

**EFFICACY OF UJJAYI PRANAYAMA ON HYPOTHYROIDISM IN
ADULTS – A RANDOMIZED CONTROLLED TRIAL**

By

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IN

YOGA

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The Institutional Ethics Committee of Government Yoga and Naturopathy Medical College, reviewed and discussed the application for approval of the proposal “EFFICACY OF UJJAYI PRANAYAMA ON HYPOTHYROIDISM IN ADULTS – A RANDOMIZED CONTROLLED TRIAL”, for project work submitted by Dr.S.VINUDHA, 2nd year M.D. YOGA, Post Graduate,
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Date:

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LIST OF ABBREVIATIONS

TSH	Thyroid Stimulating Hormone
T3	Tri-iodothyroxine
T4	Thyroxine
BMI	Basal Metabolic Index
TRH	Thyrotropin releasing Hormone
TSHR	Thyroid Stimulating Hormone Receptor
DNA	Deoxyribonucleic Acid
CG	Control Group
SG	Study Group
MIT	Monoiodotyrosin
DIT	Diiodotyrosine
cAMP	Cyclic Adenosine Mono Phosphate
TBG	Thyroxine Binding Globulin
TBPA	Thyroxine Binding Pre Albumin
SCH	Sub Clinical Hypothyroidism

ABSTRACT

Objective: The intended research work aims to evaluate the effect of 12 week Ujjayi pranayama on Hypothyroidism in adults and to compare the changes in BMI and Thyroid Function Test [Tri- iodothyronine T3,Thyroxine T4, Thyroid-stimulating hormone] before and after Psychic breathing technique .Many studies reported that the practice of yoga, especially pranayama‘ influences BMI. The current study was conducted to determine the effect of practicing Ujjayi Pranayama on Hypothyroidism in Adults, followed by monitoring BMI and Thyroid Function Test.

Study Design: The current research work employed A Randomized Controlled Trail.

Method:

Potential subject will be screened and eligible patients will be recruited for the study.A minimum of 60 participants in Study group and minimum of 60 participants in Control group belonging within the age group of 18-55 participate in the study. After obtaining informed consent both the group will be subjected to general measures like BMI, Thyroid Function Test before and after the study. The study Group will be subjected to Ujjayi Pranayama for 15 minutes twice a day for 6 days a week for 12 weeks.

Result:

Results of the pre and post measurements on T3, T4, TSH, Body weight and BMI among Ujjai pranayama along with standard drug group for a period of 90 days shows that Body weight was reduced and T3 got raised statistically significant after the yoga intervention

where as T4 doesn't show's any statistical significance after the yoga intervention. Even though in yoga intervention group T4 doesn't show statistical significance its mean value raised to a marked level from 8.05 to 8.54 mg/dl .This shows that ujjai pranayama is influencing the T4 secretion. TSH level reduced significantly after the practice of ujjai pranayama for a period of 90 days.

Conclusion:

This study showed that 90 days of Ujjayi Pranayama reduced Body mass index and Thyroid Stimulating Hormone (TSH), Triiodothyronine (T3) and no significant differences in Thyroxine (T4) hypothyroid patients. This revealed that yoga practice has significant role in improvement in the weight reduction. Further research need in this field with a larger sample size and duration is warranted to reveal accurate changes in this field.

Keywords:

Hypothyroidism, Ujjayi Pranayama, Basal Metabolic Index, Thyroid Stimulating
Hormone,

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1.0 INTRODUCTION

Hypothyroidism is defined as a clinical state resulting from insufficient secretion of the thyroid hormone from thyroid gland due to some of the structural or functional impairment of the thyroid hormone production(1). The thyroid gland is located inside the neck, just below adam's apple and It produces two thyroid hormones, triiodothyronine (T3) and thyroxine (T4), which regulate the body metabolic rate(2). Hypothyroidism affects all the organ systems and main clinical findings are fatigue, weakness, dryness, coarseness of the skin, cold intolerance, swelling of extremities, lack of concentration, memory, constipation and weight gain, menorrhagia, paresthesia, hearing disorder, diffuse alopecia, bradycardia, delayed relaxation of tendon reflexes, carpel tunnel syndrome, serous cavitory effusion(3). There are intricate feedback mechanisms between the thyroid and anterior pituitary, hypothyroidism is classified as primary when thyroxin (T4) and triiodothyronine (T3) levels are low but levels of thyroid stimulating hormone (TSH) secreted by anterior pituitary high(4). It is classified as secondary when TSH is low and T4 and T3 levels are high and presents a large epidemiological burden in India(5). Imbalance in production of thyroid stimulating hormone (TSH) or hypothalamus, which regulates the pituitary gland via thyrotropin releasing hormone(TRH)(6). Thyroid disorders can range from a small, harmless goiter (enlarged gland) that needs no treatment to life threatening cancer(7). The most common thyroid problems involve abnormal production leads to hypothyroidism, as the result of subtle and non specific clinical symptoms and signs, the condition often go undiagnosed and are not adequately treated when it is detected(8). There is heterogeneity in the diagnostic and treatment approaches to hypothyroidism(9). As a result of the physiological changes in thyroid hormones with age and illness, it is important to tailor the diagnosis and management of

this condition in specific populations including pregnant women, infants, children, geriatric patients, and those with comorbid conditions(10).

1.1 YOGA

Yoga is an art and science of healthy living. The word 'Yoga' is derived from the Sanskrit root 'Yuj', meaning 'to join' or 'to yoke' or 'to unite'. As per Yogic scriptures the practice of Yoga leads to the union of individual consciousness with that of the Universal Consciousness, indicating a perfect harmony between the mind and body, Man & Nature(11). The aim of Yoga is Self-realization, to overcome all kinds of sufferings leading to 'the state of liberation' (Moksha) or 'freedom' (Kaivalya). Living with freedom in all walks of life, health and harmony shall be the main objectives of Yoga practice. "Yoga" also refers to an inner science comprising of a variety of methods through which human beings can realize this union and achieve mastery over their destiny (12). Yoga, being widely considered as an 'immortal cultural outcome' of Indus Saraswati Valley civilization dating back to 2700 B.C., has proved itself catering to both material and spiritual upliftment of humanity. Basic humane values are the very identity of Yoga Sadhana. Yoga is also commonly understood as a therapy or exercise system for health and fitness. While physical and mental health is natural consequences of yoga, the goal of yoga is more far-reaching (13). "Yoga is about harmonizing oneself with the universe. It is the technology of aligning individual geometry with the cosmic, to achieve the highest level of perception and harmony."

Patanjali's definition of yoga

The great sage Patanjali, in the system of Raja Yoga, gave one of the best definitions of yoga. He said, 'Yoga is the blocking (nirodha) of mental modifications (chitta vritti) so that the seer (drashta) re-identifies with the (higher) Self. Patanjali's system has come to

be the epitome of Classical Yoga Philosophy and is one of the 7 major philosophies of India(14). Patanjali gives a wide range of techniques that slowly harmonizes the mind and gradually induces more subtle perception. However, the main path of Patanjali is contained within eight fundamental stages. The first five are:

- Yama (social code)
- Niyama (personal code)
- Asana (sitting pose)
- Pranayama (control of prana)
- Pratyahara (sense withdrawal)

These first five stages are the esoteric/bahiranga (external) practices of yoga. They progressively prepare the body-mind for the last stages:

- Dharana (concentration)
- Dhyana (meditation)
- Samadhi (superconsciousness)

These last three stages are the esoteric or antaranga (internal) practices of yoga. The first five stages negate consciousness, whilst the last three stages expand consciousness.

1.2 PRANAYAMA

Practicing Pranayama helps in controlling the breath. The terminology was coined from the two root words namely ‘prana’ meaning ‘vital energy’ and ‘ayama’ meaning ‘extension/breath’. The practice of pranayama cannot be considered as a simplified breathing exercise; rather it aims at channeling the flow of excess oxygen into the lungs,

thereby, transporting it to all the systemic organs of the body(15).In the pranayama practices there are four important aspects of breathing which are utilized. These are:

- Pooraka or inhalation
- Rechaka or exhalation
- Antarkunbhaka or internal breath retention
- Bahirkumbhaka or external breath retention.

As Yoga was globally regarded as 'The ancient Indian science' which comprised of practices, which involved specific postures (asanas) and regulated breathing (Pranayama). There were reports suggesting different types of pranayama exhibiting different autonomic and cardiac responses among healthy humans(16). Many reports claimed that the practice of pranayama aids in eliminating the toxins away from the body and helps in maintaining a good health. There are different variations/types of pranayama such as

- AnulomVilom Pranayama
- Bahya Pranayama
- Bhastrika Pranayama
- Bhramari Pranayama
- Digra Pranayama
- Kapalbhati Pranayama
- NadiSodhana Pranayama
- Shitali Pranayama
- Udgit Pranayama
- Ujjayi Pranayama

1.3 GHERANDA SAMHITA

Gheranda Samhita is a Sanskrit text of Yoga in Hinduism and it is one of the three classic texts of hatha yoga . The Gheranda Samhita calls itself a book on ghatastha yoga, which literally means "vessel yoga", wherein the body and mind are depicted as vessels that carry and serve the soul (atman, purusha). The text teaches a seven limbed. Gheranda Samhita is a step by step detailed manual of yoga taught by sage Gheranda to student Chanda.^[14] Unlike other hatha yoga texts, the Gheranda Samhita speaks of a sevenfold Yoga and Pranayama is one of the important practice explained in this text

1.4 UJJAYI PRANAYAMA – The Psychic Breath

Ujjayi Pranayama or the psychic breath soothes the mind and induces a meditative state. Ujjayi means to 'lift up'. In Ujjayi pranayama, the chest is slightly lifted up as if the inhalation is done from the throat. Ujjayipranayama is mentioned in the yoga text Hatha Yoga Pradeepika and in the Gheranda Samhita. The Procedure of Ujjayi pranayama or Psychic breathing according to Gherenda Samhita:

- Sit in a comfortable meditative pose Siddhasana or Swastikasana, or Vajrasana.
 - Contract the glottis, so that the passage of the throat is partially closed
 - Roll the tongue up and let the lower side of the tongue touch the upper palate
 - Breath in slowly through the throat, making a slight hissing snoring sound.
 - When the inhalation is complete, swallow the breath and perform Jalandhara Bandha(the chin lock)
 - Retain the breath inside for as long as you are comfortable
 - Release the chin lock (Jalandhara Bandha) and exhale through both the nostrils.
 - This is one round of Ujjayi Pranayama. Do as many rounds as comfortable for 15
- Benefits of Ujjayi Pranayama[8]

The current study focuses on Ujjayi pranayama on adult hypothyroidism and its impact on BMI and Thyroid Function Test. Thus Ujjayi is considered as supportive and complimentary therapy in conjunction with medical therapy for the treatment of hypothyroid disorder. Though Ujjayi pranayama is being widely used as a yoga therapy for various diseases in Yogic system of medicine, to the best of our knowledge, there is lack of scientific evidence in reporting the effect of Ujjayi pranayama on adult Hypothyroidism. Hence the rationale is to observe the changes in BMI and Thyroid profile in adult Hypothyroidism.

2.0 AIMS AND OBJECTIVES

2.1 AIM

The aim of this study was to assess the effect of Ujjayi pranayama on adult Hypothyroidism

2.2 OBJECTIVES OF THE STUDY

2.2.1 Primary Objective:

To evaluate the effect of 12 week Ujjayi Pranayama on Hypothyroidism adult patients (in- and out-patients) of Government Yoga and Naturopathy Hospital, Arumbakkam, Chennai.

2.2.2 Secondary Objective: To compare the changes in BMI and Thyroid Function

Test – [Tri-iodothyronine T₃, Thyroxine T₄, Thyroid stimulating hormone] before and after the Ujjayi Pranayama (Psychic breathing technique).

3.0 REVIEW OF LITERATURE

3.1 HYPOTHYROIDISM

Hypothyroidism is defined as a clinical state resulting from insufficient secretion of the thyroid hormone from thyroid gland due to some of the structural or functional impairment of the thyroid hormone production(14). The thyroid gland is located inside the neck, just below adam's apple. It produces two thyroid hormones, triiodothyronine (T3) and thyroxine (T4), which regulate the body metabolic rate(17).

