mechanisms (13). This study is designed to evaluate the efficacy of Integrated *Ayurveda* treatment protocol with the primary objective of to assess the effectiveness of the Integrated *Ayurveda* therapy plan for subclinical hypothyroidism along with secondary objective of to compare the effectiveness of the entire conventional standard treatment regimen for subclinical hypothyroidism and quality of life with the additive effect of the *Ayurveda* treatment protocol.

Material and Methods

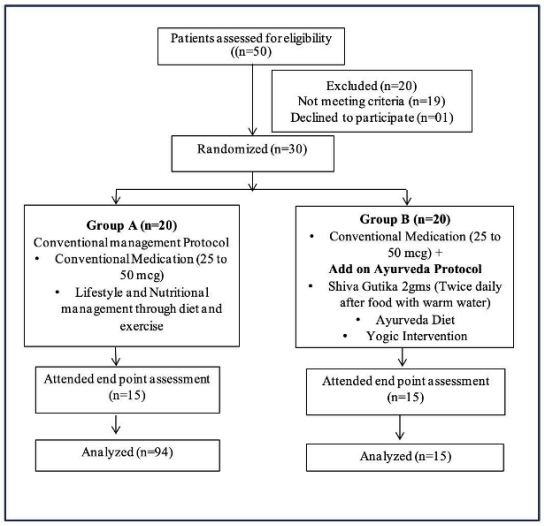
Participants

A randomized controlled pilot clinical trial was carried out involving 30 participants diagnosed with subclinical hypothyroidism, with serum TSH levels ranging from 5 to 50 mU/L. The study included individuals of any gender aged between 18 and 60 years. All participants were already receiving standard medication with dosages between 25 mcg and 50 mcg. Exclusion criteria included those with drug-induced or immune-mediated hypothyroidism, individuals with goitre (enlarged thyroid gland) and those suffering from systemic diseases such as tuberculosis or central nervous system disorders like encephalopathy. Additionally, participants with significant health issues such as cardiac conditions, renal failure, as well as pregnant or nursing women, were not included in the study. The ethical committee at KAHER approved this research involving human subjects under Protocol No. (BMK/20/PG/KC/1), dated July 30, 2021 and CTRI No. (CTRI/2022/03/041010). Participants were recruited from the outpatient and inpatient departments of KLE's Ayurveda Hospital in Belagavi between January 2022 and June 2023.

Research Design

The study was a pilot randomized controlled clinical trial that utilized a block randomization allocation process with 15 blocks, each containing two participants. Patients were divided into control and intervention groups in a 1:1 ratio. The principal investigator oversaw the creation of the random sequence online and ensured that the allocation concealment was achieved through the sealing of opaque envelopes, both of which were blinded [fig.01]. Adherence to medication, *yoga* and *ayurveda* diet was monitored utilizing unused adherence diaries, with follow-up assessments completed every 30 days. The study sought to ensure confidentiality and efficiency in treatment assignments. At each evaluation time point, the investigators assessed the outcome factors. A convenient sample size of 15 patients per group was selected considering the challenges in patient recruitment during the COVID-19 pandemic, this sample size was deemed practical for the study. However, due to the limited sample size, no formal statistical power calculation was performed.

Fig.01: Subject flowchart through the study



Intervention

Patients meeting inclusion criteria of the study for Subclinical Hypothyroidism with suboptimal response to stable levothyroxine therapy were recruited for the study and randomly assigned to two groups: Group A (Control) received Standard Thyroid Treatment Protocol (STTP), which comprised modern allopathic management using levothyroxine along with standard dietary and lifestyle guidance. Group B (Trial) had Integrated Ayurveda Treatment Protocol (IATP). IATP on the other hand, intervened with polyherbal formulation *Shiva Gutika*, *ayurveda* diet and *yoga* in addition to conventional therapy for a duration of 60 days.

The suggested dietary guidance for STTP emphasizes a diet rich in selenium, iodine, zinc and iron which includes foods like meat, fish, eggs, dark leafy vegetables, nuts, seafood and dairy products (14). Lifestyle recommendations included maintaining a regular sleep schedule, engaging in moderate exercise and managing stress through meditation (15).

In the IATP group, patients received conventional medicine with an add-on intervention of *Ayurveda* polyherbal formulation *Shiva Gutika*. The formulation was administered at a dosage of 2 grams twice daily, taken after meals with water. The selection of *Shiva Gutika* was based on classical reference as mentioned in the *Ayurveda* text *Bhaishajya Ratnavali (16)*. To ensure the quality and standardization of the formulation, it was procured from a GMP-certified *Ayurvedic* pharmacy, the Sadvaidyasala Pvt. Ltd. Nanjangud, Karnataka. This procurement included a comprehensive analysis certificate, which confirmed its physical and microbiological characteristics along with key test parameters including loss on drying, total ash content, acid-insoluble ash and the solubility of both alcohol- and water-extractable compounds. **[Table 1].**

