

Protocol

Efficacy of yoga in controlling subclinical-hypothyroidism: a randomized controlled trial

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ABSTRACT

Background: A huge population in India is at high-risk of developing thyroid related disorders. Unhealthy lifestyle (lack of physical activity and consumption of junk food) is common among Indian population. Yoga is a form of physical activity and helps prevent many lifestyle disorders. The research question to be addressed by this randomised controlled trial (RCT) is whether yoga based intervention is effective in preventing overt hypothyroidism among sub clinical hypothyroid people in India as compared to untreated participants.

Methods: This is a single-blinded, two-arm, parallel-group RCT. Eligible participants should be aged 21-59 years, suffering from sub clinical hypothyroidism (serum thyroid stimulating hormone i.e. TSH level 4.2 mIU/l >TSH level <10 mIU/l; T3 and T4 within normal range). At least 100 participants will be randomised either to the intervention group or the control group. Intermediate follow up at 3 month and final follow-up will be at six month post intervention. This study is designed to study the effect of yoga intervention on biochemical tests {thyroid function tests (fT3, fT4 and TSH)}, physical parameters (waist circumference, waist hip ratio, fat percentage and BMI) and psychological parameters {quality of life (QOL) as assessed by World Health Organization (WHO)-QOL, sleep quality (assessed by PSQI) and depression (assessed by BDI-II)} in sub-clinical hypothyroid patients.

Conclusions: We are now conducting a RCT in Delhi, India to assess the efficacy of yoga in preventing progression of subclinical- hypothyroidism to overt hypothyroidism. If the yoga intervention used in this study is effective, it will be a low-cost feasible treatment for subclinical hypothyroidism in India.

Trial registration: Trial registration number is CTRI/2020/03/024023

Keywords: Yoga, Subclinical hypothyroidism, Thyroid stimulating hormone, Randomized controlled trial

INTRODUCTION

Thyroid dysfunction disorders are among the most common endocrine disorders across the globe. Studies indicate an estimated 42 million people in India suffer from thyroid diseases.¹ Among various thyroid diseases, hypothyroidism is most prevalent. As per a study conducted in eight major cities (Bangalore, Chennai,

Delhi, Goa, Mumbai, Hyderabad, Ahmedabad and Kolkata) of India, the prevalence of hypothyroidism among adult population was 10.95%. Prevalence was significantly higher in females (15.86%) as compared to males (5.02%).² Among developed countries, the prevalence of overt hypothyroidism in the general population ranges from between 0.2% and 5.3% in Europe and 0.3% and 3.7% in USA.³ Increasing prevalence of

thyroid disorders has significant social and economic consequences.⁴

As per the American thyroid association guidelines, sub-clinical hypothyroidism (SCH) refers to a condition where serum thyroid-stimulating hormone (TSH) levels are above the upper normal limit, despite normal levels of free serum thyroxin (fT3 and fT4). SCH occurs in 3% to 8% of the general population and is more common in women than men. 80% of SCH patients have a serum TSH of less than 10 mIU/l.

Patients with SCH have a high rate of progression to clinically overt hypothyroidism [2.6% for anti thyroperoxidase (TPO) antibodies negative patients and 4.3% for anti TPO positive patients].^{5,6} Subclinical hypothyroidism may be associated with adverse cardiovascular events, cardiac dysfunction, lipid metabolism, neuromuscular dysfunction and neuropsychiatric symptoms.⁷⁻¹¹

Yoga is an ancient mind-body discipline that originated in India. Yoga is considered safe, can be easily learnt and can be practiced both indoors and outdoors.¹² Yoga can be practiced across all genders and age groups.

As per American college of sports medicine (ACSM) and the American heart association (AHA) classification, the intensity of holding most poses and of full yoga sessions ranged from light [less than 3 METS (metabolic equivalents)] to moderate-intensity (3-6 METS), with the majority classified as a light-intensity physical activity.¹³ As a moderate to low intensity exercise, yoga can have beneficial effects for people with hypothyroidism—and help in reducing negative symptoms associated with the disease, such as weight gain, depression, stiffness, joint aches and muscle weakness.

