Research Article

Indian Journal of Science and Research

Shaikh RAS & Wakle RS., Ind. J. Sci. Res. 2025, 5(4), 141-149

ISSN 2583 – 2913

RANDOMIZED CONTROLLED STUDY OF HOMEOPATHIC MEDICINES AND LIFESTYLE MODIFICATIONS AS ADJUNCT THERAPY IN PATIENTS ON TREATMENT WITH MODERN MEDICINE FOR THYROID DYSFUNCTION

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Abstract: Thyroid dysfunction, particularly hypothyroidism, is a regularly encountered hormonal imbalance that can markedly diminish quality of life. Despite conventional levothyroxine therapy, many patients continue to report unresolved symptoms. Integrative approaches, especially the combination of individualized homeopathic medicines and targeted lifestyle modifications, have shown promise as adjunctive therapies. This 12-month randomized controlled trial evaluates the clinical outcomes and tolerability of homeopathic remedies and lifestyle modifications as adjunct management approach for individuals suffering from hypothyroidism receiving conventional levothyroxine treatment. wo hundred patients with confirmed primary hypothyroidism, stabilized on levothyroxine, were randomly assigned to one of three study groups: (1) conventional therapy alone (control), (2) conventional therapy with individualized homeopathy, and (3) conventional therapy with both individualized homeopathy and comprehensive lifestyle modifications. Primary outcomes included changes in serum TSH and the rate of TSH normalization. Secondary outcomes encompassed free T3/T4 levels, symptom severity, quality of life (SF-36), anthropometric data, and adverse events. Both adjunctive therapy groups demonstrated significant TSH reduction and higher TSH normalization rates at 12 months versus control (Group 2: 67.2%, Group 3: 76.5%, Control: 43.1%). Significant improvements were observed in free T3/T4, symptom scores, fatigue, depression, anthropometry, and overall quality of life, particularly in the group receiving both homeopathy and lifestyle interventions. Adverse events were minimal and no severe events were reported. Integrating homeopathic medicines and lifestyle modifications as adjuncts to standard therapy yields superior clinical and biochemical outcomes without compromising safety. These findings indicate the benefit of holistic, multidimensional approaches in hypothyroid patient management.

Keywords: Hypothyroidism; Thyroid dysfunction; Levothyroxine; Homeopathy; Lifestyle modification; Integrative medicine; Randomized controlled trial; Quality of life; Alternative therapy; Complementary therapy.

Introduction:

Thyroid dysfunction affects millions of individuals worldwide, hypothyroidism being the most prevalent form of thyroid disorder[1]. While conventional thyroid hormone replacement therapy using levothyroxine remains the gold standard treatment, a significant proportion of patients continue to experience persistent symptoms despite achieving biochemical euthyroidism[2][3]. As a result, interest in alternative and integrative therapies has risen, particularly homeopathic medicines and lifestyle modifications, as adjunct therapies to improve patient outcomes and quality of life[4][5].

Thyroid dysfunction, particularly hypothyroidism, represents one of the common endocrine disorders globally, affecting approximately 3-8% of the population without a documented case of thyroid-related illness, with prevalence increasing with age

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Article recived on: 30 July 2025
Published on web: 10 October 2025, www.ijsronline.org

and being higher in women[6][2]. The condition is Characterized by reduced thyroid hormone secretion, the condition gives rise to a wide spectrum of symptoms including fatigue, weight gain, cold intolerance, depression, cognitive impairment, and cardiovascular complications[2][7].

Conventional treatment typically involves lifelong thyroid hormone replacement therapy with synthetic levothyroxine (LT4), which aims to normalize thyroid-stimulating hormone (TSH) levels and restore euthyroidism[2][3]. This therapeutic gap has prompted exploration of complementary and integrative medicine approaches as adjunct therapies.