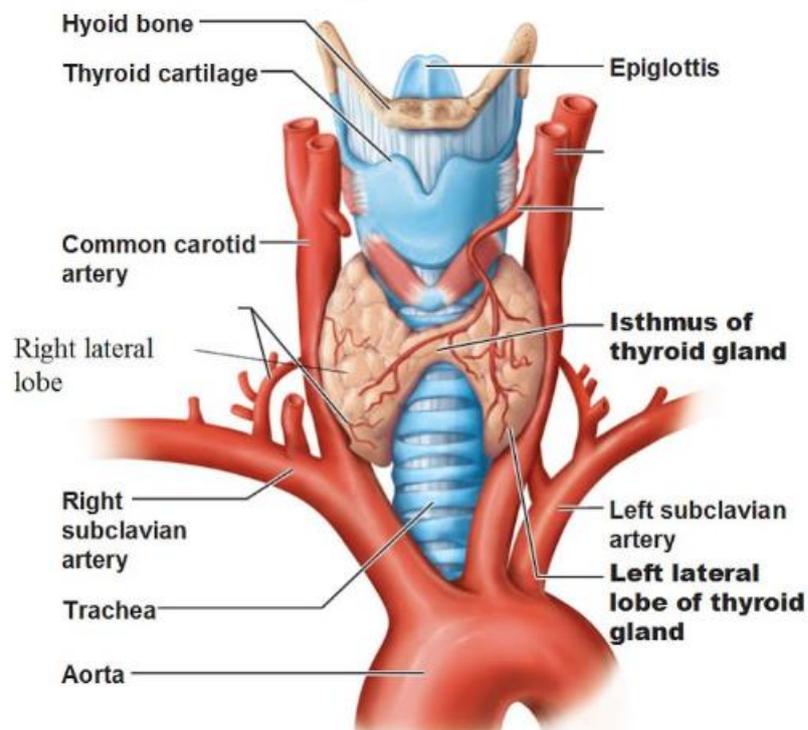


Figure 1 : Anatomy of thyroid gland

There are intricate feedback mechanisms between the thyroid and anterior pituitary, hypothyroidism is classified as primary when thyroxin (T4) and triiodothyronine (T3) levels are low but levels of thyroid stimulating hormone (TSH) secreted by anterior pituitary high. It is classified as secondary when TSH is low and T4 and T3 levels are high(18).

3.2 PREVALENCE OF HYPOTHYROIDISM

The prevalence of hypothyroidism in developed countries is about 4% - 5%, when compared to the western countries (UK,2%;USA,4.6%),a higher prevalence of hypothyroidism is reported in India is around 10.95% . One in ten adults is said to have hypothyroidism in India(19). In fact an estimated 108 million people in India suffer from endocrine and metabolic disorders. Several of these diseases are caused by environmental factors .therefore , their prevalence is several fold higher. Thyroid disorders are the most common among all the endocrine diseases in India (20).

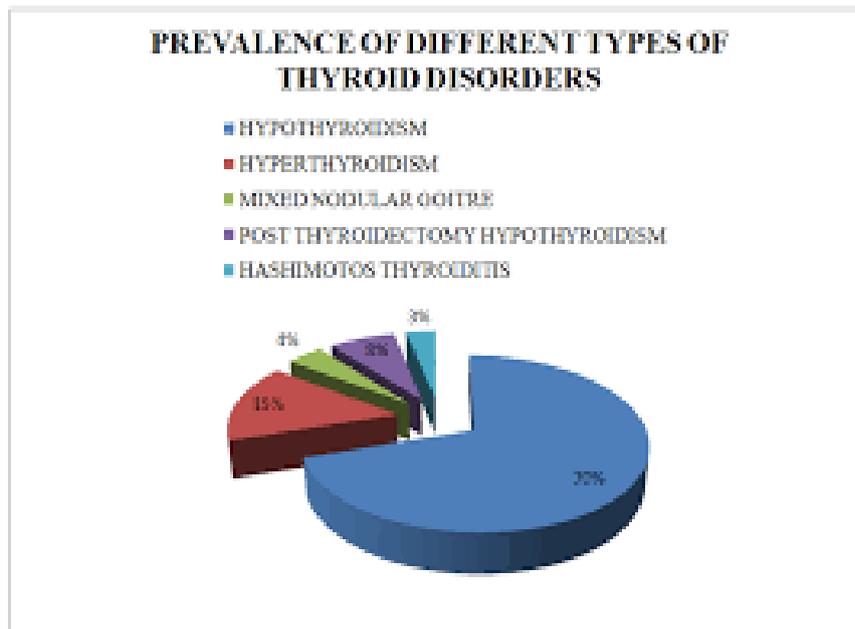


Figure 1 : Anatomy of thyroid gland

Hypothyroidism presents a large epidemiological burden in India. . Imbalance in production of thyroid stimulating hormone (TSH) ,or hypothalamus, which regulates the pituitary gland via thyrotropin releasing hormone(TRH). Thyroid disorders can range from a small, harmless goiter (enlarged gland) that needs no treatment to life threatening cancer. The most common thyroid problems involve abnormal production leads to

hypothyroidism(21). As a result of subtle and non specific clinical symptoms and signs, the condition often go undiagnosed and are not adequately treated when it is detected. There is heterogeneity in the diagnostic and treatment approaches to hypothyroidism. As a result of the physiological changes in thyroid hormones with age and illness, it is important to tailor the diagnosis and management of this condition in specific populations including women, infants, children, geriatric patients, and those with comorbid conditions(22).

3.3 THE THYROID GLAND

Thyroid gland is an endocrine gland in the neck, consisting of two lobes connected by an isthmus and is found at the front of the neck, below the Adam's apple. The thyroid gland secretes three hormones, namely the two thyroid hormones (thyroxine/T₄ and triiodothyronine/T₃), and calcitonin(23). The thyroid hormones primarily influence the metabolic rate and protein synthesis. Calcitonin plays an important role in calcium homeostasis. Hormonal output from the thyroid is regulated by thyroid-stimulating hormone (TSH) secreted from the anterior pituitary gland, which itself is regulated by thyrotropin-releasing hormone (TRH) produced by the hypothalamus(24).

HPT Axis

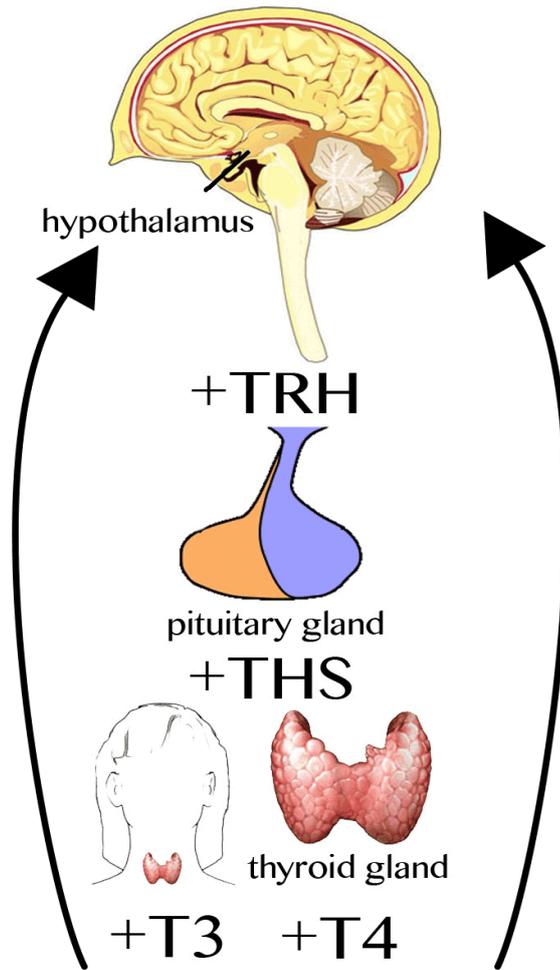


Figure 3: Flow chart of HPT axis

Thyroid is affected by many diseases. Hypothyroidism is a state of insufficient thyroid hormone production. the most common cause is iodine deficiency. Thyroid hormones are important for development, and hypothyroidism secondary to iodine deficiency remains the leading cause of preventable intellectual disability(25). In iodine-sufficient regions, the most common cause of hypothyroidism is Hashimoto's thyroiditis, also an autoimmune disorder. In addition, the thyroid gland may also develop several types of nodules and cancer.

3.3.1 BLOOD SUPPLY OF THYROID GLAND

The thyroid is supplied with arterial blood from the superior thyroid artery, a branch of the external carotid artery, and the inferior thyroid artery, a branch of the thyro cervical trunk, and sometimes by an anatomical variant the thyroid in an artery, which has a variable origin(26). The superior thyroid artery splits into anterior and posterior branches supplying the thyroid, and the inferior thyroid artery splits into superior and inferior branches(27). The superior and inferior thyroid arteries join together behind the outer part of the thyroid lobes(28). The venous blood is drained via superior and middle thyroid veins, which drain to the internal jugular vein, and via the inferior thyroid veins(29). The inferior thyroid veins originate in a network of veins and drain into the left and right brachiocephalic veins(30). Both arteries and veins form a plexus between the two layers of the capsule of the thyroid gland.

3.3.2 THE LYMPH SUPPLY

Lymphatic drainage frequently passes the pre laryngeal lymph nodes (located just above the isthmus), and the pre tracheal and para tracheal lymph nodes(31).

3.3.3 THE NERVOUS SUPPLY

The gland receives sympathetic nerve supply from the superior, middle and inferior cervical ganglion of the sympathetic trunk. The gland receives parasympathetic nerve supply from the superior laryngeal nerve and the recurrent laryngeal nerve(32).

3.3.4 VARIATION:

Sometimes there is a third lobe present called the pyramidal lobe. This lobe often stretches up the hyoid bone from the thyroid isthmus and may be one to several divided

lobes and it present in 18.3% to 44.6%. It mainly arises from the left side and occasionally separated. The pyramidal lobe is also known as Lalouette's pyramid(33). A small horn at the back of the thyroid lobes, usually close to the recurrent laryngeal nerve and the inferior thyroid artery, is called Zuckerkandl's tubercle(34). Other variants include a levator muscle of thyroid gland, connecting the isthmus to the body of the hyoid bone and the presence of the small thyroid ima artery(35).

3.3.5 MICROANATOMY

Section of thyroid gland under the microscope:

1. Follicles
2. Follicular cells
3. Para follicular cells

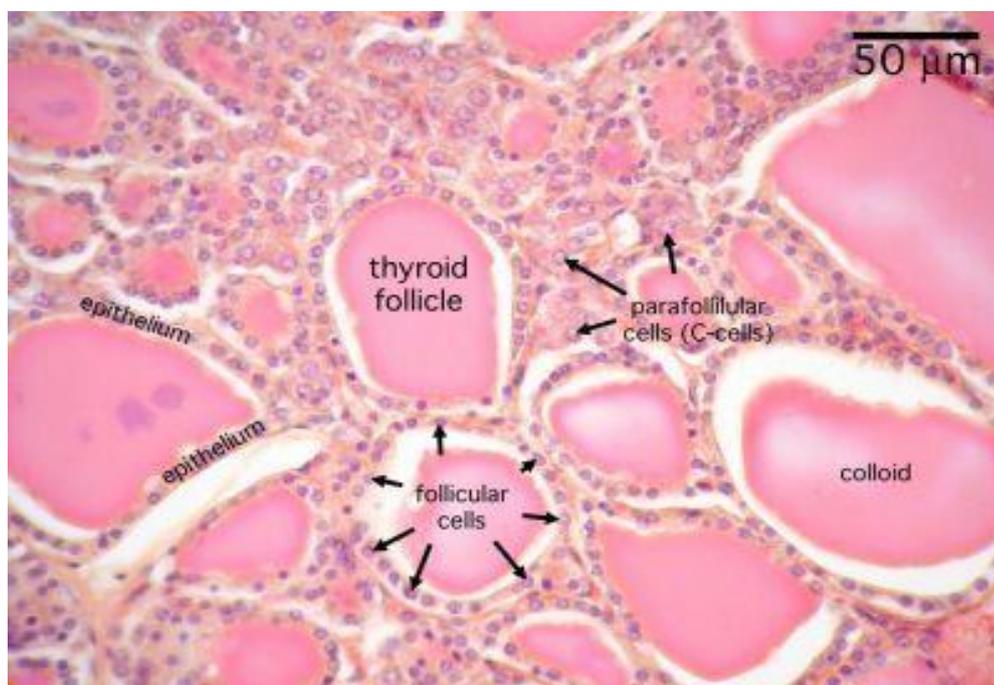


Figure 4 : Microscopic representation of thyroid follicles

FOLLICLES

Thyroid follicles are small spherical groupings of cells 0.02–0.9mm in diameter that play the main role in thyroid function(36). They consist of a rim that has a rich blood supply,

nerve and lymphatic presence, that surrounds a core of colloid that consists mostly of thyroid hormone precursor proteins called thyroglobulin, an iodinated glycoprotein(31).

FOLLICULAR CELLS

The core of a follicle is surrounded by a single layer of follicular cells. When stimulated by thyroid stimulating hormone (TSH), these secrete the thyroid hormones T₃ and T₄. They do this by transporting and metabolising the thyroglobulin contained in the colloid(37). Follicular cells vary in shape from flat to cuboid to columnar, depending on how active they are.

PARA FOLLICULAR CELLS

Scattered among follicular cells and in spaces between the spherical follicles are another type of thyroid cell, parafollicular cells secrete calcitonin and so are also called C cells(4).

3.3.6 THYROID HORMONES

The primary function of the thyroid is the production of iodine containing thyroid hormones such as

- Tri -iodothyronine (T₃)
- Thyroxine (T₄)
- The Peptide hormone Calcitonin

The thyroid hormones are created from iodine and tyrosine. T₃ is so named because it contains three atoms of iodine per molecule and T₄ contains four atoms of iodine per molecule. The thyroid hormones have a wide range of effects on the human body.

