

A study protocol for a randomized controlled trial on immediate effect of cooling breathing techniques in generalized anxiety disorder

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World Journal of Biology Pharmacy and Health Sciences, 2024, 19(03), 612–617

Publication history: Received on 18 August 2024; revised on 25 September 2024; accepted on 27 September 2024

Article DOI: <https://doi.org/10.30574/wjbphs.2024.19.3.0692>

Abstract

Background: Generalized anxiety disorder (GAD) is a mental and behavioural illness characterized by excessive, uncontrollable worry about particular things. The people with GAD are excessively anxious about everyday concerns which affects the day-to-day activities. Some symptoms that may be present include excessive worry, restlessness, insomnia, exhaustion, irritability, sweating, and shaking. Yoga is a potential intervention that has gained popularity and accessibility. Sheetal and sheetkari pranayama bring about increased parasympathetic activity, with decreased respiratory rate and blood pressure being attributed to the predominant vagal tone following slow-breathing techniques. Additionally, they ease the internal heat and calm the brain activity.

Objective: The objective of the study is to determine the impact of immediate effect of sheetal sheetkari pranayama yogic intervention on generalized anxiety disorder patients.

Method: Total of 80 patients with the GAD will be recruited to participate in this randomized control study. All the eligible subjects (n=80) will be divided into two groups, study group and control group by randomization. The study group will undergo sheetal and sheetkari pranayama for 30 minutes, 20 rounds each, while the control group will receive normal breathing for 30 minutes. The outcome measures will be taken for study and control group before and after the intervention.

Results: Data analysis will be done using the appropriate statistical tests in Statistical Package for the Social Sciences, version, 16. Inferential data of Paired sample 't' test will be used to find the probability of within group and Independent 't' test will be used for between group.

Conclusion: The present study findings will provide high quality clinical evidence on the efficacy of sheetal and sheetkari on generalized anxiety disorder. If the observations of this study ascertain positive results, it could be recommended as an adjuvant therapy for generalized anxiety disorder subjects along with conventional care.

Keywords: Sheetal; Sheetkari; Pranayama; Yoga; Generalized anxiety disorder; Hamilton anxiety scale

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1. Introduction

Generalized anxiety disorder (GAD) is characterized by diffuse, uncontrollable worry that is unreasonable, extreme and lasts for at least one month or longer [1]. The causes of GAD are finances, family, health, about the future stress full events like death of loved ones, abuse, unemployment and divorce and is also associated with depression, alcohol, substance abuse, physical and mental health problems [2]. The average age of onset for generalized anxiety disorder is around 22 years old which affects women more frequently than males [3]. At the world level, anxiety illnesses affect 4.6% more women than men [4]. According to the fifth criteria of the most recent Diagnostic and Statistical Manual of Mental Disorders, GAD has a weighted incidence rate of 5.8% in the Indian community. World Health Organization estimates that in 2015, 3.6% of the world's population suffered from anxious illness [5].

Sometimes GAD may common among general public, they may suffer from overwhelming fear and worry, physical strain and additional behavioural and cognitive symptoms due to anxiety. If untreated, they can be quite distressing and hard to manage the family, social, academic, and professional lives and can negatively impact everyday activities [6]

This disorder has multiple causes which is difficult to control, when intensified it is typically accompanied by psychological and physical symptoms like restlessness, fatigue, facing difficulty in concentrating on something, irritability, palpitation, having a sense of impending danger, panic or doom, muscle tension and sleep disturbance [2].

Anxiety has been divided into three categories by psychologists: Trait, State condition, and Situation specific. Trait anxiety -It is a tendency to worry without any triggers is called as trait anxiety. State anxiety – This type of anxiety is a reaction to a provoking event. Situation specific anxiety -It was sparked by particular circumstances eg: worry about public speech. GAD can progress from fleeting minor symptoms to full-blown anxiety disorders [6].

