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Effect of *Sūrya Nāḍī Prāṇāyāma* (Right Nostril Breathing) on insulin resistance in type 2 diabetes mellitus: A study protocol for a randomized controlled trial

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Abstract

Background: Type 2 Diabetes Mellitus (T2DM) is a heterogeneous group of disorders characterized by hyperglycaemia due to impaired insulin secretion or function. T2DM is one of the greatest public health challenges in today's world. Its higher prevalence is primarily due to lifestyle factors like sedentary lifestyle, physical inactivity, cigarette smoking and alcohol consumption. Comprehensive yogic practice like asanas, pranayama, meditation and relaxation techniques plays a vital role in managing diabetes mellitus. To our knowledge no scientific exploration was done on *Sūrya Nāḍī Prāṇāyāma* (SNP) on insulin resistance in T2DM patients.

Aim: This study is to explore the efficacy of *sūrya nāḍī prāṇāyāma* on insulin resistance among T2DM patients.

Methods: A randomized controlled trial will be conducted with a sample size of 80 T2DM subjects. Participants aged between 30 to 65 years, diagnosed with type 2 diabetes mellitus on oral hypoglycaemic drugs will be recruited. We randomly divide the subjects into two groups, namely study group (N=40) and control group (N=40). Study group will be advised to practice 21 times of SNP for 4 rounds daily once for 21 days in addition to their oral hypoglycaemic drugs, whereas the control group will be only on oral hypoglycaemic drugs without any additional intervention.

Result: The baseline and post-assessment will be performed after 21 days for all the individuals; homeostatic model assessment of insulin resistance (HOMA-IR). Descriptive statistics such as means and standard deviations will be calculated for each variable measured by the HOMA-IR. Additionally, inferential statistics such as t-tests will be performed to compare the HOMA-IR value between intervention and control groups. The level of significance will be set at $p \leq 0.05$. Any outliers or missing data points will be carefully addressed and handled accordingly.

Discussion: The SNP is a simple effective technique, 21 days of SNP might improve HOMA-IR, which may be recommended as an adjuvant therapy for T2DM patients along with conventional care. The study is prospectively registered in the Clinical Trial Registry of India (CTRI/2024/05/065088) and International Institute of Yoga and Naturopathy Medical Sciences Ethical Committee (IEC) approval was obtained; vide letter number 446/ME-II/2023.

Keywords: Randomized controlled, adjuvant therapy, naturopathy medical

Introduction

Type 2 Diabetes Mellitus is a heterogeneous group of disorders characterized by hyperglycaemia due to impaired insulin secretion or function [1]. More than 400 million people worldwide suffer from type 2 diabetes mellitus (T2DM), and by 2040, there will be more than 640 million cases of the disease globally [2]. T2DM is expected to double in prevalence over the next 20 years due to factors such as aging, obesity, and the number of high-risk ethnic groups in the population [3]. Asian Indians having an increased prevalence of type 2 DM generally exhibit a thin body mass index phenotype and they account for 1 in 7 adults living worldwide with type 2 DM having a prevalence of 74.2 million people in 2021 [4].

Etiologic classification of diabetes mellitus includes type 1 (beta cell destruction leading to absolute insulin deficiency) type 2 (may range from predominantly insulin resistance with relative insulin deficiency to a predominantly insulin secretory defect with insulin resistance), gestational diabetes mellitus & other specific defects in genetic function of beta cells and insulin action with the diseases of the exocrine pancreas [5]. Type 2 diabetes accounts for over 90% of all diabetes worldwide [6].

Diabetes mellitus is primarily due to lifestyle factors and genetics. Lifestyle factors include sedentary lifestyle, physical inactivity, cigarette smoking and munificent drinking of alcohol [7]. Obesity contributes to approximately 55% of cases of type 2 DM [8]. Conventional treatments for type 2 diabetes mellitus typically involve a combination of medication, such as metformin, sulfonylureas, or insulin, along with lifestyle modifications including dietary changes and increased physical activity [9]. However, adjuvant therapies like herbal supplements, acupuncture, yoga, and dietary supplements seems to be increasing its importance due to its positive impact on health and diseased state [10].