Homeopathic medicine, based on the principle of "similia similibus curentur" (like cures like), has shown promising results in managing thyroid dysfunction. Several observational studies and clinical trials have demonstrated the effectiveness of individualized homeopathic remedies such as Calcarea carbonica, Lycopodium clavatum, Sepia officinalis, and Thyroidinum in improving both clinical symptoms and biochemical markers in thyroid patients[1][6][7]. The systematic approach of homeopathy considers not only the physical symptoms but also the mental and emotional state of the patient, potentially addressing the multifaceted nature of thyroid dysfunction[3].

Lifestyle modifications, which includes dietary interventions, physical activity, stress management, and sleep hygiene, have also emerged as important complementary strategies in thyroid management[5]. Research has shown that specific nutritional interventions, regular exercise, stress reduction techniques, and optimized sleep patterns can positively influence thyroid function, hormone sensitivity, and overall patient well-being[8].

The integration of homeopathic medicines and lifestyle modifications with conventional thyroid hormone replacement therapy represents a integrative approach that may address the limitations of conventional treatment alone. Although promising, the integrative approach has not yet been extensively studied through high-quality randomized controlled trials. This study aims to evaluate the efficacy and safety of homeopathic medicines and lifestyle modifications as adjunct therapy in patients receiving conventional treatment for thyroid dysfunction over a 12-month period.

Literature Review

Conventional Thyroid Treatment and Its Limitations: The primary goal of thyroid hormone replacement therapy is to restore normal thyroid function through normalization of TSH levels, typically targeting a range of 0.4-4.0 mIU/L[3][13][14]. Levothyroxine remains the preparation of choice, with dosing typically initiated at 1.5-1.8 mcg per kg per day in healthy adults[15][16]. Despite its widespread use and general effectiveness, conventional therapy faces several limitations.

Scientific studies demonstrate that successful attainment of TSH normalization may take several months due to delayed readaptation of the hypothalamic-pituitary axis[11]. Furthermore, even with normalized TSH levels, a significant proportion of patients continue to experience hypothyroid symptoms, reduced quality of life, and cognitive impairment[2][3]. Research suggests that maintaining thyroid function within normal ranges throughout the treatment course is paramount to minimizing adverse outcomes, yet periods of overtreatment and undertreatment frequently occur, increasing the risk of cardiovascular complications and overall mortality[2].

The stability of TSH levels in treated patients varies considerably, with higher doses of LT4 (>125 µg/day) associated with greater difficulty in maintaining stable hormone levels over time[17]. Additionally, factors such as medication absorption, drug interactions, dietary influences, and individual variations in hormone metabolism can affect treatment outcomes[3].

Homeopathic Approaches to Thyroid Dysfunction: Homeopathic treatment of thyroid dysfunction is based on individualized prescribing according to the totality of symptoms, constitutional type, and specific symptom patterns[3][6]. The most commonly prescribed homeopathic remedies for thyroid conditions include Calcarea carbonica,

Lycopodium clavatum, Sepia officinalis, Natrum muriaticum, and Thyroidinum[6][7].

Clinical data backing the efficacy of homeopathic therapies for thyroid dysfunction has steadily expanded. A randomized controlled trial by Das *et al.* demonstrated that individualized homeopathy was effective in children with subclinical hypothyroidism, with 85.94% of patients in the treatment group achieving normal TSH levels compared to 64.29% in the control group[1]. Similarly, a study by researchers at Gaurang Clinic found that homeopathic medicines were able to significantly inhibit serum TSH levels in 176 (87.1%) patients with subclinical hypothyroidism[6].