Mechanism underlying the beneficial effects of yoga on thyroid disorders has not yet been fully understood. Few assumptions suggest that yogic relaxation techniques may be producing psycho-somatic harmonization influencing the hypothalamic pituitary thyroid axis (HPT axis) and inducing a sense of calm due to hypo-metabolic activity.¹⁴ Rawal et al suggested that reduction in metabolic activity could be indirectly reducing the bodily demand for thyroxin.¹⁵

Very few studies have been conducted on the effects of yoga on thyroid function. A study conducted by Swami et al reported significant improvement in forced expiratory volume (FEV), maximum voluntary ventilation (MVV) and inspiratory capacity (IC) following 21 days of pranayama and meditation, suggesting beneficial effect on pulmonary functions of hypothyroid patients along with conventional treatment.¹⁶ In another study, it was reported that yoga was valuable in helping the hypothyroid patients to manage their disease-related symptoms. Quality of life scores improved among female patients following one hour yoga session for one month.¹⁷

An RCT conducted by Nagendra et al reported reduction in TSH level, total cholesterol, low-density lipoprotein (LDL), triglycerides along with significant improvement in high-density lipoprotein (HDL) in hypothyroid patients.¹⁸ Another study conducted on 150 obese and hypothyroid female patients reported remarkable benefits from low-calorie diet along with yoga.¹⁹

Another RCT recently conducted to assess the effect of yoga on overt hypothyroid patients carried out in Delhi also reported beneficial effects on both biochemical parameters (TSH, T3, T4) as well as on psychological parameters (WHO-QOL, PSQI, BDI-II) following 6 months of yoga intervention.^{20,21} This will be the first clinical trial to study the effect of yoga on sub-clinical hypothyroidism. There is only one case report published by Bhavnani et al reporting the beneficial effect of yoga on a patient suffering from sub clinical hypothyroidism.²² To the best of our knowledge, this will be the first clinical trial to assess the effects of yoga based intervention on sub-clinical hypothyroidism.

The primary objective of this RCT is to study whether a yoga based intervention can prevent progression from SCH to overt hypothyroidism and revert SCH to euthyroid stage.

METHODS

Study design

This is a single-blind, two-arm, parallel-group RCT.

Study location

The study is conducted in the northern part of India at Bapu Nature Cure Hospital and Yogashram (BNCHY, Delhi).

Screening and recruitment strategies

Multiple screening approach is used to identify potential participants: advertisement through posters and pamphlets; screening camps at yoga centres, communities and religious places etc. and door to door visits in various nearby localities.

Individuals will be provided participant information sheet (describing the study and answering any questions), people interested in the study are requested to sign the written informed consent. Venous blood samples are collected from those providing the written informed consent. Serum TSH, T3 and T4 are estimated using standardised method (Table 1).

Those participants with TSH, T3 and T4 levels as per eligibility criteria are invited to BNCHY to sign informed consent form and are further re-assessed against the remaining eligibility criteria for the study.

Table 1: Details of data collection.

Parameter	Assessment details	Screening and recruitment	Baseline	3 rd month assessment	6-month assessment
Eligibility assessment		√			
Socio-demographics			√		
Medical, surgical and family history			√		
Biochemical parameters					√
Fasting plasma glucose	Glucose oxidase-peroxidase (GOD-POD) method		√		√
Glycated haemoglobin (HbA1c)	High-performance liquid chromatography (HPLC) method		√		√
Thyroid function test (TFT)	CLIA method		√	√	√
Anti-TPO	CLIA method		√	√	√
Aspartate aminotransferase (AST)	Colorimetric enzymatic method		√	√	√
Alanine aminotransferase (ALT)	Colorimetric enzymatic method		√	√	√
Serum creatinine (SC)	Colorimetric enzymatic method		√	√	√
Physiological parameters			√	√	√
Blood pressure	Omron HEM-7201		√	√	√
Heart rate	Omron HEM-7201		√	√	√
Anthropometric parameters			√	√	√
Waist circumference	Seca 201 (measuring tape)		√	√	√
Hip circumference	Seca 201 (measuring tape)		√	√	
Weight	Omron HBF-375-IN body composition monitor		√	√	√
Height	Seca 206 (stadiometer)		√	√	√
Body mass index (BMI)	Omron HBF-375-IN body composition monitor		√	√	√
Fat percentage	Omron HBF-375-IN body composition monitor		√	√	
Current medications			√	√	√
Diet	Time-recall: past 1-week		√	√	√
Tobacco usage			√	√	√
Alcohol consumption			√	√	√
Quality-of-life	World Health Organization Quality of Life (WHO-QOL) (BREF) ³³		√	√	√
Depression	Beck depression inventory - II (BDI-II) ³⁴		√	√	√
Sleep quality	Pittsburgh sleep quality index (PSQI) ³⁵			√	
Yoga practice	Time-recall: past 1-week		√	√	√