Table 1: Botanical Details of Ingredients in *Shiva Gutika*

S.No	Sanskrit Name	Botanical Name (Author)	Family	Part Used	Quantity
1	***Haritaki***	*Terminalia chebula* Retz.	Combretaceae	Fruit	1 part
2	***Vibhitaki***	*Terminalia bellirica* Roxb.	Combretaceae	Fruit	1 part
3	***Amalaki***	*Phyllanthus emblica* L.	Phyllanthaceae	Fruit	1 part
4	***Bilva***	*Aegle marmelos* (L.) Corrêa	Rutaceae	Fruit, root, bark,	180 mg
5	***Agnimantha***	*Premna serratifolia* L.	Lamiaceae	Root, leaf,	1 part
6	***Shyonaka***	*Oroxylum indicum* (L.) Kurz	Bignoniaceae	Root bark	1 part
7	***Patala***	*Stereospermum suaveolens* DC.	Bignoniaceae	Root bark	1 part
8	***Gambhari***	*Gmelina arborea* Roxb.	Verbenaceae	Root, bark, fruit,	1 part
9	***Shaliparni***	*Desmodium gangeticum* (L.)	Fabaceae	Root, Panchanga	1 part
10	***Prishniparni***	*Uraria picta* Desv.	Fabaceae	Root, Panchanga	1 part
11	***Kantakari***	*Solanum xanthocarpum* Schrad. & Wendl.	Solanaceae	Root, Panchanga	1 part
12	***Brihati***	*Solanum indicum* L.	Solanaceae	Root, Panchanga	1 part
13	***Gokshura***	*Tribulus terrestris* L.	Zygophyllaceae	Root, Fruit	1 part
14	***Guduchi***	*Tinospora cordifolia* (Willd.)	Menispermaceae	Panchanga	60 mg
15	***Patola***	*Trichosanthes dioica* Roxb.	Cucurbitaceae	Panchanga	60 mg
16	***Gomutra***	–	–	Cow urine	60 ml
17	***Madhuyashti***	*Glycyrrhiza glabra* L.	Fabaceae	Root	60 mg
18	***Godugdha***	–	–	Cow milk	60 ml
19	***Draksha***	*Vitis vinifera* L.	Vitaceae	Fruit	60 mg
20	***Shatavari***	*Asparagus racemosus* Willd.	Asparagaceae	Root tuber	80 mg
21	***Vidarikanda***	*Pueraria tuberosa* DC.	Fabaceae	Tuber	80 mg
22	***Varahikanda***	*Dioscorea bulbifera* L.	Dioscoreaceae	Tuber	80 mg
23	***Pushkaramoola***	*Inula racemosa* Hook.f.	Asteraceae	Root	80 mg
24	***Kutaja***	*Holarrhena pubescens* Wall. ex	Apocynaceae	Bark, Seed	80 mg
25	***Karkatashrungi***	*Pistacia integerrima* J.L. Stewart ex Brandis	Anacardiaceae	Gall	80 mg
26	***Katuki***	*Picrorhiza kurroa* Royle ex	Plantaginaceae	Root	80 mg
27	***Rasna***	*Pluchea lanceolata* (DC.)	Asteraceae	Rhizome, Leaf	80 mg
28	***Nagarmotha***	*Cyperus rotundus* L.	Cyperaceae	Tuber	80 mg
29	***Lajjalu***	*Mimosa pudica* L.	Fabaceae	Root	80 mg
30	***Danti***	*Baliospermum*	Euphorbiaceae	Root, Seed, Leaf	80 mg
31	***Chitraka***	*Plumbago zeylanica* L.	Plumbaginaceae	Root, Fruit	80 mg
32	***Gajapippali***	*Piper chaba* Hunter	Piperaceae	Fruit	80 mg
33	***Jeevaka***	*Malaxis acuminata* D.Don	Orchidaceae	Tuber	80 mg
34	***Vrishabhaka***	*Malaxis muscifera* (Lindl.)	Orchidaceae	Tuber	80 mg
35	***Meda***	*Polygonatum*	Asparagaceae	Tuber	80 mg
36	***Mahameda***	*Polygonatum verticillatum* (L.)	Asparagaceae	Tuber	80 mg
37	***Kakoli***	*Fritillaria roylei* Hook.f.	Liliaceae	Tuber	80 mg
38	***Ksheerakakoli***	*Lilium polyphyllum* D.Don	Liliaceae	Tuber	80 mg
39	***Vriddhi***	*Habenaria intermedia* D.Don	Orchidaceae	Tuber	80 mg
40	***Riddhi***	*Habenaria edgeworthii* Hook.f.	Orchidaceae	Tuber	80 mg
41	***Musali***	*Chlorophytum borivilianum* Santapau &	Asparagaceae	Tuberous root	80 mg
42	***Meshashringi***	*Gymnema sylvestre* (Retz.)	Apocynaceae	Leaf	16 mg
43	***Shunthi***	*Zingiber officinale* Roscoe	Zingiberaceae	Rhizome	16 mg
44	***Pippali***	*Piper longum* L.	Piperaceae	Fruit	16 mg
45	***Maricha***	*Piper nigrum* L.	Piperaceae	Fruit	16 mg
46	***Talisa***	*Abies webbiana* Lindl.	Pinaceae	Bark	36 mg
47	***Tila***	*Sesamum indicum* L.	Pedaliaceae	Seed, Oil	2 parts
48	***Madhu***	–	–	Honey	60 mg
49	***Sharkara***	–	–	Sugar	120 mg
50	***Vamshalochana***	*Bambusa arundinacea* Willd.	Poaceae	Siliceous exudate	4 mg