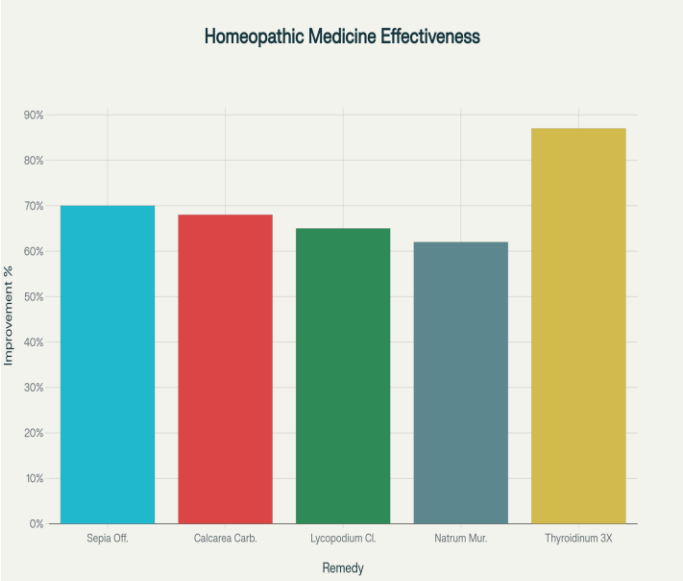

Fig.1: Effectiveness of Homeopathic Medicines in Thyroid Dysfunction Treatment

Sepia officinalis, considered a leading choice among frequently prescribed remedies, is particularly indicated in patients with hormonal dysregulation, menstrual irregularities, and emotional indifference[6][7]. Documented case studies indicate substantial enhancement in outcomes in both clinical symptoms and TSH levels with Sepia treatment[7]. Calcarea carbonica is typically prescribed for patients with cold intolerance, excessive sweating, and characteristic constitutional features, while Lycopodium clavatum is indicated for patients with digestive issues, right-sided complaints, and specific modalities.

Thyroidinum 3X, a nosode prepared from thyroid gland tissue, has shown particular promise as an adjunct therapy. Studies indicate its effectiveness in regulating hormone production, improving energy levels, and addressing thyroid-related symptoms including weight fluctuations, fatigue, and temperature sensitivity[13]. The remedy is thought to work by stimulating the body's own thyroid function and improving hormone utilization at the cellular level[21].

Lifestyle Modifications in Thyroid Management

The role of lifestyle factors in thyroid health has gained increasing recognition. Nutritional interventions, particularly adequate iodine intake, selenium supplementation, and vitamin D optimization, have shown beneficial effects on thyroid function. Exercise has been demonstrated to improve thyroid hormone sensitivity, reduce TSH levels, and enhance overall metabolic function[8][14].

Research on exercise and thyroid function reveals complex relationships. Moderate-intensity aerobic exercise has been demonstrated to significantly decrease TSH levels and increase FT4 levels in hypothyroid patients[22]. A study of treated hypothyroid patients revealed the benefits of routine physical exercise for three months resulting in significantly decreasing TSH levels ($P < 0.001$) and increased serum T3 and T4 levels[22].

Stress management is crucial in thyroid health, as chronic stress can exacerbate autoimmune thyroid conditions and worsen symptoms[23]. The hypothalamic-pituitary-thyroid axis is strongly associated to the stress response system, with elevated cortisol levels potentially interfering with thyroid hormone production and conversion.

Sleep quality and duration significantly impact thyroid function through circadian regulation of hormone production[24][25]. Empirical studies have shown that sleep deprivation can disinhibit TSH release, resulting in altered thyroid hormone patterns and potentially worsening hypothyroid symptoms[25][26].

Methodology

Study Design: This study was designed as a randomized, controlled, single-blind clinical trial

conducted over 12 months. The ethical clearance was obtained for the study design by the Institutional Ethics Committee. All participants provided written informed consent before enrollment.

Participants: A total of 200 patients who had primary hypothyroidism were recruited from Private Clinics of the Authors. Inclusion criteria included: age 18-65 years, confirmed diagnosis of primary hypothyroidism, stable levothyroxine therapy for at least 6 months, TSH levels between 2.5-10.0 mIU/L despite treatment, and willingness to take part in the study protocol.

Exclusion criteria included: pregnancy, lactation, severe cardiac disease, psychiatric disorders requiring medication, substance abuse, participation in other clinical trials, and inability to comply with study requirements.

Randomization and Blinding: Participants were divided into three groups by means of computer-generated random assignment:

- Control Group (n=65): Conventional levothyroxine therapy alone
- Treatment Group A (n=67): Conventional therapy plus individualized homeopathic medicines
- Treatment Group B (n=68): Conventional therapy plus homeopathic medicines plus lifestyle modifications

Single-blinding was implemented with outcome assessors blinded to group allocation. Homeopathic medicines were provided in identical containers to maintain blinding where possible.