Scientific research on yoga has amassed a compelling body of evidence supporting its myriad benefits for physical, mental, and emotional well-being. Numerous studies have demonstrated yoga's effectiveness in reducing stress, anxiety, and depression through its emphasis on mindfulness, regulation of breath, and meditation [11]. Moreover, research has consistently shown that regular yoga practice can improve flexibility, strength, balance, and cardiovascular health, making it a valuable tool for enhancing physical fitness and reducing the risk of chronic diseases such as hypertension, diabetes, and obesity [12].

Yoga plays a vital role in managing diabetes mellitus. Yoga holds significant promise for individuals with diabetes mellitus due to its holistic approach to health and well-being. Unlike many other forms of exercise, yoga not only focuses on physical activity but also incorporates elements of mindfulness, regulation of breath, and relaxation, all of which are particularly beneficial for managing diabetes mellitus [13]. The physical postures in yoga help improve flexibility,

strength, and circulation, which can aid in better glucose metabolism and insulin sensitivity. Moreover, the emphasis on mindfulness breathing techniques can reduce stress levels and regulate the body's stress response, which is crucial as stress can exacerbate insulin resistance and worsen blood sugar control [14].

Prāṇāyāma is one of the important aspects of yoga, offers potential benefits for managing diabetes mellitus. Through controlled breathing techniques, Prāṇāyāma encourages relaxation and stress reduction, which are crucial for stabilizing blood glucose levels. Deep breathing exercises enhance oxygenation and circulation, promoting better insulin sensitivity and glucose utilization in the body [15]. In the yogic text Gheranda Samhitha, mentioned that Surya Bheda Prāṇāyāma can be efficient Prāṇāyāma for enhancing the metabolism and produce tranquilizing effect. The above-mentioned practice is similar like Sūrya Nāḍī Prāṇāyāma [16]. Since, impaired metabolism and stress are known causative factors for T2DM [17], this can be addressed by SNP. Even after strenuous literature review, no study was done on SNP and T2DM. Hence, we are planning to do this study on whether SNP can reduce insulin resistance or not in T2DM subjects.

Materials and Methods

Study design & Setting

The present study is a randomized controlled trial, subject will be recruited from Out Patient of Government Yoga and Naturopathy Institution Medical Sciences in Chengalpattu district, Tamil Nadu. The study is prospectively registered in the Clinical Trial Registry of India (CTRI/2024/05/065088) and Institutional Ethical Committee (IEC) approval was obtained; vide letter number 446/ME-II/2023.

Sample Size

In a feasibility trial, estimation of formal sample size calculation is not required [18]. It is recommended to recruit a minimum of 50 participants in a feasibility trial. Thus, in this trial we have planned to recruit 80 participants after taking into consideration drop out or loss of follow-up. The trial profile of the study is depicted in figure 1.