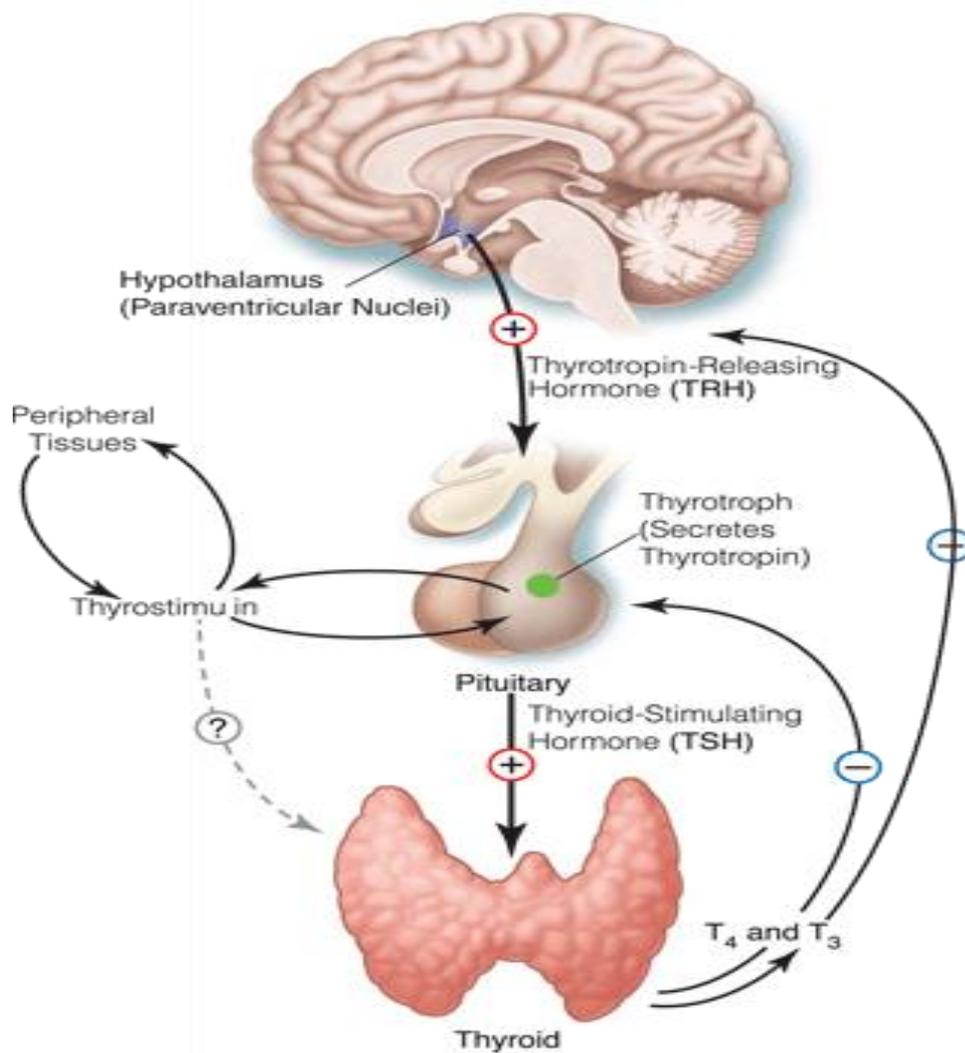


Figure 5 : Hypothalamic pituitary thyroid axis

METABOLISM

The thyroid hormones increase the basal metabolic rate and have effects on almost all body tissues. Appetite, the absorption of substances, and gut motility are all influenced by thyroid hormones(38). They increase the absorption in the gut, generation, uptake by cells, and breakdown of glucose. They stimulate the breakdown of fats, and increase the number of free fatty acids. Despite increasing free fatty acids, thyroid hormones decrease cholesterol levels by increasing the rate of secretion of cholesterol in bile.

Thyroid system

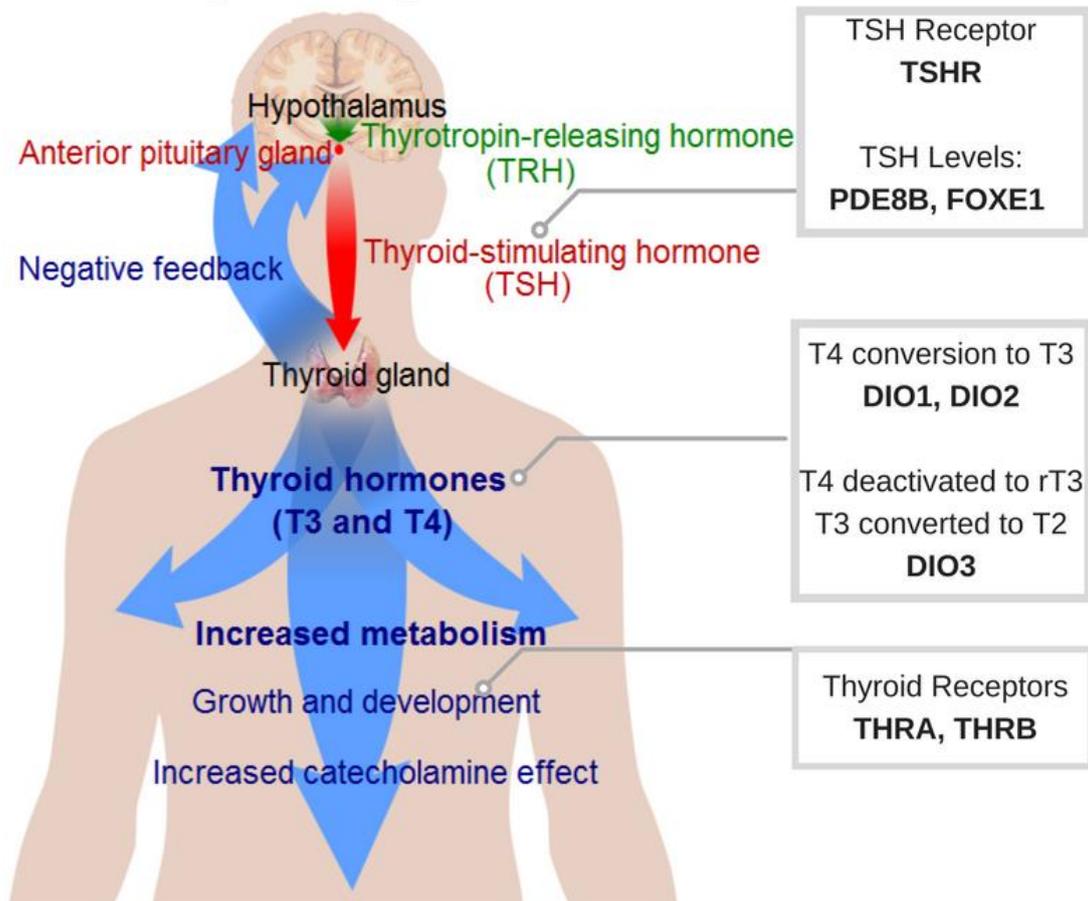


Figure 6 : Feedback mechanism of thyroid system

CARDIOVASCULAR:

Thyroid hormones increase the rate and strength of the heartbeat. They increase the rate of breathing, intake and consumption of oxygen, and increase the activity of mitochondria(39). Combined, these factors increase blood flow and the body's temperature.

DEVELOPMENT:

Thyroid hormones are important for normal development. They increase the growth rate of young people, and cells of the developing brain .Thyroid hormones play a particularly

crucial role in brain maturation during fetal development and first few years of postnatal life(1).

SEXUAL FUNCTION:

Thyroid hormones also play a role in maintaining normal sexual function, sleep, and thought patterns. Increased levels are associated with increased speed of thought generation but decreased focus. Sexual function, including libido and the maintenance of a normal menstrual cycle, are influenced by thyroid hormones(28). After secretion, only a very small proportion of the thyroid hormones travel freely in the blood. Most are bound to thyroxine binding globulin (about70%), transthyretin (10%), and albumin (15%). Only the 0.03% of T₄ and 0.3% of T₃ traveling freely have hormonal activity(40). In addition, up to 85% of the T₃ in blood is produced following conversion from T₄ by iodothyronine deiodinases in organs around the body. Thyroid hormones act by crossing the cell membrane and binding to intracellular nuclear thyroid hormone receptors TR- α_1 , TR- α_2 , TR- β_1 and TR- β_2 , which interact with hormone response elements and transcription factors to modulate DNA transcription. In addition to these actions on DNA, the thyroid hormones also act within the cell membrane or within cytoplasm via reactions with enzymes, including calcium ATPase, adenylyl cyclase, and glucose transporters(24).

3.3.7 HORMONE PRODUCTION

Iodine is essential for the production of the thyroid hormones. Iodine (I⁰) travels in the blood as iodide (I⁻), which is taken up into the follicular cells by a sodium-iodide symporter. This is an ion channel on the cell membrane which in the same action transports two sodium ions and an iodide ion into the cell(14). Iodide then travels from within the cell into the follicular space, through the action of pendrin, an iodide-chloride antiporter. In the follicular space, the iodide is then oxidized to iodine. This

makes it more reactive, and the iodine is attached to the active tyrosine units in thyroglobulin by the enzyme thyroid peroxidase(41–43). This forms the precursors of thyroid hormones monoiodotyrosine (MIT), and diiodotyrosine (DIT).

Thyroid

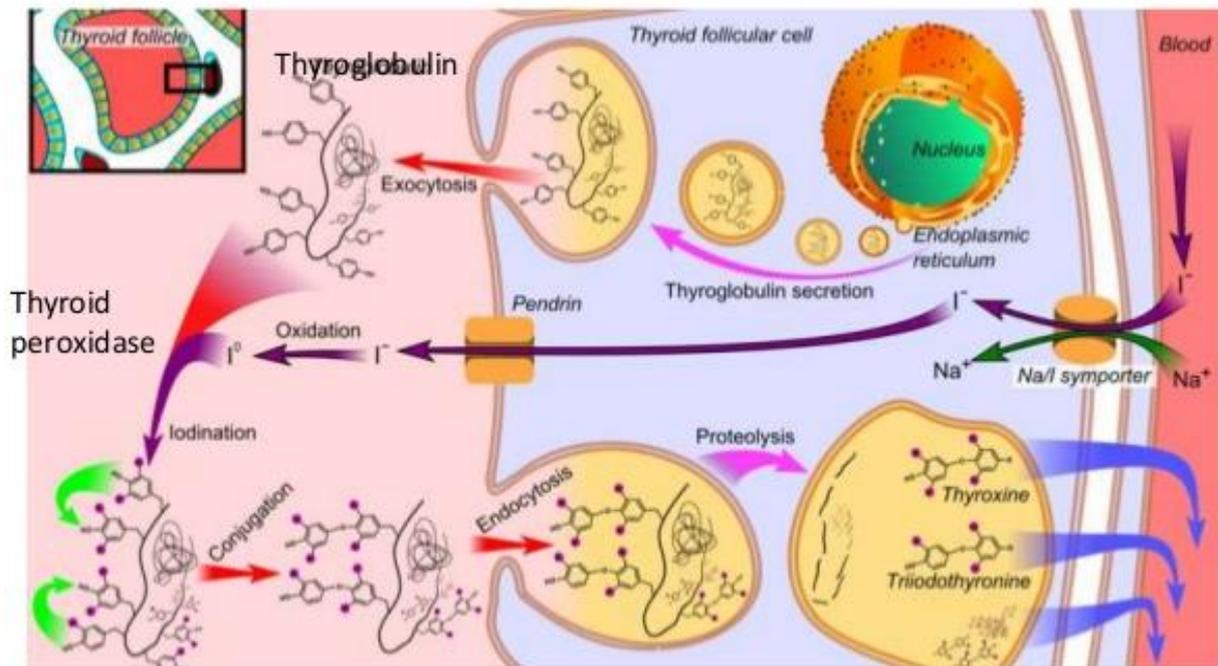


Figure 7 : Schematic representation of thyroid hormone secretion

When the follicular cells are stimulated by thyroid-stimulating hormone, the follicular cells reabsorb thyroglobulin from the follicular space. The iodinated tyrosines are cleaved, forming the thyroid hormones T_4 , T_3 , DIT, MIT, and traces of reverse triiodothyronine(14). T_3 and T_4 are released into the blood. The hormones secreted from the gland are about 80–90% T_4 and about 10–20% T_3 . Deiodinase enzymes in peripheral tissues remove the iodine from MIT and DIT and convert T_4 to T_3 and RT_3 . This is a major source of both RT_3 (95%) and T_3 (87%) in peripheral tissues. The signs and symptoms of hypothyroidism vary, depending on the severity of the hormone deficiency. Problems tend to develop slowly, often over a number of years. At first, you may barely notice the symptoms of hypothyroidism, such as fatigue and weight gain. Or you may

simply attribute them to getting older(42). But as your metabolism continues to slow, you may develop more-obvious problems.

3.3.8 ETIOLOGY

Hypothyroidism results when the thyroid gland fails to produce enough hormones., the balance of chemical reactions in the body can be upset and have an enormous impact on health, affecting all aspects of metabolism. These hormones also influence the control of vital functions, such as body temperature and heart rate(44). There can be a number of causes, including autoimmune disease, hyperthyroidism treatments, radiation therapy, thyroid surgery and certain medications.