Eligibility criteria**Inclusion criteria**

Participants should be: aged 21-59 years; T3 level normal range (2.0-4.0 pg/ml); T4 level normal range (0.8-1.8

ng/dl); 4.2 mIU/l>TSH level<10 mIU/l, normal range (0.5-4.20 mIU/l); subclinical hypothyroidism patients with or without thyroid peroxidase (TPO) antibody test positive; willing and able to attend the intervention/control sessions on their own; and able to provide written informed consent.

Exclusion criteria

Patients suffering from obesity grade III; TSH level >10 mIU/l; diabetes mellitus patients who are on Insulin and poorly controlled type-II diabetes mellitus patients where HbA1c >10%; patients who have a past history of severe cardiac dysfunction (atrial fibrillation, heart failure, myocardial infarction, uncontrolled hypertension, or stroke); patients with concurrent serious hepatic disorders defined as aspartate transaminase (AST) and/or alanine aminotransferase (ALT) >3 times of the upper normal limit; patients with concurrent serious renal disorders defined as serum creatinine >1.5 mg/dl; patients with concurrent serious pulmonary dysfunction; patient with cerebrovascular event during the last 12 months; women who are pregnant or lactating or planning pregnancy in near future; patient with any type of tumour or malignancy or any history of malignancy; and drugs and alcohol dependents.

Randomisation process

Participants found eligible as per the inclusion/exclusion criteria are randomised either to the yoga group or the control group according to a pre computer-generated randomisation schedule (1:1, block randomisation, stratified by sex), done by an independent statistician. To avoid contamination, participants recruited from the same household, close relatives or friends are co-randomised to the same group. After randomisation, baseline data are collected. As it is a yoga based intervention where both participants and intervention providers cannot be 'blinded' to group allocation, the outcome assessor is an independent person not related to the trial and hence is blinded.

Treatments

Intervention (yoga)

After baseline investigations, intensive information, education and counselling about the disease and yoga practices will be given to all the participants. The intervention consists of an evidence based yoga schedule (Table 2). The yoga schedule includes breathing practices, loosening exercises, surya namaskar (sun salutation exercises), asana (yogic poses), kriyas, pranamayas (breathing practices), bandhas, and relaxation practices. The intervention has been systematically developed through reviewing earlier studies on effects of yoga practises on hypothyroidism and its symptoms.²³⁻²⁷ The intervention is delivered by a qualified and experienced yoga instructor, qualified with formal training provided on the intervention protocol. Yoga sessions are run as per convenience of the participants. Once participants complete the intervention period they will be encouraged to maintain the same healthy lifestyle in future. The duration of yoga therapy will be one hour. The frequency of treatment will be minimum twice a week for six months i.e. 72 sittings.

Table 2: Yoga schedule for sub clinical hypothyroidism.

Practice	Duration (min)
Opening prayer	3
Breathing practices	5
Loosening exercise	12
Suryanamaskara	5
Asanas	20
Kriya	1
Pranayamas and bandha	7
Relaxation	7
Total duration	60

Control

Currently, no intervention is available for people affected with sub-clinical hypothyroidism. The control group participants are receiving a diet chart. This is delivered by a different team member (i.e. not by the yoga instructor). The diet chart would ensure that control group participants feel that there are benefits to participation and minimize dropout from control group.

Study parameters and data collection

The parameters: symptom score, physical examination, blood chemistry. These parameters will be recorded at baseline, 3 months and 6 months; anti TPO antibody levels will be assessed at baseline and 6 months; psychological parameters will be studied by WHO-QOL Pittsburg sleep quality index (PSQI) and Beck depression inventory-II (BDI-II). These psychological parameters will be assessed at baseline, 3rd month and 6th month post intervention.