51	***Tejapatra***	*Cinnamomum tamala* (Buch.-Ham.) Nees & Eberm.	Lauraceae	Leaf	4 mg
52	***Nagakesara***	*Mesua ferrea* L.	Calophyllaceae	Stamens	4 mg
53	***Ela***	*Elettaria cardamomum* (L.)	Zingiberaceae	Seed	4 mg
54	***Shilajatu***	*Asphaltum punjabianum*	–	Mineral Resin	120 mg

The *Ayurveda* dietary plan was planned after a comprehensive review of existing literature. The recommended diet emphasizes nutrient-dense foods that are integrated with *Ayurveda* principles. This plan focuses on balancing the *Kapha dosha*, enhancing *Agni* (digestive fire) and metabolism and providing essential micronutrients, such as iodine and selenium, to support the body's *dhatus* (tissues) while offering immunomodulatory, anti-inflammatory and antioxidant benefits that promote optimal thyroid health (17-19). This consists meals spread out the day, therapeutic eating, herbal processed drinks and millet-based meals. The details of the overall diet plan are outlined in the table. [**Table 2].**

Table 2 : *Ayurveda* dietary plan

Timing diary	Menu Items
Breakfast (b/w 8 am – 9 am)	Millet Upma (nutritious dish made with millets, vegetables and spices), Herbal Tea (Made with *Sunthi* – Ginger)
Post-Breakfast (b/w 9 am – 10 am)	*Haridra* Milk (Milk mixed with turmeric powder) 100 ml
Lunch (b/w 11 am – 1 pm)	Ragi Roti (Finger millet) / Jowar Roti (Sorghum) with Dry or Green Chili Chutney with 1 bowl of properly cooked vegetable
Post-Lunch (b/w 1 pm – 2 pm)	*Takra* (Buttermilk) with added *Trikatu* churna (a combination of medicinal spices *Marich (Black pepper), Pippali (Long Pepper) and Shunthi (Dry Ginger)*- 1 glass (150 ml)
Evening Drink (b/w 5 pm – 6 pm)	Herbal Tea (Made with *Sunthi* – Ginger)
Dinner (b/w 8 pm – 9 pm)	Whole Wheat Chapati / Ragi Roti (Finger millet)/ Jowar Roti (Sorghum) with Curd OR 1 bowl of properly cooked vegetable OR Sambar – 1 bowl
Dinner Alternative (b/w 8 pm – 9 pm)	Turmeric Millet Rice (Rice made using millets and turmeric powder) OR Mung Dal Khichadi with Mung Soup – 1 bowl
Post-Dinner (b/w 9 pm – 10 pm)	*Panchakola Peya* (herbal drink made from five (*Pancha*) medicinal spices)– 100 ml

The Systemic *Yoga* plan was created after a comprehensive review of the current literature on *yoga* science, incorporating insights from *yoga* therapists. The plan includes specific practices designed to improve glandular and metabolic function in the body. Certain poses specifically target the thyroid gland, helping to regulate its function and hormonal secretion. This promotes optimal thyroid health and supports overall hormonal balance (20). The overall *yoga* plan is outlined in the table.[**Table 3.]**

Table 3 : Therapeutic Yoga technique with appropriate duration and remarks

Name and duration	Posture	Practices
Yoga exercise or Body loosening exercise (5 min each)	Standing	Padahastasana (hand to foot pose), Ushtrasana (Camel Pose), Ardha chakrasana (half wheel position), Virabhadrasana (Warrior Pose)
	Sitting	Simhasana (Lion Pose)
	Supine	Halasana (Plow Pose), Sarvangasana (Shoulder stand pose)
	Prone	Bhujangasana (Cobra Pose), Dhanurasana (Bow Pose)
Relaxation for 5 min	-	Instant relaxation technique
Pranayama (Breathing Practice) (10 min)	Sitting	Brahmari[Humming bee breath], Nadi Shodhana[Alternate nostril breathing technique], Suryabhedi (Inhale through right nostril and exhale through left nostril), Ujjaii (Ocean breath)
Meditation (20 min)	Sitting	Cyclic meditation

Primary Assessment Criteria:

Serum TSH measured at baseline and 60th day of intervention.