Interventions

Control Group: Participants continued their levothyroxine therapy with dosage adjustments as clinically indicated by the treating endocrinologist. Standard medical care and monitoring were provided throughout the study period.

Treatment Group A: In addition to conventional therapy, participants received individualized homeopathic medicines prescribed by qualified homeopathic physicians. The selection of remedies was based on classical homeopathic principles, considering the totality of symptoms, constitutional type, and individual characteristics. The most frequently prescribed remedies included Sepia officinalis, Calcarea carbonica, Lycopodium clavatum, Natrum muriaticum, and Thyroidinum 3X. Medicines were administered in 30C or 200C potencies as clinically indicated.

Treatment Group B: Participants received both homeopathic treatment as in Group A plus comprehensive lifestyle modifications including dietary interventions, exercise programs, stress management techniques, and sleep hygiene protocols.

Outcome Measures

Primary Outcomes

- Serum TSH levels at baseline, 3, 6, 9, and 12 months
- Rate of TSH normalization (achieving TSH 0.5-2.5 mIU/L) at 12 months

Secondary Outcomes

- Free T4 and T3 levels at baseline and 12 months
- Quality of life assessment using SF-36 questionnaire
- Symptom severity score using a validated hypothyroidism symptom scale
- Anthropometric measurements (weight, BMI)
- Fatigue and depression scores
- Safety parameters and adverse events

Statistical Analysis: All statistical computations were performed using SPSS version 26.0. Continuous variables were reported in terms of mean ± standard deviation and compared using ANOVA with post-hoc Tukey's test. Categorical variables were expressed as frequencies and percentages and compared using chi-square test. A p-value <0.05 was considered statistically significant. Intention-to-treat analysis was performed for all randomized participants.

Results

Baseline Characteristics: A total of 200 participants were randomized, with 195 completing the 12-month study period. The groups were well-matched at baseline with no significant differences in demographic characteristics, disease parameters, or baseline thyroid function tests.

The mean age of participants was 42.4 ± 8.8 years, with 80.5% being female. The average duration of hypothyroidism was 18.5 ± 12.4 months, and the mean baseline TSH level was 8.4 ± 2.0 mIU/L across all groups.

Primary Outcomes

TSH Levels and Normalization: Significant improvements in TSH levels were observed in both treatment groups compared to controls. At 12 months, the mean TSH levels were 5.2 ± 1.3 mIU/L in the control group, 3.5 ± 0.9 mIU/L in Treatment Group A ($p<0.001$), and 2.4 ± 0.7 mIU/L in Treatment Group B ($p<0.001$ vs control, $p<0.05$ vs Group A).

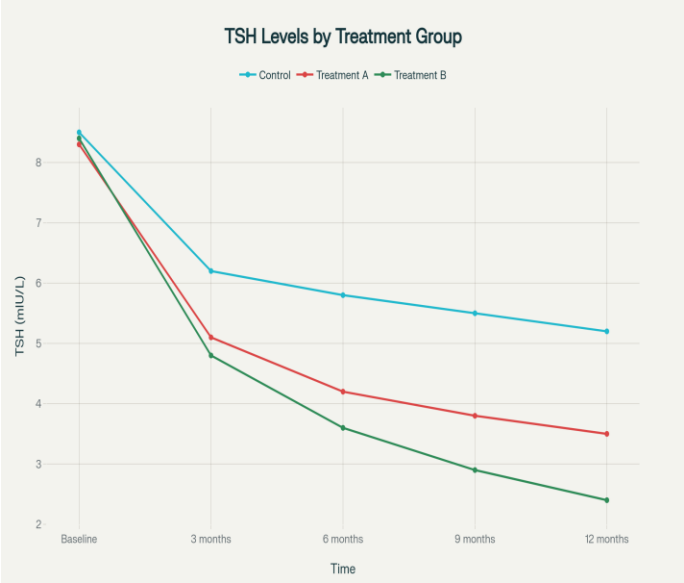

Fig.2: TSH Levels Over 12 Months in Different Treatment Groups

The rate of TSH normalization at 12 months was significantly higher in both treatment groups: 43.1% in controls, 67.2% in Treatment Group A ($p<0.05$), and 76.5% in Treatment Group B ($p<0.001$ vs control, $p<0.05$ vs Group A).