Hypothyroidism may be due to a number of factors, including:

AUTOIMMUNE DISEASE:

The most common cause of hypothyroidism is an autoimmune disorder known as Hashimoto's thyroiditis. Autoimmune disorders occur when your immune system produces antibodies that attack its own tissues. Sometimes this process involves your thyroid gland.

OVER RESPONSE TO HYPERTHYROIDISM TREATMENT:

People who produce too much thyroid hormone (hyperthyroidism) are often treated with radioactive iodine or anti-thyroid medications. The goal of these treatments is to get thyroid function back to normal. But sometimes, correcting hyperthyroidism can end up lowering thyroid hormone production too much, resulting in permanent hypothyroidism.

THYROID SURGERY:

Removing all or a large portion of your thyroid gland can diminish or halt hormone production. In that case, you'll need to take thyroid hormone for life.

RADIO THERAPY:

Radiation used to treat cancers of the head and neck can affect your thyroid gland and may lead to hypothyroidism.

MEDICATION:

A number of medications can contribute to hypothyroidism. One such medication is lithium, which is used to treat certain psychiatric disorders. If you're taking medication, ask your doctor about its effect on your thyroid gland.

CONGENITAL DISEASE:

Some babies are born with a defective thyroid gland or no thyroid gland. In most cases, the thyroid gland didn't develop normally for unknown reasons, but some children have an inherited form of the disorder. Often, infants with congenital hypothyroidism appear normal at birth. That's one reason why most states now require new-born thyroid screening.

PITUITARY DISORDER:

A relatively rare cause of hypothyroidism is the failure of the pituitary gland to produce enough thyroid-stimulating hormone (TSH) usually because of a benign tumor of the pituitary gland.

PREGNANCY:

Some women develop hypothyroidism during or after pregnancy (postpartum hypothyroidism), often because they produce antibodies to their own thyroid gland. Left

untreated, hypothyroidism increases the risk of miscarriage, premature delivery and preeclampsia, a condition that causes a significant rise in a woman's blood pressure during the last three months of pregnancy. It can also seriously affect the developing fetus.

IODINE DEFICIENCY:

The trace mineral iodine is mainly found primarily in seafood, seaweed, plants grown in iodine-rich soil and iodized salt which is essential for the production of thyroid hormones. Too little iodine can lead to hypothyroidism, and too much iodine can worsen hypothyroidism in people who already have the condition. In some parts of the world, iodine deficiency is common, but the addition of iodine to table salt has virtually eliminated this problem in the United States.

Complications

Untreated hypothyroidism can lead to a number of health problems:

- **Goiter.** Constant stimulation of your thyroid to release more hormones may cause the gland to become larger — a condition known as a goiter. Although generally not uncomfortable, a large goiter can affect your appearance and may interfere with swallowing or breathing.
- **Heart problems.** Hypothyroidism may also be associated with an increased risk of heart disease and heart failure, primarily because high levels of low-density lipoprotein (LDL) cholesterol the "bad" cholesterol that can occur in people with an underactive thyroid.

- **Mental health issues.** Depression may occur early in hypothyroidism and may become more severe over time. Hypothyroidism can also cause slowed mental functioning.
- **Peripheral neuropathy.** Long-term uncontrolled hypothyroidism can cause damage to your peripheral nerves. These are the nerves that carry information from your brain and spinal cord to the rest of your body. For example, your arms and legs. Peripheral neuropathy may cause pain, numbness and tingling in affected areas.
- **Myxedema.** This rare, life-threatening condition is the result of long-term, undiagnosed hypothyroidism. Its signs and symptoms include intense cold intolerance and drowsiness followed by profound lethargy and unconsciousness. A myxedema coma may be triggered by sedatives, infection or other stress on your body. If you have signs or symptoms of myxedema, you need immediate emergency medical treatment.
- **Infertility.** Low levels of thyroid hormone can interfere with ovulation, which impairs fertility. In addition, some of the causes of hypothyroidism such as autoimmune disorder that can also impair fertility.
- **Birth defects.** Babies born to women with untreated thyroid disease may have a higher risk of birth defects compared to babies born to healthy mothers. These children are also more prone to serious intellectual and developmental problems. Infants with untreated hypothyroidism present at birth are at risk of serious problems with both physical and mental development(45). But if this condition is diagnosed within the first few months of life, the chances of normal development are excellent.

3.3.9 CLINICAL FEATURES

Hypothyroidism signs and symptoms may include:

- Fatigue
- Increased sensitivity to cold
- Constipation
- Dry skin
- Weight gain
- Puffy face
- Hoarseness
- Muscle weakness
- Elevated blood cholesterol level
- Muscle aches, tenderness and stiffness
- Pain, stiffness or swelling in your joints
- Heavier than normal or irregular menstrual periods
- Thinning hair
- Slowed heart rate
- Depression
- Impaired memory

Symptoms of HYPOTHYROIDISM

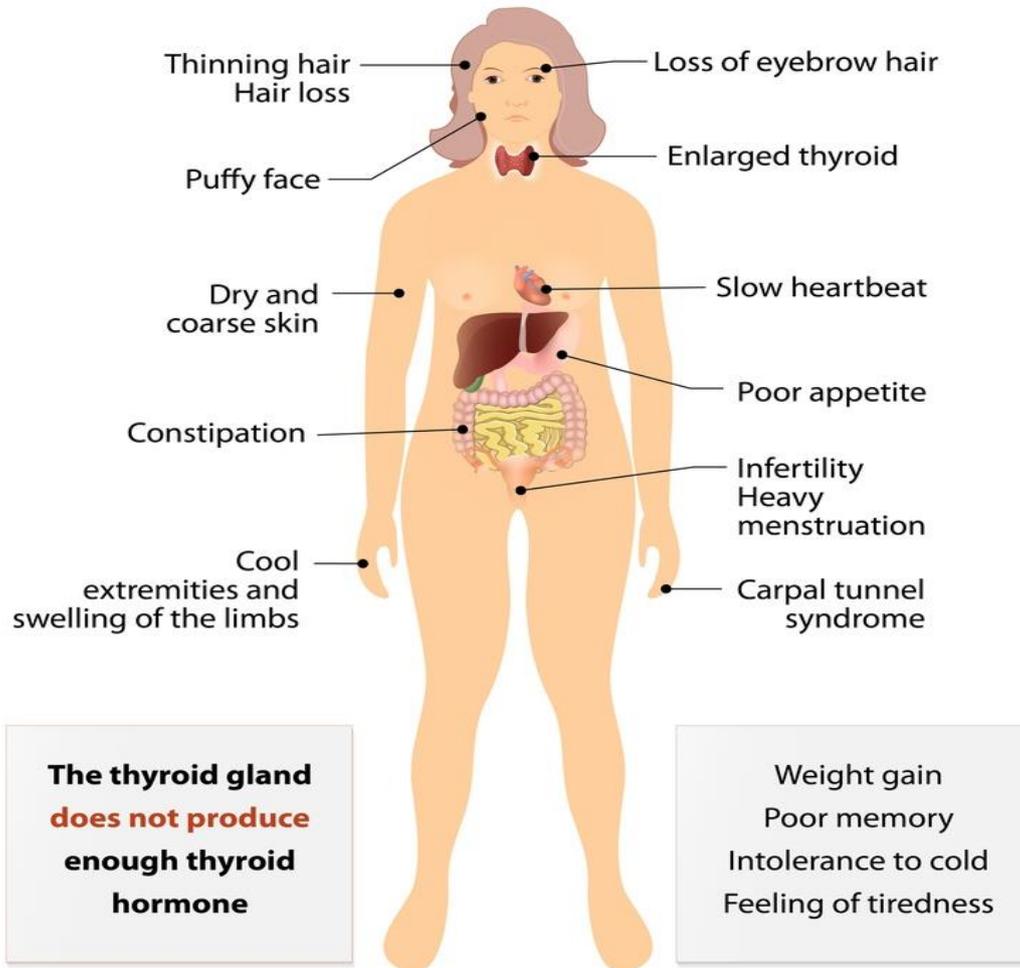


Figure 9: Symptoms of hypothyroidism

3.3.10 PATHOPHYSIOLOGY OF HYPOTHYROIDISM:

The thyroid is a butterfly-shaped gland located in the front of the neck just above the trachea. It weighs approximately 15 to 20 grams in the adult human. The thyroid produces and releases into the circulation at least two potent hormones, thyroxine (T_4) and triiodothyronine (T_3), which influence basal metabolic processes and/or enhance oxygen consumption in nearly all body tissues(20). Thyroid hormones also influence

linear growth, brain function including intelligence and memory, neural development, dentition, and bone development(1).The thyroid gland produces T₄ and T₃ utilizing iodide obtained either from dietary sources or from the metabolism of thyroid hormones and other iodinated compounds. About 100 µg of iodide is required on a daily basis to generate sufficient quantities of thyroid hormone. Dietary ingestion of iodide in the United States ranges between 200 and 500 µg/day and varies geographically; ingestion is higher in the western part of the United States than in the eastern states. The specialized thyroid epithelial cells of the thyroid gland are equipped with a Na/I symporter that helps concentrate iodide 30 to 40 times the level in plasma to ensure adequate amounts for the synthesis of thyroid hormone. The iodide trapped by the thyroid gland is subsequently oxidized to iodine by the enzyme thyroid peroxidase(38). The iodine then undergoes a series of organic reactions within the thyroid gland to produce tetraiodothyronine or thyroxine (T₄) and triiodothyronine (T₃)(46). T₃ is also produced in other tissues such as the pituitary, liver, and kidney by the removal of an iodine molecule from T₄. T₄ is considered to be more of a pro-hormone, while T₃ is the most potent thyroid hormone produced. T₄ and T₃ are both stored in the thyroglobulin protein of the thyroid gland and released into the circulation through the action of pituitary derived thyrotropin (thyroid stimulating hormone or TSH)(47). A normal individual produces from the thyroid gland approximately 90 to 100 µg of T₄ and 30 to 35 µg of T₃ on a daily basis. An estimated 80 percent of the T₃ produced daily in humans is derived from peripheral metabolism (5'-monodeiodination) of T₄, with only about 20 percent secreted directly from the thyroid gland itself. On a weight basis, T₃ is about 3 to 5 times more potent as a thyroid hormone than T₄ and is believed to be the biologically active form of the hormone(48). TSH, secreted by thyrotroph cells located in the anterior pituitary gland, regulates thyroid gland function and hormone synthesis and release(40).

The pituitary secretion of TSH in turn is influenced by the releasing factor, thyrotropin-releasing hormone (TRH) produced in the hypothalamus. The secretion of both TSH and TRH is regulated by negative feedback from thyroid hormone, predominantly T_3 , from the circulation and/or T_3 that is produced locally from intracellular conversion of T_4 to T_3 . When circulating thyroid hormone levels are elevated, both the synthesis and secretion of serum TSH are blunted(49). In contrast, when circulating levels of T_4 and T_3 are low, serum TSH levels are increased in a compensatory fashion. The geometric mean level of serum TSH in normal individuals is approximately $1.5 \mu\text{U/ml}$ as recently reported in the NHANES III study(50). When hypothalamic pituitary function is intact, serum TSH levels are markedly suppressed (to $<0.05 \mu\text{U/ml}$) in patients with hyperthyroidism and elevated circulatory levels of serum thyroxine, while a marked increase in TSH ($>5 \mu\text{U/ml}$) occurs in patients with hypothyroidism and low blood levels of serum T_4 . The mechanism through which TSH binds to and activates the thyroid gland is well understood. TSH binds to a specific membrane receptor located on the surface of the thyroid epithelial cell and activates the cell signaling mechanisms through the enzyme adenylate cyclase located in the plasma membrane(51). Activation of adenylate cyclase increases intracellular cyclic adenosine monophosphate (cAMP) levels, which in turn stimulate additional intracellular signaling events that lead to thyroid hormone formation and secretion. T_4 and T_3 circulate bound primarily to carrier proteins. T_4 binds strongly to thyroxine binding globulin (TBG, ~ 75 percent) and weakly to thyroxine binding prealbumin (TBPA, transthyretin, ~ 20 percent) and albumin (~5 percent). T_3 binds tightly to TBG and weakly to albumin, with little binding to TBPA. The geometric mean for serum T_4 in normal individuals is approximately $8 \mu\text{g/dl}$, while the mean serum T_3 level is approximately 130 ng/dl . Under normal protein binding conditions, all but 0.03 percent of serum T_4 and 0.3 percent of serum T_3 is protein bound. Only a small

amount of unbound (or free) T₄ (approximately 2 ng/dl) and T₃ (approximately 0.3 ng/dl) circulates in a free state, and it is this free concentration that is considered responsible for the biological effects of the thyroid hormones(52).

There are physiologic situations associated with a change in the serum concentration of these thyroid-binding proteins—such as pregnancy, non-thyroidal illness, or ingestion of drugs—that affect the level and/or affinity of these binding proteins(53). Under these circumstances, the serum concentrations of total T₄ and total T₃ change in parallel to the changes that occur in the thyroid hormone binding proteins, but the serum concentrations of free T₄ and free T₃ remain normal and the individual remains euthyroid(54). In contrast, the serum concentration of free T₄ and free T₃ are raised in hyperthyroidism and decreased in hypothyroidism.