Secondary Assessment Criteria:

T3, T4, Weight, BMI (Body Mass Index), ZULEWSKI score and WHOQOL-BREF. T3, T4 were measured on baseline and 60th day. Weight, BMI, ZULEWSKI score and WHOQOL-BREF were taken at the baseline, 30th and the 60th day.

Statistical Test

For the statistical analysis, IBM Corporation based in Chicago, Illinois, employed SPSS Version 25.0 (IBM Corporation, Chicago, Illinois). Independent t-tests were utilized to compare groups across different time points, while the mann-whitney U test and wilcoxon matched pairs test were implemented to assess values within the same group at a specific moment. A p-value of less than 0.05 was deemed statistically significant, and results are presented as mean ± standard deviation.

Result

A total of 50 patients were assessed for the study. Out of these, 20 patients were excluded:19 did not meet the inclusion criteria and 1 declined to participate. As a result, 30 patients were recruited for the study. There were no dropouts, discontinuations or

withdrawals due to adverse events and no major adverse events were reported throughout the study.

Demographic Profile

The study found that both groups were similar in terms of age (p=0.70), height (p=0.24) and key measurements such as systolic blood pressure (p=0.78) and diastolic blood pressure (p=1.00). The majority of participants in both groups were from urban areas and exhibited a *Vata-Pitta Pradhan Prakriti* (dominant constitution) with 73% and 60% in IATP and STTP respectively. Furthermore, most individuals in both groups were part of the upper-middle socioeconomic class and were married, with ages ranging from 18 to 60 years. In addition, women comprised 93.33% of the patients in both groups, while men accounted for 6.67% **[Table 4.]**

Table 4. : Baseline data

Demographic Profile	STP (n=30)	ITP (n=30)	P value
Mean Age	43.8	43.8	0.7066
Mean Height	155.01	158.57	0.2482
Gender- Male:Female	14:1	14:1	-
Married: Unmarried: divorced: Widowed	15:0:0:0	14:1:0:0	-
Socio-economic status- Upper class : Middle class : Lower class	0:15:0	0:14:1	-
Mean SBP	122.67	123.33	0.7847
Mean DBP	82.00	82.00	1.000

Primary Outcome

Thyroid Profile

The effect of intervention on Serum TSH showed significant difference (p<0.0001) favouring IATP group (P<0.001) with a larger mean percentage change in IATP (75.00%) than STP (4.57%). In IATP, serum TSH level before to after intervention change was 7.12 to 1.78. Impact of intervention on serum T3 level showed comparable outcome (p=0.37), however within the group IATP showed significance (p=0.02). The outcome difference of serum T3 (p=0.07) and T4 (p=0.56) showed no significant change between groups and even within the group no significant changes. **[Table 5]**

Secondary Outcome

Anthropometric Parameters

Weight and BMI

The result of the intervention on weight revealed that there is comparable outcome between the group (p=0.83). However, within the group, IATP showed significance on 60th day (p=0.02). **[Table 5]**

Waist Circumference and Waist-Hip Ratio

Study showed that, interventional impact on waist circumference and waist hip circumference revealed non-significant both between and within the group. **[Table 5]**

ZULEWSKI Score

The Zulewski score is a 12-point clinical tool for assessing hypothyroidism based on symptoms and signs. A higher score indicates a greater probability of hypothyroidism. The outcome of intervention on ZULEWSKI score showed a significant difference (p<0.0001) revealed that IATP had greater improvement. Within the group, both STTP(p=0.005) and IATP(p=0.0007) were significant. **[Table 5]**

WHOQOL-BREF

Study showed that result of intervention on WHOQOL-BREF showed comparable outcome between the group (p=0.49). Within the group, IATP showed significance on 60th day (p=0.007), whereas STTP showed non-significant changes. **[Table 5]**

Statistical tests used:

- **Between-group comparisons** were done using **Independent Student's t-test** for normally distributed variables and **Mann Whitney U test** for non-parametric data.
- **Within-group comparisons** were done using **paired t-test** or **Wilcoxon signed-rank test**, as appropriate.
- All values are expressed as **Mean ± SD**; significance level: $p < 0.05$.
- **t-statistic**, **Wilcoxon values (W)**, **SE** and **df** have been included where applicable

Table 5. : Effect on Outcome variables – Thyroid Profile, Anthropometric measures, ZULEWSKI score and WHO QOL BREF