When it comes to effective GAD interventions, traditional cognitive behaviour therapy (CBT) is the gold standard treatment for treating anxiety disorders, many individuals are still unable to receive CBT. There exist multiple obstacles that prevent individuals from receiving scientifically supported psychotherapy, such as excessively high fees, the prevailing face-to-face delivery model, insufficient resources to meet the growing requirements for mental health [7].

Yoga is a multifaceted behavioural practice that combines physical postures, breath management techniques, deep relaxation methods, and meditation/mindfulness when practiced in its traditional contemplative practice format. Indeed, according to a recent survey, 8.9% of people have used yoga as a therapeutic intervention [8].

Yogic breathing technique has a profound effect on the nervous system functions, reduces tension, and fosters calm [10]. The Sanskrit word sheetalī means "cooling." The yoga books Hatha Yoga Pradeepika and Gheranda Samhita both mentioned about sheetalī pranayama. Those who find it difficult to do Sheetalī Pranayama can easily practice Sheetkari and get similar benefits [9]. Swami Swatmarama claimed that sheetalī and sheetkari pranayama cool the body, balance pitta and body heat by controlling body temperature and alters the function of important regions of brain by encouraging the free passage of prana throughout the body, they help lessen mental and emotional excitement. Study found that Sheetalī and Sheetkari pranayamas bring about increased parasympathetic activity, with decreased respiratory rate and blood pressure being attributed to the predominant vagal tone following slow-breathing techniques [10].

It has been suggested that the vagus nerve mediates the psychobiological mechanism by which pranayama works. Increased parasympathetic activity has also been proposed to decrease stress-related hormone release and improve GABA inhibition from the insula and prefrontal cortex to the amygdala, which lowers the latter's activity as well as the psychological and physical symptoms linked to stress [11].

2. Materials and methods

2.1. Study setting

The present study will be a randomized controlled trial, which will be conducted on patients from the outpatient department of International Institute of Yoga and Naturopathy Medical Sciences and Hospital. Institutional Ethical Committee (IEC) approval from the institutes has been taken, vide letter numbers Ref N0.446/ME-II/2023. The Clinical Trial registration: CTRI/2024/02/063019.

2.2. Sample size

In the feasibility trial, estimation of formal sample size calculation is not required [12]. It is recommended to recruit minimum 50 participants in a feasibility trial. thus, in this trail we have planned to recruit 80 participants after taking into consideration of drop out or loss of follow up.

2.3. Randomization and blinding

All the subjects will be randomly allocated to either a subject or a control group (1:1 ratio) using 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.