3.3.11 TESTING FOR DIAGNOSIS OF HYPOTHYROIDISM

The most sensitive test in an ambulatory population at risk for thyroid dysfunction is the serum TSH. Serum TSH assays today have sufficient sensitivity and specificity to identify individuals with all forms of thyroid dysfunction in the general population(55). However, among individuals with serious, acute illness, the serum TSH is less specific for thyroid disease because a serious illness alone can depress TSH. TSH screening of the neonatal population to detect congenital hypothyroidism before it is clinically evident is mandated throughout the United States and in many other countries. Serum TSH measurements may yield misleading results for individuals with changing levels of thyroid hormones. For example, a serum TSH level may remain high for weeks in hypothyroid patients treated with T₄. Similarly, serum TSH levels may remain low for weeks after the serum T₄ level falls to normal in patients treated for hyperthyroidism.

Diagnosis of Hypothyroidism:

Hypothyroidism is a hypometabolic state that results from a deficiency in T_4 and T_3 . Its major clinical manifestations are fatigue, lethargy, cold intolerance, slowed speech and intellectual function, slowed reflexes, hair loss, dry skin, weight gain, and constipation. It is more prevalent in women than men. The most common cause of hypothyroidism is disease of the thyroid itself, primary hypothyroidism. The most common cause of primary hypothyroidism is chronic autoimmune thyroiditis (Hashimoto's disease), in which the thyroid is destroyed by antibodies or lymphocytes that attack the gland. Other causes are radioactive iodine and surgical therapy for hyperthyroidism or thyroid cancer, thyroid inflammatory disease, iodine deficiency, and several drugs that interfere with the synthesis or availability of thyroid hormone. Hypothyroidism may also occur rarely (<1 percent of cases) as a result of deficiency of TRH or impaired TSH secretion due to hypothalamic or pituitary disease, respectively. This is known as secondary or central hypothyroidism because of the negative feedback relationship between serum T_4 and T_3 levels and TSH secretion. People with primary hypothyroidism have high serum TSH levels. If an individual has a high serum TSH value, serum free T_4 should be measured. The concomitant finding of a high serum TSH concentration and a low free T_4 level confirms the diagnosis of primary hypothyroidism. People with a high serum TSH concentration and a normal or low-normal serum free T_4 level have, by definition, subclinical hypothyroidism. The diagnosis of secondary hypothyroidism is based on the findings of a low serum free T_4 level and a serum TSH level that is normal or low. People with secondary hypothyroidism are unlikely to be detected by a screening program based on measurements of serum TSH, but the condition is much less common than primary hypothyroidism.

3.3.12 CONVENTIONAL TREATMENT FOR HYPOTHYROIDISM

Historical perspective

By the end of the 19th century, myxedema had been attributed to diminished thyroid function and a cretinism-like condition (also described as cachexia strumipriva) had been observed following thyroidectomy in animals and humans(56). Moreover, xenotransplantation of animal thyroid gland had been shown to improve symptoms in women suffering from myxedema temporarily. In 1891, Murray described the first regime of thyroid hormone replacement, subcutaneously injecting extract of sheep thyroid into a patient with hypothyroidism(2). It was soon shown that oral administration of thyroid extract was as effective. In 1914, Kendall purified thyroxine crystals, which became commercially available(3). Harrington identified the structure of thyroxine in 1926 and synthetic thyroxine was available for clinical use by the 1930s. However, it took many more years before thyroxine became preferable to desiccated thyroid extract as the treatment of choice for hypothyroidism(4). In 1952, Gross and Pitts-River identified the more potent liothyronine.

Dosage of levothyroxine

Levothyroxine is the treatment of choice for hypothyroidism. It has a 7 day half-life, allowing daily dosing. A randomized controlled trial has shown that, in patients with no significant comorbidities, initiation of levothyroxine at a full dose based on body weight (1.6 µg/kg/day) is safe, effective, and requires fewer resources than using a more traditional approach of starting with a small dose and gradually titrating upward(36). The

exceptions to this are the elderly and patients with known ischemic heart disease (see the “Levothyroxine replacement in special circumstances” section of this review).

Timing of levothyroxine

Conventionally, hypothyroid patients are advised to take levothyroxine on an empty stomach half an hour before breakfast to prevent impairment of absorption by food. Several recent studies have looked at whether a bedtime dosage of levothyroxine is preferable(57). A small nonrandomized study involving eleven hypothyroid patients on a stable dose of morning levothyroxine found a decrease in mean TSH and an increase in free thyroid hormone levels when the timing of levothyroxine dosage was changed to bedtime(58). The same investigators, in a subsequent randomized double-blind crossover trial of 105 consecutive patients, have reaffirmed that biochemical control was best achieved by night-time dosing. Taking levothyroxine at bedtime resulted in a decrease in mean TSH of 1.25 mIU/L (95% confidence interval [CI] 0.60–1.89), and an increase in free T4 of 0.07 ng/dL (95% CI 0.02–0.13) and total T3 of 6.5 ng/dL (95% CI 0.9–12.1).[34]However, there were no improvements in quality of life scores, blood pressure, or lipid profile. A retrospective study of 15 elderly patients in a nursing home showed a no significant decrease in mean TSH of 0.29 mIU/L when the time of administration of levothyroxine was changed from early morning to midnight(59). In contrast, a randomized crossover trial in the US compared taking levothyroxine in the fasting state, with breakfast, or at bedtime in 65 patients with primary hypothyroidism and thyroid cancer, and found that TSH levels were significantly lower and less variable when levothyroxine was taken in the fasting state than at other times(60). Furthermore, Rajput et al randomized 77 patients with newly diagnosed autoimmune hypothyroidism to taking their levothyroxine half an hour before breakfast or two hours after their evening meal,

and found no difference in TSH, lipid profile, clinical symptoms, quality of life scores, or the dose required to achieve euthyroidism between the two groups(61). The conflicting findings of different studies may reflect heterogeneity in the conditions of patients studied (for example, newly diagnosed patients versus patients on a stable dose of levothyroxine, and patients with thyroid cancer versus patients with autoimmune hypothyroidism) as well as in eating habits in relation to bedtime in the different study populations. Nevertheless, these studies suggest that bedtime dosing of levothyroxine could be tried as an alternative strategy in those patients who have problems in taking morning levothyroxine on an empty stomach(62).

Monitoring thyroid function during levothyroxine replacement

When initiating levothyroxine therapy, serum TSH should be measured to monitor for adequate replacement. TSH can take up to 4 months to normalize, even when starting on a full dose replacement regimen, due to thyrotroph hyperplasia(60). It is recommended that the TSH is measured 6–8 weeks after initiation of, or a change in levothyroxine dose. Once the patient is on a stable dose of levothyroxine, annual monitoring of TSH is recommended, although a retrospective study suggests that the monitoring interval could be safely increased to 18 months(10). Common causes of persistently elevated TSH in patients on levothyroxine replacement. Causes of persistently elevated thyroid stimulating hormone in a patient on levothyroxine replacement are

- Inadequate levothyroxine dose
- Poor compliance with medication (biochemistry usually showing high thyroid-stimulating hormone with normal free T4)
- Interaction with concomitant drugs

- Taking levothyroxine with food
- Malabsorption
- Coexisting celiac disease or autoimmune gastritis
- Interference with the laboratory assay due to heterophil antibodies
- Coexisting thyroid hormone resistance (rare)

It is generally recommended to aim for a TSH in the lower half of the normal range, ie, typically <2.5 mIU/L in patients with primary hypothyroidism on levothyroxine replacement(12,37). In a small study of 21 patients with primary hypothyroidism, titrating the dose of levothyroxine until the TSH was at the lower end of reference range or suppressed below the reference range was found to be associated with improved wellbeing in some patients.[40]However, this observation was not confirmed by a double-blind randomized crossover trial, which has shown that small changes in levothyroxine dose to achieve a lower TSH do not result in an improved quality of life score(29). Furthermore, in a recent prospective study of 42 patients initiating levothyroxine treatment for newly diagnosed primary hypothyroidism, there was no difference in lipid profile, body composition, or bone mineral density in patients maintained on low TSH (0.4–2.0 mIU/L) as compared with those maintained on higher TSH (2–4 mIU/L) for 12 months, although resting energy expenditure was higher in patients maintained on the lower TSH target(58). Finally, overtreatment with levothyroxine leading to a suppressed TSH of below 0.1 mIU/L has been shown to be associated with adverse skeletal health, particularly in the elderly . Taken together, these observations suggest that the target TSH level for most nonpregnant patients with primary hypothyroidism on levothyroxine replacement should be the population

reference range and one should not necessarily increase the dose of levothyroxine in asymptomatic people with a TSH in the upper half of the normal range.

Drug interactions with levothyroxine

Several medications, supplements, and food can interfere with the absorption and action of levothyroxine. Common drugs that can affect levothyroxine absorption include iron, calcium, cholestyramine, and aluminum and levothyroxine must be taken at least 4 hours apart from these drugs(10). Enzyme inducers, such as phenytoin, carbamazepine, phenobarbital, and rifampicin can increase the clearance of levothyroxine, necessitating an increased dose(15). Of women starting estrogen hormone replacement treatment, 35% were shown to need an increase in levothyroxine dose, thought to be due to increased thyroxine-binding globulin(25). It is noteworthy that hypothyroidism itself can lead to altered metabolism of medications, such that when rendered euthyroid, patients with hypothyroidism may need alterations in the dose of their medications. For example, initiation of levothyroxine in a hypothyroid patient may enhance the effect of warfarin, which may need dose adjustment(63).

Substances that interact with levothyroxine

Drugs and supplement that decrease the effect of Levothyroxine are Iron, Calcium carbonate, Cholestyramine, Aluminum, Cimetidine, Sucralfate, Iodine, Selenium, Magnesium, Zinc, Soya, Fiber, Caffeine, Antacids, Increased levothyroxine clearance, Phenytoin, Carbamazepine, Phenobarbital, Rifampicin, Increased Levothyroxine binding, Estrogen hormone replacement therapy, Drug affected by levothyroxine, Drug effect enhanced by levothyroxine, Warfarin, Amitriptyline, Drug effect decreased by levothyroxine, Propranolol.(20,61)

3.3.13 COMPLEMENTARY TREATMENT FOR HYPOTHYROIDISM:

The National Institutes of Health National Center for Complementary and Alternative Medicine (NIH NCCAM) defines complementary medicine as being used along with standard medical treatments, and alternative medicine as being used in place of standard medical treatments. Integrative medicine is a comprehensive approach to care that includes a patients' mind body and spirit; this combines standard medicine with CAM practices

TYPES OF COMPLEMENTARY AND ALTERNATIVE MEDICINE (CAM)

The NIH NCCAM uses five categories to describe the different types of CAM. It would be difficult to create a comprehensive list, but some examples are described below:

MIND-BODY MEDICINES

These are based on a belief that the mind is able to affect your body. Examples include:

- Yoga
- Meditation
- Hypnosis

BIOLOGICALLY-BASED PRACTICES

These include things most often found in nature, and includes dietary supplements and herbal products. Examples include:

- Vitamins
- Herbs
- Special diets

The patients with Hypothyroidism are recommended to practice a special diet that avoids foods that contain iodine. In fact, use of iodine either in liquid form or as a supplement is

not recommended. It's also common for patients to be told to take Vitamin D or calcium supplementation.

MANIPULATIVE AND BODY-BASED PRACTICES

These are based on working with the body and are thought to have underlying benefits for the mind as well. Examples include:

- Massage
- Chiropraxy

ENERGY MEDICINE

Energy medicine invokes the belief that the body has energy fields that can be manipulated for healing and wellness. Examples include:

- Reiki
- Tai Chi

WHOLE MEDICAL SYSTEMS

These systems include beliefs and approaches to healing and wellness that come from all of the world and from many cultures[44]. Examples include:

- Naturopathy
- Homeopathy
- Chinese medicine
- Vodun/Expiritism
- Ayurvedic medicine

3.3.14 EFFECT YOGA AND PRANAYAMA ON HYPOTHYROIDISM

Yogic disciplines involving Pranayama claimed to have very good effect on Thyroid function , thus creating psychic and somatic equilibrium of the bodily functions.

Pranayama in actuality is regarded as the science of controlled as well as conscious expansion of the prana representing the life force. The practice of pranayama helps in facilitating the therapeutic potential for several systemic complications. The study conducted on Diagnosis and Management of Hypothyroidism states that hypothyroidism presents a large epidemiological burden in India(37). As a result of subtle and non specific clinical symptoms and signs, the condition often goes undiagnosed and is not adequately treated when it is detected. There is heterogeneity in the diagnostic and treatment approaches to hypothyroidism. As a result of the physiological changes in thyroid hormones with age and illness, it is important to tailor the diagnosis and management of this condition in specific populations including pregnant women, infants, children, geriatric patients, and those with comorbid conditions. Enhanced understanding and education of physicians and patients can help to improve the outcomes of treatment in hypothyroidism which should be focused on patient-centered care. Policies and reforms should be crafted and implemented at the national level to curb public health challenges of hypothyroidism. This publication summarizes the recommendations of a national advisory board meeting to identify and bridge the gaps in understanding of the diagnosis and treatment of hypothyroidism in India. As a complement to clinical judgment, these recommendations will foster the diagnosis and management of hypothyroidism in the community and clinics for the benefit of the patients. In the study conducted in 2017 stated that hypothyroidism is a commonly prevailing disorder in adult Indian population(63). Hypothyroidism may occur as a result of primary gland failure or insufficient thyroid gland stimulation by the hypothalamus or pituitary gland. Hypothyroidism is a common endocrine disorder resulting from deficiency of thyroid hormone or, more rarely, from their impaired activity at tissue level.