Parameter	Group	Baseline (Mean ± SD)	60th Day (Mean ± SD)	p-value	Test Used	Test Value	df
Serum TSH	STP	7.16 ± 1.57	6.83 ± 1.48	0.014	Paired t-test	t = 2.67	df = 14
	IATP	7.12 ± 1.99	1.78 ± 1.54	<0.0001	Paired t-test	t = 9.23	df = 14
Serum T3	STP	97.81 ± 19.50	101.2 ± 26.67	0.07	Independent t-test	t = 0.89	df = 28
	IATP	97.71 ± 1.45	92.67 ± 18.36	0.02	Paired t-test	t = 2.45	df = 14
Serum T4	STP	9.06 ± 5.33	9.13 ± 1.12	0.56	Independent t-test	t = 0.59	df = 28
	IATP	8.62 ± 1.47	8.72 ± 1.50	0.38	Paired t-test	t = 0.87	df = 14
Weight	STP	170.71 ± 48.49	162.62 ± 0.71	0.83	Independent t-test	t = 0.21	df = 28
	IATP	173.57 ± 52.50	135.03 ± 9.50	0.02	Paired t-test	t = 2.51	df = 14
BMI	STP	242.64 ± 58.61	227.04 ± 8.14	0.81	Independent t-test	t = 0.25	df = 28
	IATP	243.64 ± 66.85	172.20 ±	0.01	Paired t-test	t = 2.96	df = 14
Waist Circumference	STP	165.62 ± 80.72	-	0.64	Independent t-test	t = 0.47	df = 28
	IATP	182.22 ± 93.83	-	0.61	Independent t-test	t = 0.51	df = 28
Hip Circumference	STP	49.57 ± 6.28	39.00 ± 8.48	<0.001	Paired t-test	t = 4.21	df = 14
	IATP	48.80 ± 7.48	27.53 ± 8.09	<0.001	Paired t-test	t = 5.12	df = 14

Waist to Hip Ratio	STP	56.36 ± 7.84	44.89 ± 9.67	<0.001	Paired t-test	t = 5.03	df = 14
	IATP	50.69 ± 9.86	31.10 ± 8.79	<0.001	Paired t-test	t = 6.03	df = 14
Zulewski Score	STP	7.53 ± 2.45	7.41 ± 1.80	0.005	Wilcoxon signed-rank test	W = 21	-
	IATP	8.26 ± 3.70	7.33 ± 1.36	0.0007	Wilcoxon signed-rank test	W = 9	-
WHOQOL-BREF	STP	8.79 ± 2.38	7.37 ± 2.34	0.21	Wilcoxon signed-rank test	W = 16	-
	IATP	8.58 ± 2.40	5.80 ± 1.81	0.007	Wilcoxon signed-rank test	W = 6	-

Discussion

The study revealed that the trial intervention which consisted of oral medication *Shiva gutika*, *Ayurveda* diet and *Yoga* group showed beneficial effects on serum TSH levels compared to the standard thyroid treatment group. The study group also demonstrated favourable results in the Zulewski score.

Analysis of demographic data indicated that most patients were aged between 40 and 50 years in both groups. While subclinical hypothyroidism can occur at any age, the risk increases with advancing age (21,22). In both groups, the majority of patients were female. Subclinical hypothyroidism is more prevalent in females, with a ratio of 6:1 compared to males (2,22). Furthermore, it is well established that the prevalence of hypothyroidism increases after pregnancy and during the postpartum period, as noted by the American Thyroid Association (23). Most patients were married and belonged to the upper middle class. In both groups, the predominant prakriti was *Vatapitta*, with 73% in the STTP group and 60% in the IATP group. The IATP group (96.47%) demonstrated a higher rate of diet adherence than the control group (91.87%). Similarly, the trial group (93.33%) also exhibited better adherence to *yoga* and exercise than the control group (88.27%).

Shiva Gutika an esteemed poly-herbal formulation is recognized as effective *Rasayana* in traditional *Ayurvedic* literature (24). This preparation contains 54 distinct herbs. The main ingredient *Shilajit* possesses *Rasayana* and *Yogavahi* (bioenhancer) qualities. A few studies stated its anti-inflammatory, analgesic, immune-modulating, and antioxidant properties, making it beneficial for addressing inflammation (25-27). The other components of *Shiva Gutika* aid in balancing *Kapha* and *Vata* doshas. The formulation includes *Piper longum* L., *Plumbago zeylanica* L., *Zingiber officinale* Roscoe. and *Terminalia chebula* Retz., among others, all of which are known to have an appetite-enhancing effect and promote metabolism and energy production helping to alleviate the sluggishness associated with hypothyroidism (28). The phytochemical constituents of *Shiva Gutika* are abundant in antioxidants which help in lowering oxidative stress throughout the body (29). This reduction enhances the health of organs and tissues, thereby improving metabolic functions.

Diet plays a crucial role in managing subclinical hypothyroidism by supporting symptom reduction and weight control. A diet rich in *Katu, Tikta* (bitter and pungent) tastes and possessing *Ushna* (warm), *Teekshna* (penetrating), *Sara* (mobile) and *Rooksha* (dry) qualities helps balance *Kapha dosha*, enhances *agni* (digestive fire) and boosts metabolism. Meals were spread throughout the day to regulate metabolism effectively.

The suggested dietary plan includes millet recipes and ginger tea for breakfast, followed by 100 ml of *turmeric infused* milk afterward. Millet, regarded as a superfood in India, is extensively used in everyday meals and practices. Reviews indicate that millet possesses antioxidant properties (29-30). Ginger is high in zinc, potassium and magnesium, and its anti-inflammatory qualities contribute to improved thyroid function. Turmeric, a widely used spice in Indian cooking is significant since autoimmune disorders are the leading cause of hypothyroidism. Additionally, previous studies have consistently shown that *haridra* has both immunomodulatory and antioxidant effects (31).