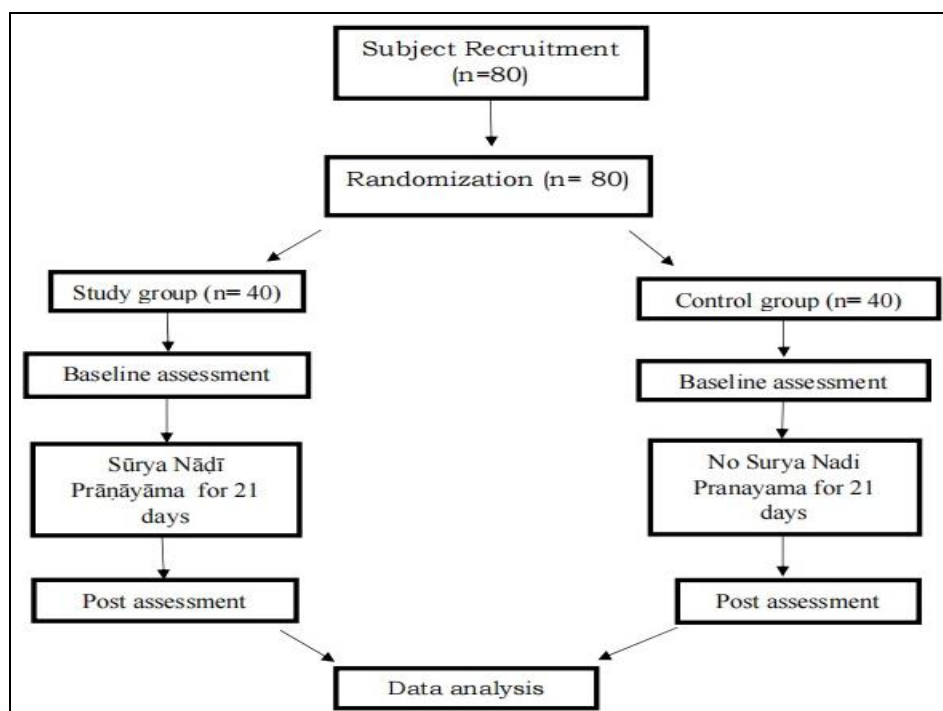


Fig 1: Trail Profile

Randomization and blinding

All the subjects will be randomly allocated to either a subject or a control group (1:1 ratio) using a computerized randomization. Random concealment will be done using SNOSE (Sequentially numbered, opaque, sealed envelope) technique. The participants will not be blinded to the study and control group.

Selection of Participants**Inclusion criteria**

Subjects of both genders diagnosed with type 2 diabetes mellitus, may or may not be with oral hypoglycaemic drugs under the age group of 30 to 65 years and willing to participate in the study by providing consent will be included in the study.

Exclusion criteria

Persons having ischemic heart disease, angina, hepatic or renal dysfunction, gastritis, bleeding disorders, stroke,

pregnant and lactating women, hypertensive with systolic pressure greater than 160 mm Hg and diastolic pressure greater than 100 mm Hg and uncontrolled diabetes with fasting and postprandial blood sugar value greater than 200 mg/dl and 300 mg/dl respectively will be excluded from the study.

Intervention group

Subjects will be advised to practice 21 times of Surya Nadi Pranayama for 4 rounds daily once for 21 days.

Intervention procedure

Subjects will be advised to sit in any comfortable position in a relaxed manner. Subjects will be requested to close their left nostril gently and do inhalation and exhalation at the pace of 5 seconds each through the right nostril (SNP); 21 times for 4 rounds.^[16] Subjects will be instructed to do normal breathing for 30 seconds in between each round of SNP. Intervention flowchart with duration is depicted in Figure 2.

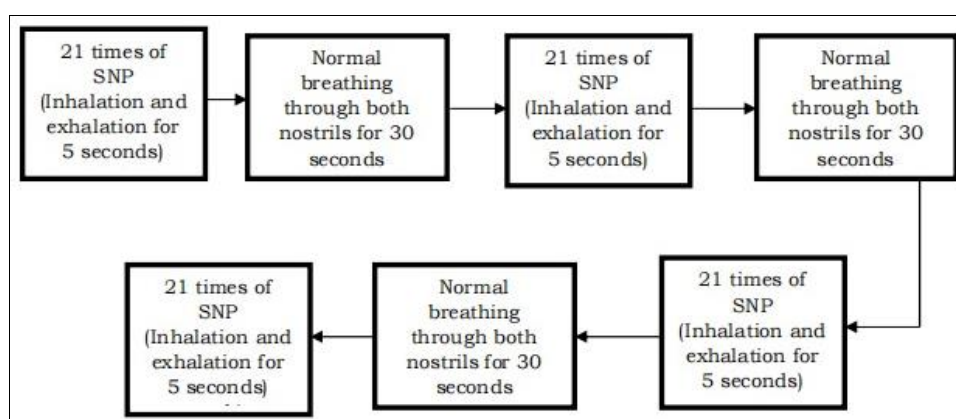


Fig 2: Flowchart of the intervention

Control group

Subjects in the control group will not receive any additional intervention apart from their routine conventional care for 21 days.