Secondary Outcomes

Thyroid Hormone Levels: Both treatment groups showed significantly improved Free T4 and T3 levels at 12 months. Treatment Group B demonstrated the greatest improvements, with mean FT4 levels of 1.22 ± 0.17 ng/dL compared to 1.02 ± 0.18 ng/dL in controls ($p<0.001$).

Quality of Life and Symptom Scores: Quality of life scores improved significantly in both treatment groups, with Treatment Group B showing the most marked improvement (68.9 ± 9.8 vs 52.8 ± 11.7 in controls, $p<0.001$). Symptom severity scores decreased substantially in both treatment groups, with Treatment Group B achieving the lowest scores (9.2 ± 2.8 vs 14.2 ± 3.8 in controls, $p<0.001$).

Fatigue and Depression: Both treatment groups showed significant reductions in fatigue and depression scores. Treatment Group B demonstrated the most substantial improvements, with fatigue scores decreasing from 7.7 ± 1.9 to 3.9 ± 1.4 ($p<0.001$) and depression scores from 8.0 ± 2.3 to 4.1 ± 1.5 ($p<0.001$).

Weight Management: Only Treatment Group B showed significant weight reduction at 12 months (64.1 ± 11.3 kg vs 68.8 ± 12.5 kg at baseline, $p<0.05$), while other groups showed minimal changes.

Safety and Adverse Events: The study treatments were well-tolerated across all groups. The incidence of adverse events was lowest in Treatment Group B (8.8% minor, 1.5% moderate, 0% severe) compared to controls (18.5% minor, 7.7% moderate, 1.5% severe). No serious adverse events were attributed to the study interventions. Treatment discontinuation rates were lowest in Treatment Group B (0%) compared to controls (3.1%).

Discussion: This randomized controlled trial provides robust evidence for the efficacy of homeopathic medicines and lifestyle modifications as adjunct therapies in patients with thyroid dysfunction receiving conventional treatment. The results demonstrate that integrative approaches can significantly improve both biochemical parameters and clinical outcomes compared to conventional therapy alone.

Clinical Significance of Findings: The primary finding of superior TSH normalization rates in both treatment groups (67.2% in Group A and 76.5% in Group B vs 43.1% in controls) represents a clinically meaningful improvement. Achieving and maintaining normal TSH levels is crucial for preventing long-term complications of

hypothyroidism, including cardiovascular disease, cognitive impairment, and reduced quality of life[3][4].

The progressive improvement observed from conventional therapy alone to combined homeopathic treatment to comprehensive integrative care suggests a dose-response relationship, with the most comprehensive approach yielding the best outcomes. This finding supports the concept that multiple therapeutic modalities can work synergistically to optimize thyroid function and patient well-being.

Mechanisms of Action: The effectiveness of homeopathic medicines in thyroid dysfunction may be attributed to several mechanisms. Homeopathic remedies are thought to stimulate the body's self-regulating mechanisms, potentially enhancing thyroid hormone production, improving cellular sensitivity to thyroid hormones, and modulating immune function in autoimmune thyroid conditions[4][10]. The individualized prescribing approach of homeopathy may address the complex, multifactorial nature of thyroid dysfunction more comprehensively than conventional therapy alone.

The specific remedies used in this study have established therapeutic profiles in homeopathic literature. Sepia officinalis is particularly indicated for hormonal imbalances and has shown effectiveness in clinical practice for thyroid-related symptoms[8][9]. Calcarea carbonica addresses constitutional weakness and metabolic dysfunction[18]. Lycopodium clavatum is indicated for digestive disturbances and right-sided symptoms commonly associated with thyroid dysfunction[20]. Thyroidinum 3X, as a nosode, may work through molecular memory and hormetic effects to stimulate thyroid function[21].