Lunch diet includes Ragi (finger millet) Roti or Jowar (sorghum) Roti, which are millet-based flatbreads served with a side of dry or green chili chutney. Millets, such as finger millet offer numerous nutritional benefits as they are rich in essential micronutrients and antioxidants (32,33). They cater to diverse dietary needs, are gluten-free, aid in weight management and enhance digestion and metabolism (34,35). Considering the autoimmune and anti-inflammatory aspects of the disease, buttermilk spiced with Ayurveda herb *trikatu* [a combination of *Marich (Piper Nigrum L.), Pippali (Piper longum* L*) and Shunthi (Zingiber officinale Rosc.*)] was advised after lunch. Both ingredients are known to enhance digestive fire (36) and metabolism. Additionally, buttermilk is a rich source of iodine and selenium (37), while trikatu acts as an immunomodulatory and anti-inflammatory agent (17).

Evening drink of *Shunthi* tea, as it pacifies *kapha* and *vata dosha*. It also improves the digestive fire, thereby helping with metabolism (38). In *Shunthi*, *Zingiberene* is the principal alkaloid of *Zingiber officinale*, decreasing lipid peroxidation and increasing the activity of antioxidant enzymes which in turn stimulate the thyroid gland's normal functioning (18,39). Since wheat is a significant source of selenium, which improves the conversion of T4 into T3, dinners consisting of whole wheat chapati, finger millet roti, or sorghum roti are served with curd raita (19,40). Packed with nutrients, curd is crucial for promoting digestion and supplying the body with the iodine it needs for healthy thyroid function (36). Dinner time alternatives include millet rice with turmeric or mung dal khichadi with mung soup, which are important for human nutrition since they are high in protein and minerals like selenium. Along with these nutrients, mung beans also have bioactive substances with antioxidant qualities, like high concentrations of polyphenols and other metabolites (41). *Panchakola peya* [herbal drink made from five (*Pancha*) medicinal spices—*Pippali (long pepper), Pippalimoola (root of long pepper), Chavya (Java long pepper), Chitraka (Plumbago zeylanica)* and *Shunthi*] was advised post-dinner, as *Panchakola* is considered one of the most effective remedies for treating sluggish digestion, which in turn helps support normal metabolism (29,42). This whole diet plan was designed to support the healthy functioning of the thyroid

Overall health maintenance depends on the neuroendocrine system. Specific practices have been developed to support the

proper functioning of glands and metabolism in the body. As a result, a series of poses has been designed to target the thyroid gland to regulate its function and hormonal secretion. These poses are meant to support the thyroid's role in maintaining the body's hormonal balance and to encourage optimal thyroid health. This pose includes some *Aasanas* and Pranayama; *aasanas* include *Bhujangasana, Padahastana, Halasana, Sarvangasana, Ushtrasana, Dhanurasana, Ardha-chakrasana, Virabhadrasana* and *Simhasana. Bhujangasana, Padahastan* and *Ardha-chakrasana* are *yoga* poses that stretch and stimulate the neck, shoulders and thighs, improving blood flow to the thyroid gland and promoting healthy metabolic function. They also help to overcome lethargy by affecting the solar plexus and throat *chakras*. *Halasana* and *Sarvangasana* are inversion poses that boost blood flow to the head. Applying pressure to the thyroid gland enhances circulation and provides nourishment to support its function. *Ushtrasana* stimulates the *vishuddhi chakra*, activates the thyroid and parathyroid glands in the neck and strengthens the shoulder and thigh muscles. *Dhanurasana* and Simhasana help stretch the thyroid gland, supporting the production of essential thyroid hormones for metabolism regulation. These poses also activate the Vishuddhi Chakra and promote overall thyroid well-being. *Virabhadrasana* strengthens the spinal nerves and supports nervous system balance (20,43). Pranayama practices include *Bhramari*, *Nadi-Shodhana, Suryabhedi* and *Ujjayi*. *Bhramari* calms the mind and supports endocrine health, while *Nadi-Shodhana* balances the nervous system and helps manage stress by stimulating energy channels. *Suryabhedi* is thought to enhance overall bodily functions, and *Ujjayi* aids in thyroid activation and hormone regulation (20,43).

Conclusion

The integrated intervention protocol which includes *Ayurvedic* diet, *Yoga* and *Shiva gutika* demonstrated significant effectiveness in improving thyroid function, as evidenced by a reduction in serum TSH levels and enhanced ZULEWSKI scores. Improvements were also observed in anthropometric measures, particularly mid-thigh circumference, along with trends toward better weight and BMI outcomes. Quality of life assessments (WHOQOL-BREF) indicated marked improvements within the trial group over time. Since there were no documented side effects, the intervention was well-tolerated, demonstrating its safety and potential as a holistic approach for managing thyroid-related and associated parameters.