Hypothyroidism is characterized by a broad clinical spectrum ranging from an overt state of myxedema, end-organ effects and multisystem failure to an asymptomatic or subclinical condition with normal levels of thyroxine and triiodothyronine and mildly elevated levels of serum thyrotropin(1). The prevalence of hypothyroidism in the developed world is about 4-5%. In a developing and densely populated country like India, communicable diseases are priority health concerns due to their large contribution to the national disease burden.

The study on The Thyroid registry states that Patients with SCH have a high rate of progression to overt hypothyroidism(61). However, the true prevalence of SCH could not be determined as T4 values were not a part of the clinical assessment in majority of patients ($n = 1208$); this could be higher in our population. In the study, TSH and T4 levels were available for only 291 patients at baseline. This highlights the fact that common clinical practice is focused only on screening patients for TSH levels and does not include T4 estimation. In addition, for patients with TSH level at borderline or <10 mIU/L, it is recommended that the decision to treat should be based on T4 levels. The thyroid hormone profile, levothyroxine dose, and resolution of symptoms, if any, were being recorded for subsequent follow-up visits. However, this study brings out an important deficit in the clinical practice and management of hypothyroidism in India, warranting the need for educating our medical fraternity. Appropriate assessment with both T4 and TSH levels and when required, assessment of T3 level and thyroid peroxidase antibodies are essential and should be practiced in routine clinical setup. Guidelines suggest a diagnosis of hypothyroidism based on TSH and T4 levels. However, most of the patients from this registry study were advised treatment with levothyroxine based on TSH levels alone, thus highlighting the need for awareness and scientific education among clinicians in India. Levothyroxine replacement is the standard of

treatment for hypothyroidism and is tailored. The use of standard doses (100, 75, and 25 mcg) of levothyroxine may point toward empirical management practices. However, this needs to be further evaluated.

In the study it is observed that a significant reduction in total cholesterol (8.99%), LDL (9.81%) and triglycerides (7.65%), and significant improvement in HDL cholesterol (9.65%)(60). The mean thyroxine medication score was medication was observed in any of the subjects at the end of the study. Previously, two studies have looked into the efficacy of yoga in hypothyroidism. In a study on 20 hypothyroidism women, 1 month of yoga practice showed significant improvement in the quality of life(64), and in another study, 6 months of pranayama (yogic breathing) practice improved forced expiratory volume in lung function test of women with hypothyroidism (63). These studies are suggestive of positive role of yoga practice in hypothyroidism. Similarly, in our pilot study we observed the positive effect of yoga practice in hypothyroidism. In earlier studies, 12 weeks of yoga intervention in elderly women with diabetes showed significant reduction in triglycerides, total cholesterol, LDL and improved HDL(25). In another randomized control trial, 6 months of yoga nidra (yogic relaxation method) practice was shown to reduce the serum TSH level in females with menstrual abnormalities(10). In our study also we found similar results as that of the previous one. The exact mechanism behind these finding is not known. One of the possible mechanisms could be increased physical activity due to Suryanamaskar and physical postures might have helped in reducing triglycerides, total cholesterol, LDL and increased HDL cholesterol(29). The pranayama, relaxation practices and meditation are known to reduce stress and modulate the hypothalamo-pituitary–adrenal axis(57). Similarly, yoga practice might influence the hypothalamo-pituitary–thyroid axis and lead to decrease in serum TSH. This study shows the potential role of yoga in the management of hypothyroidism and preventions of

cardiac disease due to hypothyroidism(65).Future studies should include the randomized controlled design with a larger sample size and other objective variables like cardiovascular parameters, psychological variable along with thyroid hormones. Long-term practice of yoga may help in improving cholesterol level, serum TSH and thyroxine requirement in female patients suffering from hypothyroidism. However, further randomized controlled studies need to be conducted. The effect of yogic practices was significant for hypothyroid patients in improving their quality of life. Prior to the therapy, scores on the physical health domains were low,the improved significant after therapy indicate that the physical health of hypothyroid patients had been improved. Patients reported that they were more finding the activities of daily living easier, they were more energetic, mobile and their work capacity had increased. They also reported less pain and discomfort. The results also indicated a positive effect from yoga practice on psychological health. Following therapy patients scores had markedly improved from pre therapy scores with a post therapy scores. Subject reported feeling more positive and expressed higher perceptions of self esteem,nothing that they were happy with their body image and appearance.

In the domine of social relationships. Patients reported a significant increase in the scores, The quality of life scores on social relationship domin before yoga therapy compared to post therapy rating.The practice of yoga generally leads to a more efficient functioning of the psycho- neuro- endocrine and immune system. This is affected by increased physical flexibility and greater awareness of breathing and body posture. A continued focus upon body posture and breathing and body posture. A continued focus upon body posture andbreathing in yoga serves to emphasize an awareness of the impact of changing emotional states upon the body. In turn , Poonam singh stated that such awareness serves to promote a more balanced equilibrium between the sympathetic and

parasympathetic autonomic nervous system and thus state of health. Another study conducted by Swami G et al on effect of yogic practice on pulmonary function tests of hypothyroidism patient concludes that yoga has beneficial effect on pulmonary function test of hypothyroid, patients use to improve in their respiratory muscle strength and increased air entry which increase oxygen concentration at tissue level(54,55).A study conducted by Minal S.Pajai et al highlights the importance of Ujjayi as follows: Ujjai is sometimes called “the ocean breath”.Ujjayi is the diaphragmatic breath, which first fills the lower belly(activating the first and second chakras)and finally moves into the upper chest and throat. Inhalation and exhalation are both done through the nose. The “Ocean sound” is created by moving the glottis as air passes in and out. As the throat passage is narrowed it creates a rushing sound. The length and speed of the mind is also facilitated. It has a positive effect on whole mind and body as particularly on nervous system. It improves the functioning of all endocrine gland by its soothing effect especially thyroid gland. It helps to secrete hormones from thyroid gland in required quantity.The study concluded that yoga is valuable in helping the hypothyroidism patient to manage their disease related symptoms(66).Yoga may be concluded as supportive or complementary therapy in conjunction with medical therapy for the treatment of hypothyroid disorder. In the Research study established that the yogic Asana,Pranayama and the kriyas are the best and useful as they help not only to strengthen each organ and develop every muscle of the body but also regulate the circulation of body blood, purity of lungs, inspire the mind and thus develop the harmonious development of human personality(41).

Pranayama is the science of respiration. The author of Hatha Pradipaka give eight varieties of pranayama, one of which is Ujjayi. The chief characteristic of Ujjayi pranayama improves the circulation of blood can capable of producing very high pressure in the lung and in the thorax(62).Yogic breathing, otherwise referred to as pranayama

involves with rhythmic and slower and deeper breathing, inspired by the predominant usage of abdominal musculature as well as the diaphragm. The breathing is held momentarily with full inspiration, which is within the limits of an individual's comfort as it allowed a spontaneous exhalation at a slower pace. The respiration is paused again within the individual's limits of comfort with full exhalation. The incorporation of pranayama technique over conventional exercise in particular, appeared to have beneficial for the individuals who are susceptible to ischemic heart disease and other cardiovascular complications. The practice involving the activity which is gradually incremental, aids in accelerating the recovery processes initially after a person who suffered with myocardial infarction. Even when the practice of pranayama has been popularized only to a limited extent in Asian region, especially in India, there has been a significant shift among the western society towards practicing yoga and pranayama over the recent year.

UPANISHAD'S DEPICTION ON THE PRACTICE OF PRANAYAMA

There are several reports on ancient scripts that strongly supports the benefits of practice of pranayama.

The *Chhandogya Upanishad* (1:11:5) says

:

सर्वाणि ह वा इमानि भूतानि ।
प्राणमेवाभिसंविशंति प्राणमभ्युज्जिहते ॥

In prana all moveable and immoveable beings merge (during dissolution) and rise out of prana (during creation).¹Pranayama is the pause in the movement of inhalation and exhalation when that is secured. Inhalation and exhalation are methods of inducing retention. Retention is the key because it allows a longer period for the assimilation of prana, just as it allows more time for the exchange of oxygen and carbon dioxide in the cells. As the breath is also intimately connected with various functions and organs of the body as well as the mind, by controlling the breath we also influence all these dimensions. A balanced, sequential movement from gross to subtle, from annamayakosha to anandamayakosha, is the aim.

In the *Hatha Yoga Pradipika*(1:67) it has been said:

पीठानि कुंभकाश्चित्रा दिव्यानि करणानि च ।
सर्वाण्यपि हठाभ्यासे राजयोगफलावधिः ॥

Asanas, various types of kumbhaka (pranayama) and the other various means of illumination should all be practiced in the hatha yoga system until success in raja yoga is attained.

The *Shiva Samhita*(3:57) states:

याममात्रं यदा धर्तुं समर्थः स्यात्तदाद्भुतः ।
प्रत्याहारस्तदैव स्यान्नांतरा भवति ध्रुवम् ॥

When one attains the power of holding the breath for three hours, then certainly the wonderful state of pratya-hara is reached without fail.

It is said in the *Kathopanishad*(2:3:2):

यदिदं किं च जगत्सर्वं प्राण एजति निःसृतम् ।

This whole world - whatever there is - vibrates having originated from prana. This cosmic prana, also called *mahaprana*, came into being at the time of creation. Thus, in order to fully understand prana, one must go back to the beginning of creation. The tranquillizing practices of pranayama are designed to relax the body and mind, while simultaneously increasing the pranic capacity and conscious awareness.

YOGA

Yoga means 'union' or 'connection'. In Sanskrit, the word 'yoga' is used to signify any form of connection. Yoga is both a state of connection and a body of techniques that allow us to connect to anything. Conscious connection to something allows us to feel and experience that thing, person, or experience. The experience of connection is a state of yoga, a joyful and blissful, fulfilling experience. Awareness is the secret of yoga.

Patanjali's definition of yoga

The great sage Patanjali, in the system of Raja Yoga, gave one of the best definitions of yoga. He said, 'Yoga is the blocking (*nirodha*) of mental modifications (*chitta vritti*) so that the seer (*drashta*) re-identifies with the (higher) Self. Patanjali's system has come to

be the epitome of Classical Yoga Philosophy and is one of the 6 or 7 major philosophies of India.

Hatha yoga definition

Hatha yoga includes postures (*asana*), breathing techniques (*pranayama*), purification techniques (*shat karmas*) energy regulation techniques (*mudra* and *bandha*). The definition of yoga in the Hatha Yoga texts is the union of the upward force (*prana*) and the downward force (*apana*) at the navel center (*manipura chakra*). Hatha yoga teaches us to master the totality of our life force, which is also called prana. By learning how to feel and manipulate the life force, we access the source of our being.

Patanjali gives a wide range of techniques that slowly harmonizes the mind and gradually induces more subtle perception. However, the main path of Patanjali is contained within eight fundamental stages. The first five are:

- Yama (social code)
- Niyama (personal code)
- Asana (sitting pose)
- Pranayama (control of prana)
- Pratyahara (sense withdrawal)
- Dharana (concentration)
- Dhyana (meditation)
- Samadhi (superconsciousness)

These first five stages are the esoteric/bahiranga (external) practices of yoga. They progressively prepare the body-mind for the last stages are the esoteric or antaranga (internal) practices of yoga. The first five stages negate consciousness, whilst the last three stages expand consciousness.

1.10 PRANAYAMA

Practicing Pranayama helps in controlling the breath. The terminology was coined from the two root words namely 'prana' meaning 'vital energy' and 'ayama' meaning 'extension/breath'. The practice of pranayama cannot be considered as a simplified breathing exercise; rather it aims at channeling the flow of excess oxygen into the lungs, thereby, transporting it to all the systemic organs of the body. In the pranayama practices there are four important aspects of breathing which are utilized. These are:

- Pooraka or inhalation
- Rechaka or exhalation
- Antarkunbhaka or internal breath retention
- Bahirkumbhaka or external breath retention.

As Yoga was globally regarded as 'The ancient Indian science' which comprised of practices, which involved specific postures (asanas) and regulated breathing (Pranayama). There were reports suggesting different types of pranayama exhibiting different autonomic and cardiac responses among healthy humans. Many reports claimed that the practice of pranayama aids in eliminating the toxins away from the body and helps in maintaining a good health.