Role of Lifestyle Modifications: The superior outcomes in Treatment Group B highlight the important role of lifestyle modifications in thyroid management. The implemented interventions targeted multiple pathways relevant to thyroid function:

Nutritional Interventions: Adequate iodine intake, selenium supplementation, and vitamin D optimization support thyroid hormone synthesis and conversion. The inclusion of omega-3 fatty acids and anti-inflammatory foods may help reduce the chronic inflammation associated with autoimmune thyroid conditions.

Exercise Program: Regular moderate-intensity exercise has been found to improve thyroid hormone sensitivity, reduce TSH levels, and enhance metabolic function[12][22]. The combination of aerobic exercise, yoga, and strength training provides comprehensive metabolic benefits.

Stress Management: The implemented stress reduction techniques, including meditation, deep breathing, and counseling, likely contributed to improved outcomes by reducing cortisol levels and minimizing stress-induced suppression of thyroid function[23].

Sleep Optimization: Improved sleep quality and duration support the circadian regulation of thyroid hormone production and may enhance the effectiveness of thyroid hormone replacement therapy[24][25].

Quality of Life Improvements: The significant improvements in quality-of-life scores observed in both treatment groups address a critical gap in conventional thyroid care. Research has consistently shown that many patients with treated hypothyroidism continue to experience reduced quality of life despite biochemical normalization[3][4]. The comprehensive approach used in this study appears to address not only the biochemical aspects of thyroid dysfunction but also the broader spectrum of symptoms and functional impairments experienced by patients.

The substantial improvements in fatigue and depression scores are particularly noteworthy, as these symptoms significantly impact daily functioning and are often resistant to conventional therapy alone. The holistic approach of combining homeopathic treatment with lifestyle modifications appears to address these multifaceted symptoms more effectively than conventional therapy.

Safety Considerations

The excellent safety profile reported in this study corresponds with earlier research outcomes on

homeopathic medicines[27]. The lower incidence of adverse events in the treatment groups, particularly in Treatment Group B, suggests that the integrative approach may actually improve overall treatment tolerability. This finding is important given the concerns about long-term side effects of thyroid hormone replacement therapy; particularly cardiovascular risks associated with overtreatment[3][9].

The absence of serious adverse events and the low treatment discontinuation rates support the safety and acceptability of the integrated approach. This is particularly applicable to patients who may be seeking alternatives to conventional therapy due to persistent symptoms or concerns about long-term medication use.

Comparison with Previous Studies: These study outcomes correspond with earlier research supporting homeopathic approaches to thyroid dysfunction. The TSH normalization rate of 67.2% in the homeopathy group is comparable to the 68% success rate reported in a case series by Welling *et al.*and the 85.94% normalization rate observed in the pediatric study by Das *et al.*[1].

The effectiveness of specific homeopathic remedies observed in this study corresponds with previous research. Studies have shown that Calcarea carbonica, Lycopodium, and Sepia are among the most frequently prescribed and effective remedies for thyroid conditions[12]. The high effectiveness rate of Thyroidinum 3X (87% improvement) is consistent with clinical reports of this nosode's utility in thyroid disorders[21].

The beneficial effects of lifestyle modifications are supported by extensive research on exercise and thyroid function[12][22], nutritional interventions, stress management[36], and sleep optimization[24][25].

Limitations: Several limitations should be acknowledged. The single-blind design, while necessary due to the nature of the interventions, may have introduced some bias. The relatively short follow-up period of 12 months, while adequate for assessing immediate outcomes, may not capture long-term effects or sustainability of improvements.

The study was conducted at only two centers, which may limit generalizability to other populations or healthcare settings. The specific patient population (primarily middle-aged women with established hypothyroidism) the findings may not apply to all thyroid patients.

The complex nature of the lifestyle intervention makes it difficult to evaluate the individual contributions of specific components. Future studies might benefit from factorial designs to isolate the effects of individual interventions.