6. Future Scope of Study

Future studies could explore the molecular mechanisms behind *Ayurveda*-based interventions in thyroid regulation. Additionally large-scale, multi-center clinical trials could help establish standardized protocols for integrating *Ayurveda* with conventional subclinical hypothyroidism treatment.

Abbreviations

TSH, *Thyroid-stimulating hormone*; STTP, Standard thyroid Treatment Protocol; IATP Integrated *Ayurveda* Treatment Protocol; BMI, Body Mass Index; WHOQOL-BREF, World Health Organisation Quality Of Life Brief; SBP, Systolic Blood Pressure; DBP, Diastolic Blood Pressure

Funding

This research did not receive any funding from public, commercial or non-profit organizations.

Conflict of Interest

The authors declare that they have no known financial conflicts of interest or personal relationships that may have affected the research presented in this paper.

Author Contribution

A: Conceptualization, Software, Formal analysis, Investigation, Resources, Data curation, Writing-original draft, Visualization, Supervision. **SK**: Conceptualization, Methodology/study design, Software, Validation, Investigation, Resources, Data curation, Supervision, Writing-review and editing. **BP**: Methodology/study design, Validation, Formal analysis, Investigation, Resources, Data curation, Writing-review and editing.

Acknowledgement

We extend our gratitude to the staff of the Kayachikitsa Department and the consultants at KLE Ayurveda Hospital Belagavi for their support in completing this study.

References

1. Khandelwal D, Tandon N. Overt and subclinical hypothyroidism: who to treat and how. Drugs. 2012 Jan;72(1):17–33.
2. Gosi SY, Garla VV. Subclinical Hypothyroidism. StatPearls [Internet]. 2019. Available from: https://www.ncbi.nlm.nih.gov/books/NBK536970/
3. Peeters RP. Subclinical hypothyroidism. N Engl J Med. 2017 Jun;376(26):2556–65.
4. Han C, He X, Xia X, Li Y, Shi X, Shan Z, et al. Subclinical hypothyroidism and type 2 diabetes: a systematic review and meta-analysis. PLoS One. 2015 Aug;10(8):e0135233.
5. Vanderpump MP, Tunbridge WM, French JM, Appleton D, Bates D, Clark F, et al. The incidence of thyroid disorders in the community: a twenty-year follow-up of the Whickham Survey. Clin Endocrinol (Oxf). 1995 Jul;43(1):55–68.
6. Udovcic M, Pena RH, Patham B, Tabatabai L, Kansara A. Hypothyroidism and the heart. Methodist Debakey Cardiovasc J. 2017;13(2):55–9.
7. Rodondi N, den Elzen WP, Bauer DC, Cappola AR, Razvi S, Walsh JP, et al. Subclinical hypothyroidism and the risk of coronary heart disease and mortality. JAMA. 2010 Sep;304(12):1365–74.
8. Eghtedari B, Correa R. Levothyroxine. StatPearls [Internet]. 2024. Available from: https://www.ncbi.nlm.nih.gov/books/NBK539808/
9. Ochani S, Siddiqui A, Adnan A. Adverse effects of long-term levothyroxine therapy in subclinical hypothyroidism. Ann Med Surg (Lond). 2022;76:103503.
10. Flynn RW, Bonellie SR, Jung RT, MacDonald TM, Morris AD, Leese GP. Serum thyroid-stimulating hormone concentration and morbidity from cardiovascular disease and fractures in patients on long-term thyroxine therapy. J Clin Endocrinol Metab. 2010 Jan;95(1):186–93.
11. Pushpa VH, Jayanthi MK, Patil SM, Ramu R. Pharmacological profile of Shiva Gutika: an uncharted and versatile polyherbal drug. All Life. 2021;14(1):215–9.
12. Singh P, Singh B, Dave R, Udainiya R. The impact of yoga upon female patients suffering from hypothyroidism. Complement Ther Clin Pract. 2011 Aug;17(3):132–4.
13. Das N, Choudhary K, Goswami K. Trikatu Churna in the management of hypothyroidism. J Ayurveda. 2018;6:71–7.
14. Alkhatib D, Shi Z, Ganji V. Dietary patterns and hypothyroidism in U.S. adult population. Nutrients. 2024 Mar;16(3):382.