There are different variations/types of pranayama such as

- AnulomVilom Pranayama
- Bahya Pranayama
- Bhastrika Pranayama
- Bhramari Pranayama

- Digra Pranayama
- Kapalbhatai Pranayama
- NadiSodhana Pranayama
- Shitali Pranayama
- Udgit Pranayama
- Ujjayi Pranayama

1.11 GHERANDA SAMHITA

Gheranda Samhita is a Sanskrit text of Yoga in Hinduism. It is one of the three classic texts of hatha yoga . The Gheranda Samhita calls itself a book on ghatastha yoga, which literally means "vessel yoga", wherein the body and mind are depicted as vessels that carry and serve the soul (atman, purusha). The text teaches a seven limbed. Gheranda Samhita is a step by step detailed manual of yoga taught by sage Gheranda to student Chanda Unlike other hatha yoga texts, the Gheranda Samhita speaks of a sevenfold Yoga and Pranayama is one of the important practice explained in this text

1.12 UJJAYI PRANAYAMA – The Psychic Breath

Ujjayi Pranayama or the psychic breath soothes the mind and induces a meditative state. Ujjayi means to ‘lift up’. In Ujjayi pranayama, the chest is slightly lifted up as if the inhalation is done from the throat. Ujjayipranayama is mentioned in the yoga text Hatha Yoga Pradeepika and in the Gheranda Samhita.

Ujjayi involves a deep inhalation from both nostrils with a half closed glottis, so that a faint hissing snoring sound is made during the inhalation. Then there is retention of breath followed by exhalation. Those suffering from heart ailments and blood pressure problems should avoid Kumbhaka or retention of breath. This practice should be learnt from a qualified yoga instructor.

4.0 MATERIALS AND METHODS

4.1 SUBJECTS

A total of 120 subjects of both gender with age group ranging between 18 – 55 years will participate in the study.

4.2 DESIGN

4.2.1 Type of design: A Randomized Controlled Trial

4.3 SAMPLE SIZE

120 healthy volunteers of age group between 18 -55yrs will participate in the study. The subjects will be recruited from the Out – patient department of Government Yoga and Naturopathy Medical College Hospital, Chennai

4.4 STUDY CENTRE: Government Yoga and Naturopathy Medical College,Departement of Yoga,Arumbakkam, Chennai -106

4.5 DURATION OF THE STUDY

Duration of the entire intervention procedure:

Training period: 12 week

Intervention period: 12 week

Frequency of practice: twice per day

Duration of practice: minimum of 15 min

4.6 CRITERIA FOR DIAGNOSIS

4.6.1 Inclusion Criteria:

- Inclusion criteria
- Age between 18-55 years
- Both genders
- Pre Diagnosed Hypothyroidism patient
- Patient with Hypothyroidism who are interested in involving themselves in yogic practice.

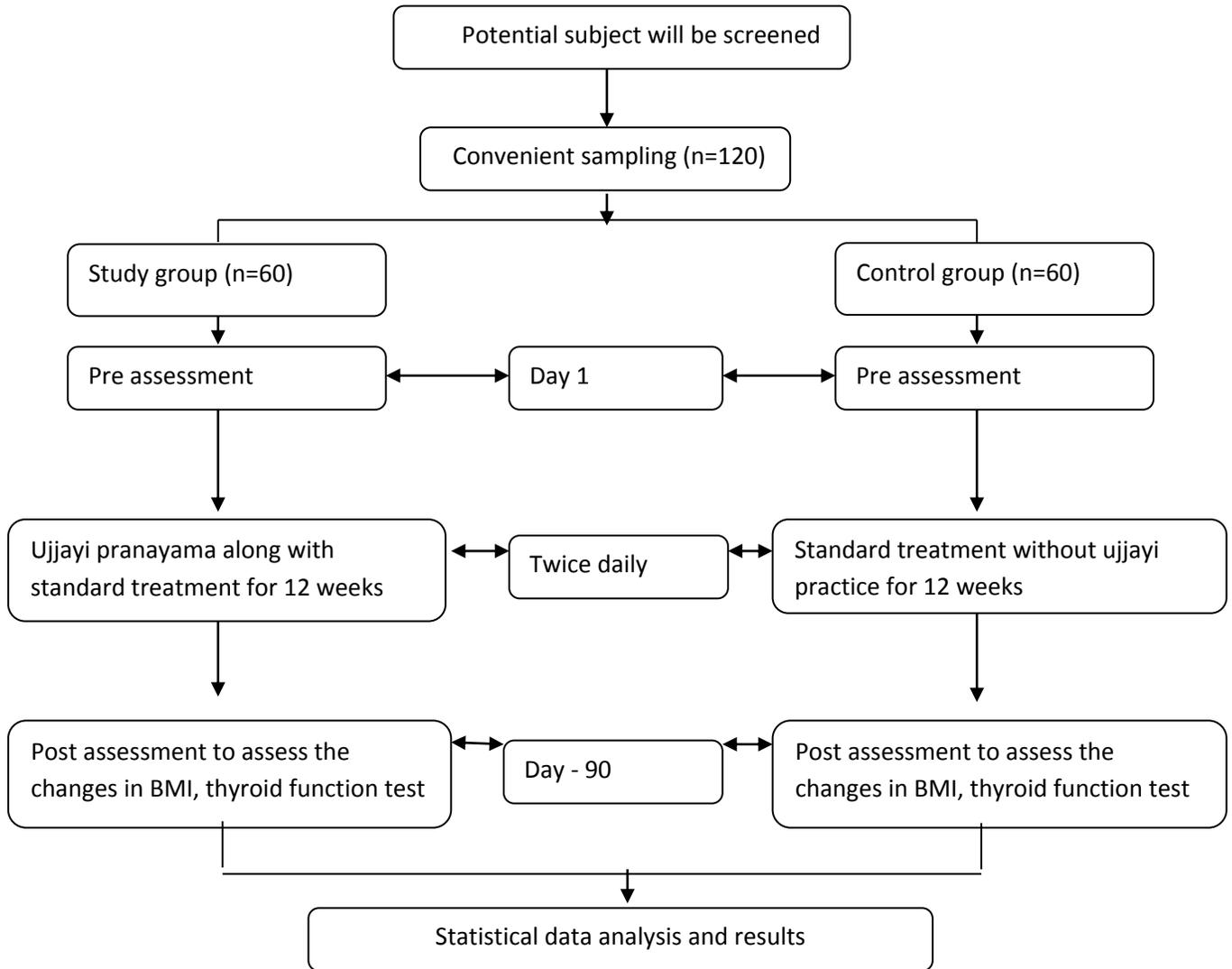
4.6.2 Exclusion criteria:

- Nervous system or respiratory ailments, hypertension and diabetes mellitus
- Cardiovascular disease, renal complications, liver disorders and locomotor disabilities
- Glaucoma, hernia, or ulcers of the stomach or intestine
- Recent abdominal or spinal surgery
- Obese female with pregnancy or Lactation and children
- Any type of Addiction like smoking, alcoholism, tobacco chewing, etc

4.7 WITHDRAWAL CRITERIA:

All subjects are free to withdraw from participation in the study at any time, for any reason, specified or unspecified, and without prejudice to further yogic practices. Subjects who are withdrawn from the study will not be replaced.

4.8 STUDY DESIGN PLAN:



4.9 ASSESSMENTS:

Yoga session for 12 weeks under supervision at Government yoga and naturopathy medical college and hospital, each session lasting for about 15 minutes twice a day for 6 days a week. BMI, Thyroid function Test-[Tri-iodothyronine, Thyroxine, Thyroid-stimulating hormone] for the Patients will be measured before and after 12 week in control group and study group.

Primary outcome variables:

(a) Body Mass Index (BMI = Weight/Height in sq.meter)

(b) Thyroid Function Test – [Tri-iodothyronine T3, Thyroxine T4, Thyroid stimulating hormone TSH]

Description :

Primary outcome variables:

(a) The body mass index (BMI)

Height: Using standard measuring tape, height in meters or centimeters or inches of each patient would be measured. Using standard measuring weighing machine KRUPS, ESSAE, EEROKA LTD to measure the weight in kilogram or pounds of each patient. The body mass index (BMI) is a value derived from the mass (weight) and height of an individual. The BMI is defined as the body mass divided by the square of the body height and is universally expressed in units of kg/m², resulting from mass in kilograms and height in metres.

(b) Thyroid Function test:

Thyroid function tests(TFTs) is a collective term for blood tests used to check the function of the thyroid.TFT is requested to patient who are thought to suffer from hyperthyroidism (overactive thyroid) or hypothyroidism(underactive thyroid) or to monitor the effectiveness of either thyroid –suppression or hormone replacement therapy. It is also requested routinely in conditions linked to thyroid disease, such as atrial fibrillation and anxiety disorder.A TFT panel typically includes thyroid hormones such as thyroid stimulating hormone(TSH),Thyroxine (T4),Triiodothyronine (T3) depending on local laboratory policy.

Thyroid hormones

Thyroid - stimulating hormone

Thyroid stimulating hormone (TSH, thyrotropin) is generally increased in hypothyroidism and decreased in hyperthyroidism. Its measurement is more sensitive test for thyroid hormone function. TSH is produced in the pituitary gland. The production of TSH is controlled by thyrotropin releasing hormone(TRH), Which is produced in hypothalamus. TSH levels may be suppressed by excess free T3 or free T4 in the blood.

Total thyroxine

Total thyroxine is rarely measured, having been largely superseded by free thyroxine tests. Total thyroxine(total T4) is generally elevated in hypothyroidism and decreased in hypothyroidism.It is usually slightly elevated in pregnancy secondary to increased levels of

thyroid binding globulin(TBG).Total T4 is measured to see the bound and unbound level of T4. The total T4 is less useful in cases where there could be protein abnormalities. The total T4 is less accurate due to the large amount of T4 that is bound. The total T3 is measured in clinical practice since the T3 has decreased amount that is bound as compared to T4. Reference range depend upon method of analysis. Results should always be interpreted using the range from the laboratory that performed the test.

Total triiodothyronine

Total triiodothyronine(Total T3) is rarely measured, having been largely superseded by free T3 tests. Total T3 is generally elevated in hyperthyroidism and decreased in hypothyroidism.

4.10 ETHICAL CLEARANCE:

Ethical Clearance: The study was convened after obtaining approval from the Institutional Ethics Committee

Informed Consent:

Subjects who fulfilled inclusion criteria were apprised about the purpose of the study and their rights as research subjects. Informed consent form was administered in English and time was given to each patient to go through the information sheet and their queries were answered. Their right to withdraw any time from the study and the need for willingness to participate voluntarily in the study was explained. The subjects who expressed their willingness to participate in the study gave a signed informed. A sample information sheet and consent form is enclosed as Annexure 1.

4.11 METHODOLOGY:

Men and women with hypothyroidism of age group between 18 - 55 years will participate in the study. The patients will be referred by the In-patient and Out-patient department of Yoga & Naturopathy, Government Medical College and Hospital, Arumbakkam, Chennai-106. After obtaining informed consent, they will be subjected to general measures like BMI, Thyroid Function Test – [Tri-iodothyronine T3, Thyroxine T4, Thyroid – stimulating hormone] and they would be subjected to psychic breath for 15 minutes/ twice a day for 12 weeks, under the supervision of Department of Yoga and Naturopathy, Government Yoga and Naturopathy Medical College, Chennai-106.

4.12 DATA COLLECTION:

- Step 1: Recruitment of patients.
- Step 2: Randomization (control group and yoga group)
- Step 3: Pre data measurement – BMI, Thyroid Function Test –[Tri-iodothyronine T3, Thyroxine T4, Thyroid stimulating hormone]
- Step 4: Ujjayi pranayama
- Step 5: Post data collection BMI, Thyroid Function Test –[Tri-iodothyronine T3, Thyroxine T4, Thyroid stimulating hormone]
- Step 6: Data entry and Analysis

4.13 STATISTICAL ANALYSIS:

Paired t test and one way ANOVA followed with post hoc test was performed to find the variation of mean using R statistical software.

5.0 RESULT:

Total of 120 hypothyroidism patient was included in the study out of that randomly 60 patients was chosen using simple random sampling to practice yoga for 90 days along with conventional medicine and the other 60 patients was included in the control group only with conventional medicine. Two samples in control group were not able to continue the study completely due personal reason. Gender wise distribution among the yoga group and control group was plotted in figure 1 and 2 respectively. Proportion of females were more in the samples, this difference existed largely due to high prevalence of hypothyroidism among females. The average age of the participants in yoga group was 40.21%. The average age of the participants in control group was 41.16%.