Outcome variables

Homeostatic Model Assessment of Insulin Resistance (HOMA-IR) Insulin resistance will be monitored with the help of fasting insulin level and fasting glucose level monitored in laboratory. HOMA-IR will be calculated according to the formula ^[19]: Fasting insulin (uIU/ml) X fasting blood glucose (mg/dl) / 405 using an auto analyzer from a National Accreditation Board for Hospitals and Healthcare Providers accredited lab. Data Extraction Data will be extracted at two points in the study. First data will be before starting of the intervention (baseline) and second data will be after 21 days of intervention (post assessment) for both groups.

Discussion

The current study is the first of its kind in exploring the effect of right nostril breathing (Surya Nadi Pranayama) on insulin resistance in type 2 diabetes patients. Research study found that comprehensive yoga practices like asanas, pranayamas, surya namaskar, kriya can reduce the fasting glucose and post prandial level, thus helps to manage type 2 diabetes mellitus.^[15] The probable mechanism could be enhanced insulin sensitivity in target tissues, which lowers insulin resistance and enhances peripheral glucose utilization and

also invigorate the pancreatic beta cells.^[16] Long-standing T2DM may have higher chances of complications like diabetic neuropathy, diabetic retinopathy, micro vascular damages ^[17]. Study concluded that yoga can be adjuvant treatment for T2DM, which also helps to tapering of hypoglycaemic drugs ^[18].

Stress is considered to be a potential etiological factor in type 2 diabetes, yogic practices inhibit the paraventricular nuclei of hypothalamus which in turn inhibits negative emotion areas and stimulates centre of median forebrain leading to reduce the stress level ^[19]. Increases of body weight is an another known etiological factor, yoga shows significant declines in the body weight, waist-hip ratio and body mass index of T2DM patients, where transition from central to peripheral obesity as a result of reduced insulin resistance was noted ^[20, 21].

A systemic review concluded that comprehensive yogic practices have shown positive impact on diabetes mellitus by reducing hyperglycaemia, insulin resistance and stress levels in individuals and also promote the quality of life ^[22]. Another study shows that yoga helps in increasing insulin binding receptors and believed to increase glucose uptake, minimize insulin resistance and promote the function of insulin by reducing the levels of circulating free fatty acids in the body ^[9].

Scientific studies found that each pranayama has its own physiological functions and health benefits ^[23, 24]. It is a known fact that domination of breathing through one nostril is due to contralateral activity of brain hemispheres. Right

hemisphere controls the left side of the body and mainly responsible for creativity, whereas left hemisphere controls the right side of the body and responsible for logical and analytical thinking^[25].

Study by vanutelli *et al* concluded that uninostil breathing have impact of psychological and cognitive well-being^[26]. Similarly, alternate nostril breathing (nadi shodhana pranayama) can improve the cardio-respiratory functions, high frequency breathing (kaphalabhati and bastrika) can have sympathetic dominance, slow frequency breathing and left nostril breathing (bhramari, sheetali) can have parasympathetic dominance and helps to reduce the stress.^[27] Hence, we believed that right nostril breathing may have sympathetic dominance and through that insulin resistance can be decreased among T2DM subjects.

Conclusions

The present study findings may provide high quality clinical evidence on the safety and efficacy of the Sūrya Nāḍī Prāṇāyāma in the treatment of type 2 diabetes mellitus. If the observations ascertain the improvement in HOMA IR values among type 2 diabetes patients, it could be recommended as an adjuvant therapy for better care and management of the diabetic patients along with conventional care.

Consent for publication

All participants provided consent for the publication of anonymized data and study findings.

Conflict of interests: The authors declare that they have no conflict of interest.

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