15. Wu K, Zhou Y, Ke S, Liu X, Li X, Li Y, et al. Lifestyle is associated with thyroid function in subclinical hypothyroidism: a cross-sectional study. BMC Endocr Disord. 2021;21(1):112.
16. Sharma G. Bhaishajya Ratnavali, Rasayan Prakarana, Chapter 73, Verses 151–173. Varanasi: Chaukhambha Prakashan; 2018.
17. Murunikkara V, Rasool M. Trikatu, an herbal compound as immunomodulatory and anti-inflammatory agent in the treatment of rheumatoid arthritis—an experimental study. Cell Immunol. 2014;287(1):62–8.
18. Masuda Y, Kikuzaki H, Hisamoto M, Nakatani N. Antioxidant properties of gingerol-related compounds from ginger. Biofactors. 2004;21(1–4):293–6.
19. Lyons GH, Genc Y, Stangoulis JC, Palmer LT, Graham RD. Selenium distribution in wheat grain, and the effect of postharvest processing on wheat selenium content. Biol Trace Elem Res. 2005;103(2):155–68.
20. Nilkantham S, Majumdar V, Singh A. Scientific yoga module for hypothyroidism: a study protocol for tele-yoga RCT. Contemp Clin Trials Commun. 2023;33:101157.
21. Kim MI. Hypothyroidism in older adults. In: Feingold KR, Anawalt B, Blackman MR, et al., editors. Endotext [Internet]. South Dartmouth (MA): MDText.com, Inc.; 2000–. Updated 2020 Jul 14.
22. Nygaard B. Hypothyroidism (primary). BMJ Clin Evid. 2010 Jan 5;2010:0605.
23. Stagnaro-Green A, Abalovich M, Alexander E, et al. Guidelines of the American Thyroid Association for the diagnosis and management of thyroid disease during pregnancy and postpartum. Thyroid. 2011 Oct;21(10):1081–125.
24. Dwivedy R. Vaidyaprabha Hindi Commentary of Chakrapanidatta on Chakradatta. Rasayanadhikara, Verses 168–177. Varanasi: Choukhamba Sanskriti Bhavan; 1997. p. 428.
25. Ghosal S. Chemistry of shilajit, an immunomodulatory Ayurvedic Rasayan. Pure Appl Chem. 1990;62:1285–8.
26. Ghosal S, Lal J, Singh SK, et al. Mast cell protecting effects of shilajit and its constituents. Phytother Res. 1989;3:249–52.
27. Wilson E, Rajamanickam GV, Dubey GP, et al. Review on shilajit used in traditional Indian medicine. J Ethnopharmacol. 2011;136:1–9.
28. More SD, Dwivedi RR. A clinical study of Panchakola Siddha Yavagu in the management of Agnimandya. Ayu. 2011;32(1):70–5.
29. Liang S, Liang K. Millet grain as a candidate antioxidant food resource: a review. Int J Food Prop. 2019;22(1):1652–61.
30. Jacob J, Krishnan V, Antony C, et al. The nutrition and therapeutic potential of millets: an updated narrative review. Front Nutr. 2024;11:1346869.
31. Fuloria S, Mehta J, Chandel A, et al. A comprehensive review on the therapeutic potential of Curcuma longa Linn. in relation to its major active constituent curcumin. Front Pharmacol. 2022;13:820806.
32. Kar S, Raza A, Khaitan J, Ghosh J. Indian millets (finger millet, kodo, sorghum, and pearl millet): potent functional foods and processing scopes. J Adv Zool. 2023;44(S6):2012–25.
33. Ghosh K, Vinodkumar T, Singh R, et al. Promising potential of millets as the staple of our plate: an Indian perspective. Discov Food. 2024;4:103.
34. Devi PB, Vijayabharathi R, Sathyabama S, et al. Health benefits of finger millet (Eleusine coracana L.) polyphenols and dietary fiber: a review. J Food Sci Technol. 2014;51(6):1021–30.
35. Nirgude R, Binorkar S, Parlikar G, Kirte M. Therapeutic and nutritional values of takra (buttermilk). Int Res J Pharm. 2013;4:29–31.
36. Buttermilk – an overview. ScienceDirect Topics [Internet]. 2019. Available from: https://www.sciencedirect.com/topics/agricultural-and-biological-sciences/buttermilk
37. Rajani A, Vyas MK, Vyas HA. Comparative study of Upavasa and Upavasa with Pachana in the management of Agnisada. Ayu. 2010;31(3):351–4.
38. Ayustaningwarno F, Anjani G, Ayu AM, Fogliano V. A critical review of ginger's (Zingiber officinale) antioxidant, anti-inflammatory, and immunomodulatory activities. Front Nutr. 2024;11:1364836.
39. Ventura M, Melo M, Carrilho F. Selenium and thyroid disease: from pathophysiology to treatment. Int J Endocrinol. 2017;2017:1297658.
40. Ganesan K, Xu B. A critical review on phytochemical profile and health promoting effects of mung bean (Vigna radiata). Food Sci Hum Wellness. 2018;7(1):11–33.
41. Chunekar KC, Pandey GS, editors. Bhavaprakasa Nighantu. 24th ed. Varanasi: Chaukhambha Bharati Academy; 1998.
42. Mishra A, Bentur SA, Thakral S, et al. The use of integrative therapy based on Yoga and Ayurveda in the treatment of a high-risk case of COVID-19/SARS-CoV-2 with multiple comorbidities: a case report. J Med Case Rep. 2021;15(1):95.

*****