Figure 10: Gender distribution within study group

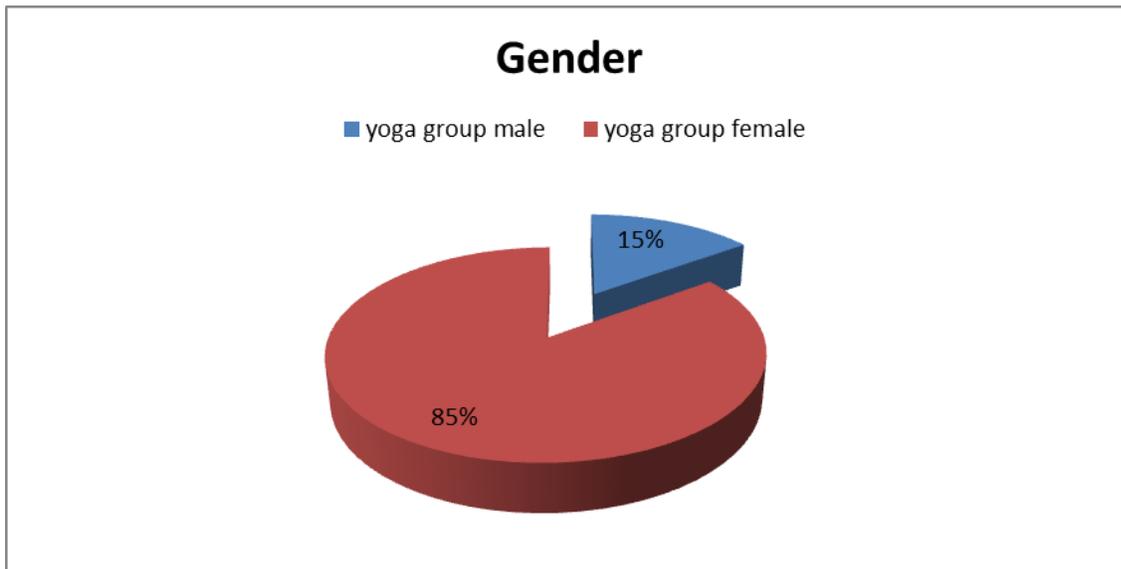
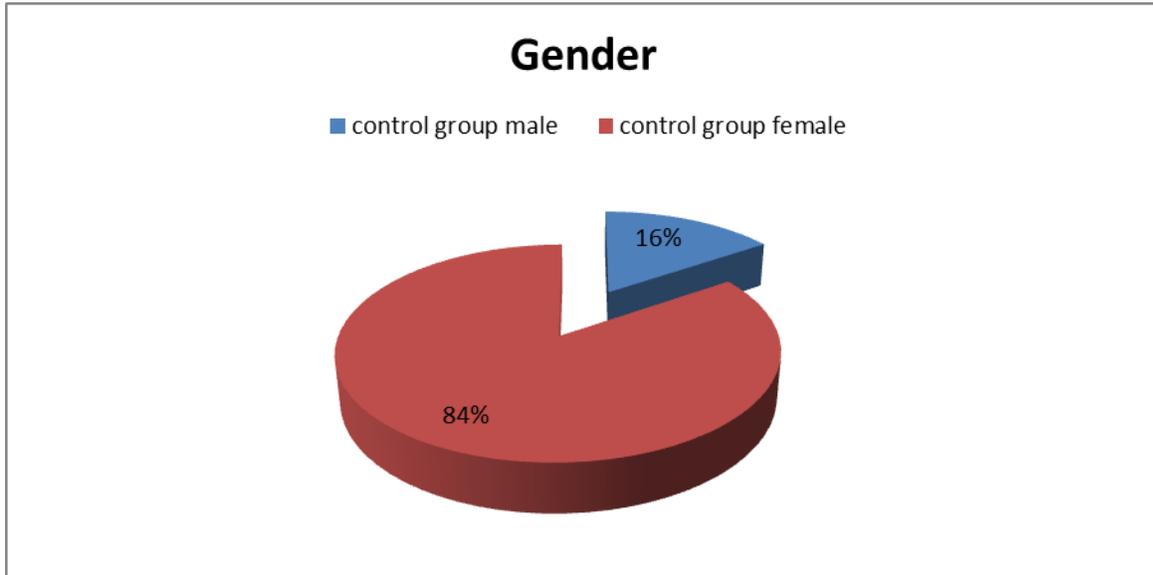


Figure 11: Gender distribution between control and study group



Results of the pre and post measurements on T3, T4, TSH, Body weight and BMI among Ujjayi pranayama along with standard drug group for a period of 90 days was tabulated in Table.1. It shows that Body weight was reduced after practicing Ujjayi pranayama for the study period. T3 got raised statistically significant after the yoga intervention where as T4 doesn't show's any statistical significance after the yoga intervention. Even though in yoga intervention group T4 doesn't show statistical significance its mean value raised to a marked level from 8.05 to 8.54ng/ml This shows that Ujjayi pranayama is influencing the T4 secretion. TSH level reduced significantly after the practice of Ujjayi pranayama for a period of 90 days.

Table 1: Representation of pre and post variables between groups

Pre_Post Variables Between Groups	Paired Differences					t	Df	P Value
	Mean	Std. Deviation	Std. Error Mean	95% Confidence Interval of the Difference				
				Lower	Upper			
BMI	1.18685	0.60099	0.07759	1.03160	1.34211	15.297	59	0.001
T3	-.25883	0.51378	0.06633	-.39156	-.12611	-3.902	59	0.001
T4	-.48317	3.07451	0.39692	-1.27740	.31106	-1.217	59	0.228
TSH	0.65250	2.17484	0.28077	0.09068	1.21432	2.324	59	0.024
WEIGHT	2.967	1.551	0.200	2.566	3.367	14.816	59	0.001

Table 2. The Descriptive Analysis between groups

Table: 2 Descriptive Statistics					
CONTROL		Mean	N	Std. Deviation	Std. Error Mean
BMI	PRE	33.0755	60	5.11100	0.65983
	POST	31.8886	60	5.09652	0.65796
T3	PRE	1.0768	60	0.53616	0.06922
	POST	1.3357	60	0.45523	0.05877
T4	PRE	8.0578	60	3.15348	0.40711
	POST	8.5410	60	2.46068	0.31767
TSH	PRE	9.8958	60	4.27655	0.55210
	POST	9.2433	60	3.39037	0.43770
WEIGHT	PRE	82.33	60	12.576	1.624
	POST	79.37	60	12.425	1.604
STUDY GROUP		Mean	N	Std. Deviation	Std. Error Mean
BMI	PRE	32.5155	58	5.25440	0.68994
	POST	32.9314	58	5.21355	0.68457
T3	PRE	1.0302	58	0.61005	0.08010
	POST	3.2921	58	16.40770	2.15444
T4	PRE	7.8640	58	2.62319	0.34444
	POST	7.9013	58	3.10327	0.40748
TSH	PRE	10.9926	58	6.13119	0.80506
	POST	11.0278	58	4.37456	0.57441
WEIGHT	PRE	81.48	58	12.998	1.707
	POST	82.53	58	12.754	1.675

Table 3: Equality of variances using independent T test.

Table: 3 INDEPENDENT T TEST										
		Levene's Test for Equality of Variances		t-test for Equality of Means						
		F	Sig.	T	Df	P value	Mean Difference	Std. Error Difference	95% Confidence Interval of the Difference	
									Lower	Upper
BMI	Equal variances assumed	0.823	0.366	-0.530	116	0.597	-.56998	1.07568	-2.70051	1.56054
	Equal variances not assumed			-0.528	107.834	0.599	-.56998	1.08014	-2.71105	1.57109
T3	Equal variances assumed	3.632	0.059	-0.923	116	0.358	-1.95640	2.11875	-6.15286	2.24006
	Equal variances not assumed			-0.908	57.085	0.368	-1.95640	2.15524	-6.27205	2.35925
T4	Equal variances assumed	2.917	0.090	1.243	116	0.216	0.63974	0.51467	-.37962	1.65910
	Equal variances not assumed			1.238	108.590	0.218	0.63974	0.51668	-.38434	1.66382
TSH	Equal variances assumed	4.764	0.031	-2.563	116	0.012	-1.83443	0.71562	-3.25179	-.41706
	Equal variances not assumed			-2.552	106.748	0.012	-1.83443	0.71882	-3.25944	-.40941

There was no statistical significant difference between the body mass index of interventional group and control group but the mean value was less in interventional group than control group. It shows that practicing ujjayi pranayama additionally leads to reduce body weight. The measurement of T3 was statistically significant between interventional group and control group whereas T4 was statistically insignificant. There was a marked reduction of TSH in interventional group and statistically significant with control group.

6.0 DISCUSSION:

The result of this study revealed that practice of Ujjayi Pranayama decreases the Body mass index and The Thyroid Function Test in the interventional group significantly in comparison to that of the control group. There are many interventions to reduce severity of disease by standard conventional treatment which is associated with multiple side effects and the present study deals with non pharmacological mode of treatment. In this study, there is a significant difference (p within the Study group) in the Body Mass Index , Thyroid Stimulating Hormone(TSH), Triiodothyronine (T3) at the end of the 90 days in comparison to their baseline data. However, no significant differences in Thyroxine (T4) within this intervention group following the intervention. Overall, the practice of Ujjayi pranayama for 90 days among hypothyroid individuals has resulted in the reduction of the Body Mass Index , Thyroid Stimulating Hormone(TSH), Triiodothyronine (T3) and no significant differences in Thyroxine (T4) ,although Ujjayi pranayama improved the quality of living and confidence of the participants. The larger sample size is needed to gain better results.

7.0 CONCLUSION:

This study showed that 90 days of Ujjayi Pranayama reduced Body mass index and Thyroid Stimulating Hormone(TSH), Triiodothyronine (T3) and no significant differences in Thyroxine (T4) hypothyroid patients. This revealed that yoga practice has significant role in improvement in the weight reduction. Further research need in this field with a larger sample size and duration is warranted to reveal accurate changes in this field.

LIMITATIONS:

- The current study was a pilot study comprising only of minimal number of subjects.
- The outcome variable used in the study, cannot be inferred, or taken as an overall mean, since the age and gender related factors could vary.

RECOMMENDATIONS:

The same study can be conducted on a larger population with suitable study design and some objective kind of outcome variables could be included to validate the current result

8.0 SUMMARY:

The intended research work aims to evaluate the effect of 12 week Ujjayi pranayama on Hypothyroidism in adults and to compare the changes in BMI and Thyroid Function Test [Tri- iodothyronine T3,Thyroxine T4, Thyroid-stimulating hormone] before and after Psychic breathing technique .Many studies reported that the practice of yoga, especially pranayama‘ influences BMI. The current study was conducted to determine the effect of practicing Ujjayi Pranayama on Hypothyroidism in Adults, followed by monitoring BMI and Thyroid Function Test.The current research work employed A Randomized Controlled Trail.In this study Potential subject will be screened and eligible patients will be recruited for the study.A minimum of 60 participants in Study group and minimum of 60 participants in Control group belonging within the age group of 18-55 participate in the study. After obtaining informed consent both the group will be subjected to general measures like BMI, Thyroid Function Test before and after the study. The study Group will be subjected to Ujjayi Pranayama for 15 minutes twice a day for 6 days a week for 12 weeks. Results of the pre and post measurements on T3, T4, TSH, Body weight and BMI among Ujjai pranayama along with standard drug group for a period of 90 days was tabulated in Table.1. It shows that Body weight was reduced after practicing ujjai pranayama for the study period. T3 got raised statistically significant after the yoga intervention where as T4 doesn’t show’s any statistical significance after the yoga intervention. Even though in yoga intervention group T4 doesn’t show statistical significance its mean value raised to a marked level from 8.05 to 8.54 mg/dl .This shows that ujjai pranayama is influencing the T4 secretion. TSH level

reduced significantly after the practice of ujjai pranayama for a period of 90 days. This study showed that 90 days of Ujjayi Pranayama reduced Body mass index and Thyroid Stimulating Hormone(TSH), Triiodothyronine (T3) and no significant differences in Thyroxine (T4) hypothyroid patients. This revealed that yoga practice has significant role in improvement in the weight reduction. Further research need in this field with a larger sample size and duration is warranted to reveal accurate changes in this field.

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10.0 ANNEXURE 1

INFORMED CONSENT FORM

Title of the study: “EFFICACY OF UJJAYI PRANAYAMA ON HYPOTHYROIDISM IN ADULTS – A RANDOMIZED CONTROLLED TRIAL”

Name of the Participant:

Name of the Principal Investigator: Dr. S.Vinudha

Name of the Institution: Government Yoga and Naturopathy Medical College, Arumbakkam, Chennai – 600 106.

Documentation of the informed consent

I _____ have read the information in this form (or it has been read to me). I was free to ask any questions and they have been answered. I am over 18 years of age and, exercising my free power of choice, hereby give my consent to be included as a participant in “Efficacy of Ujjayi pranayama on Hypothyroidism in Adults –A Randomized Control Trial ”

1. I have read and understood this consent form and the information provided to me.
2. I have had the consent document explained to me.
3. I have been explained about the nature of the study.
4. I have been explained about my rights and responsibilities by the investigator.

5. I have been informed the investigator of all the treatments I am taking or have taken in the past _____ months including any native (alternative) treatment.
6. I have been advised about the risks associated with my participation in this study.
7. I agree to cooperate with the investigator and I will inform him/her immediately if I suffer unusual symptoms.
8. I have not participated in any research study within the past _____month(s).
9. I am aware of the fact that I can opt out of the study at any time without having to give any reason and this will not affect my future treatment in this hospital.
10. I am also aware that the investigator may terminate my participation in the study at any time, for any reason, without my consent.
11. I hereby give permission to the investigators to release the information obtained from me as result of participation in this study to the sponsors, regulatory authorities, Govt. agencies, and IEC. I understand that they are publicly presented.
12. I have understood that my identity will be kept confidential if my data are publicly presented.
13. I have had my questions answered to my satisfaction.
14. I have decided to be in the research study.

I am aware that if I have any question during this study, I should contact the investigator. By signing this consent form I attest that the information given in this document has been clearly explained to me and understood by me, I will be given a copy of this consent document.

For adult participants:

Name and signature / thumb impression of the participant (or legal representative if participant incompetent)

Name _____ Signature _____

Date _____

Name and Signature of impartial witness (required for illiterate patients):

Name _____ Signature _____

Date _____