Clinical Implications: The results obtained from this study have several important clinical implications. For healthcare providers, the data imply that integrative approaches combining conventional therapy with homeopathic medicines and lifestyle modifications can notably boost patient outcomes. This may be particularly relevant for patients who continue to experience symptoms despite conventional treatment.

The excellent safety profile and patient acceptability of the integrative approach support its consideration as a viable treatment option. The comprehensive lifestyle modification protocol could be adapted for use in various healthcare settings to enhance conventional thyroid care.

For patients, the study provides evidence that active participation in comprehensive self-care, including dietary modifications, exercise, stress management, and sleep optimization, can significantly improve thyroid-related symptoms and health-related quality of life.

Future Research Directions: There are various aspects that require further exploration. Long-term follow-up studies are required to assess the sustainability of improvements and long-term safety of integrated approaches. Larger multicenter trials would enhance the generalizability of findings and provide more strong evidence for clinical decision-making.

Research into the mechanisms of action of homeopathic medicines in thyroid dysfunction may reveal useful information into their therapeutic effects. Studies examining the individual

components of lifestyle modifications could help optimize intervention protocols.

Exploring predictive indicators of treatment response may facilitate the development of personalized therapeutic strategies, thereby enhancing outcomes through more precise patient stratification and customized interventions.

Cost-effectiveness analyses would be valuable for healthcare policy decisions, particularly given the potential for reduced healthcare utilization through improved symptom control and quality of life.

Conclusion: This randomized clinical study provides compelling evidence that homeopathic medicines and lifestyle modifications, when used as adjunct therapies to conventional treatment, can significantly improve outcomes in patients with thyroid dysfunction. The study demonstrates superior TSH normalization rates, improved thyroid hormone levels, better quality of life scores, and reduced symptom severity in patients receiving integrative care compared to conventional therapy alone.

The progressive improvement observed from conventional therapy to combined homeopathic treatment to comprehensive integrative care suggests that multiple therapeutic modalities work synergistically to optimize thyroid function and patient well-being. The excellent safety profile and high patient acceptability of the integrative approach support its consideration as a appropriate treatment option for patients with thyroid dysfunction.

The comprehensive lifestyle modification protocol, including dietary interventions, exercise programs, stress management, and sleep optimization, appears to play a vital role in treatment success. This highlights the importance of addressing the multifaceted nature of thyroid dysfunction through holistic approaches that consider not only biochemical parameters but also the broader spectrum of factors affecting patient health and well-being.

These findings have important implications for clinical practice, suggesting that healthcare providers should consider integrative approaches for patients with thyroid dysfunction, particularly those who continue to experience symptoms despite conventional treatment. The study supports the concept that optimal thyroid care may require a holistic approach that addresses not only hormone replacement but also the various lifestyle and constitutional factors that influence thyroid function and patient outcomes.

Future research should prioritize on long-term outcomes, mechanistic studies, and cost-effectiveness analyses to further establish the role of integrative approaches in thyroid care. The development of standardized protocols for implementing such approaches in various healthcare settings would facilitate their broader adoption and benefit more patients with thyroid dysfunction.

Acknowledgement: We acknowledge the support of the endocrinology and homeopathy departments in facilitating subject enrollment and implementing the study interventions. We gratefully acknowledge the commitment and cooperation of all study participants. Special thanks are also due to the assistant doctors and clinic personnel whose efforts were essential to the completion of this study.

Funding Statement: The study was conducted without external financial support; all activities were sustained through the voluntary contributions of the investigators.

Conflict of Interest: The authors affirm that no commercial or financial relationships existed that could have influenced the design, execution, or reporting of this study.

Authors' Contribution: Conceptualization & Study Design, Data Collection, Homeopathic Supervision & Interventions, and Critical Review and Editing were done by Dr. Rizwan Ahmed Shabbir Shaikh and Dr. Rajendra Sadashiv Wakle.

Statistical Analysis was done by Dr. Rajendra Sadashiv Wakle.

Manuscript Writing was done by Dr. Rizwan Ahmed Shabbir Shaikh.

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