Protocol adherence

Adherence to the study protocol was determined by class attendance rates and participants' home practice rates as reported in their daily diary.

Sample size estimation

We assume that yoga at intervention group would have a significant change in biochemical tests [thyroid function tests (fT3, fT4 and TSH)], Physical parameters (waist circumference, waist hip ratio fat percentage and BMI, and psychological parameters [quality of life as assessed by WHO-QOL, sleep quality (assessed by PSQI) and depression (assessed by BDI-II)] at the end of the study. Based on similar studies, considering moderate effect size of $d=0.57$ with a power of 80%, two sided level of significance ($\alpha=0.05$) and using two sample t-test for difference between two independent means, at critical value $t=1.98$, non-centrality parameter $\delta=2.85$, for determining the study sample size, total of 40 patients are required for each group. But keeping in mind loss to follow up and drop out among patients (20%) we have rounded it to 50 for each group.^{28,29} The sample size is estimated

using statistical power analysis G*Power Version 3.1.9.4, software.

Data analyses

The data will be analyzed by an independent statistician. The mean and variance for interventional and control groups will be calculated for quantitative parameters. T-test will be used to analyze significant changes from basal to all end-points during the follow up and comparison between control and interventional groups. The statistical significance will be considered at $p < 0.05$ levels for all the parameters and the values will be expressed as mean \pm SD. Interim analysis is not planned.

Ethics and other related issues

Ethical approval is obtained from the Institutional Ethical Committee of Bapu Nature Cure Hospital and Yogashram, Delhi, India. Two languages (English and Hindi) are used to conduct the study.

Serious adverse events

Yoga is known to be safe. Information will be collected on any serious adverse events (hospitalization for more than 24 hours and death) occurring in participants during the intervention period. Based on clinical reasons, an independent clinician will determine, if there exists, relationship of such an event to the given intervention.

Participant withdrawal

Participants can withdraw from the study on their decision or if the principal investigator would find any valid reason to withdraw a participant. The participant will be informed for the reason for his/her withdrawal from the study.

The right of the participant of self-withdrawal will be informed through the participant information sheet and consent form at the time of registration. Even after a participant is withdrawn, the data collected to date may still be used in the final analysis.

DISCUSSION

Yoga is an ancient Indian therapy, having its root in India. Yoga has been a promising in the prevention and management of chronic diseases like thyroid, diabetes, and cardiac diseases. The government of India has noted its significance and hence set up the Ministry of Ayush to revive and scientifically develop and promote yoga as a form of therapy along with other traditional Indian therapies.

We are conducting this RCT in Delhi, India to assess the efficacy of yoga in preventing progression from sub-clinical hypothyroidism to overt hypothyroidism. The study started in January 2020 and we are aiming to finish the study by the end of December 2021.

This study will be helpful to motivate patients to take up responsibilities of their own health mainly by controlling diet along with improvement in exercise schedule. As stated earlier there are higher chances of progression from subclinical hypothyroidism to overt hypothyroidism. It has been suggested that yoga may have a role in revitalizing thyroid function as well as improving psycho-neuro-endocrine function on the whole.^{30,31} Though numerous studies have shown the psycho-physiological benefits and therapeutic potential of yoga.³² This study will specifically study the effectiveness of yoga on sub clinical hypothyroid condition among Indian population. The outcomes of this study will be an evidence based report of yoga intervention on thyroid disorder.

If the yoga intervention used in this study is effective, it will be a low-cost feasible treatment for subclinical hypothyroidism in India. Hypothyroidism is becoming a global health concern and has a significant cost of treatment. The outcomes of the study will also enable to conduct further larger trials to be conducted of other parameters not included in the present study.

CONCLUSION

To the best of our knowledge, this will be the first RCT to study the effect of yoga intervention on sub-clinical hypothyroidism. Subclinical hypothyroid patients have a high prevalence of converting to overt hypothyroid. The outcomes of this study will suggest whether yoga as an intervention is effective in: preventing progression from sub-clinical hypothyroid to over hypothyroid stage; and reverse sub-clinical hypothyroid to euthyroid stage. As such, there is no clinical therapy or treatment suggested for sub-clinical hypothyroidism. Based on the evidence from this study we aim to establish yoga as a simple and effective treatment for sub-clinical hypothyroid patients.

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Conflict of interest: None declared

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