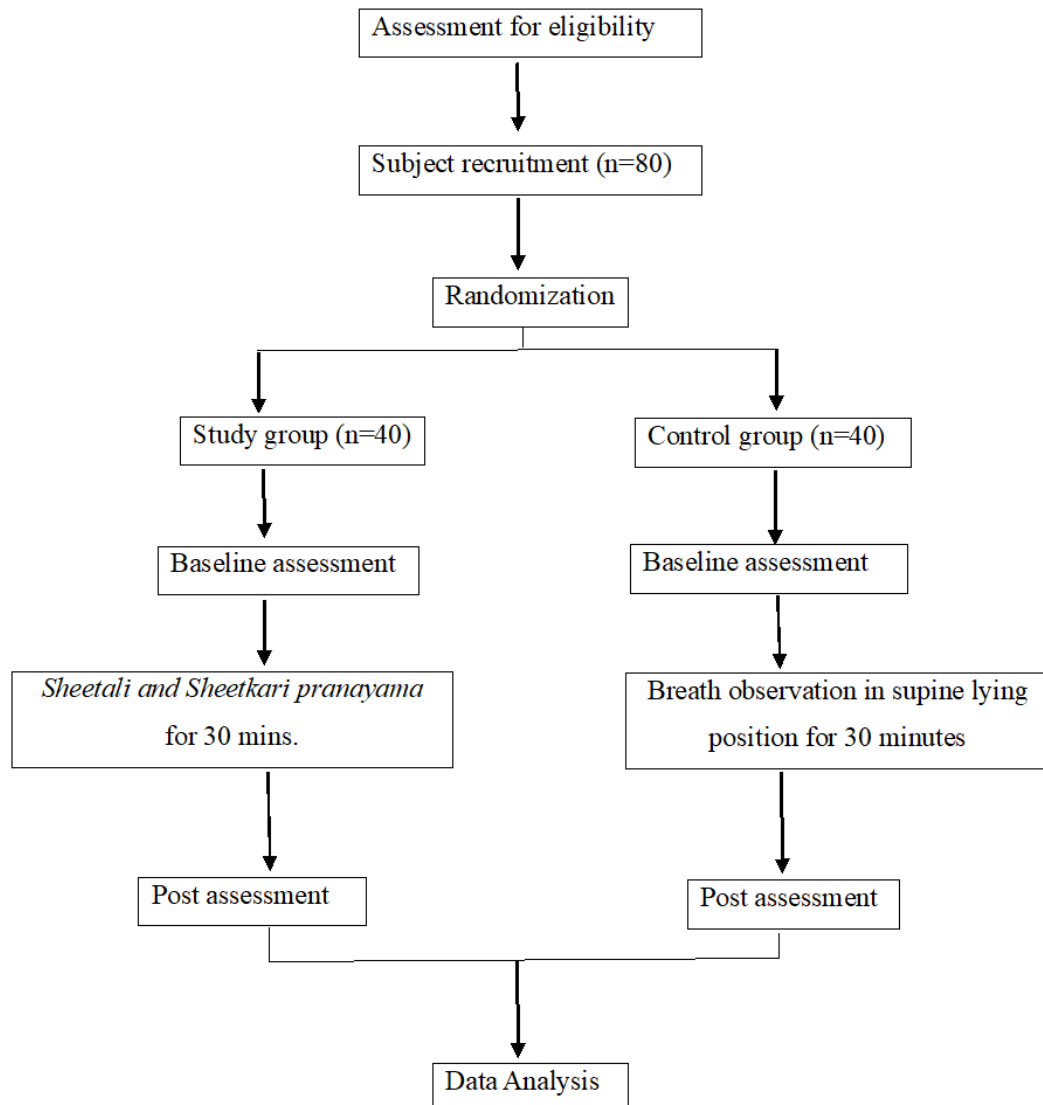


Figure 1 Trial Profile

2.4. Eligibility criteria

2.4.1. Inclusion criteria

Subject must be between the Age group of 22 years to 65 years subject can be Male and Female who were diagnosed generalized anxiety disorder according to Generalized Anxiety Disorder scale-7 questionnaire. This is calculated by assigning scores of 0, 1, 2, and 3 to the response of the participants. GAD-7 total score for the seven items ranges from 0 to 21. 1) 0–4: minimal anxiety 2) 5–9: mild anxiety. 3) 10–14: moderate anxiety 4) 15–21: severe anxiety Subjects who are willing to participate in the study.

2.4.2. Exclusion criteria

Subjects who are having missing teeth or dentures, dental caries, sensitive teeth. subjects suffering from low blood pressure, Current or past diagnosis of psychosis, schizophrenia, bipolar disorder, panic disorder with agoraphobia, major depressive disorder, social phobias, obsessive compulsive disorder, post- traumatic stress disorder or substance dependence. Subjects Who are undergoing continues practice of yoga. subjects who are suffering from cold.

2.5. Study Group

Sheetali and sheetkari are the independent variable for this study. Subjects in the study group has to practice *sheetali and sheetkari pranayama* for 30 minutes. The participants are asked to sit cross-legged posture on the floor, with the upright spine and closed eyes. The hands to be held in the Gyan Mudra Posture (the tips of the index fingers to be joined to the tips of the thumbs while keeping the other fingers extended and loose). stay calm before beginning the process.

2.6. Intervention Procedure

2.6.1. Sheetali pranayama

The participants are asked instructed to coil the sides of the tongue into a tube and stretch as far as possible. inhale via the coiled tongue's tube for 4 seconds (sec) then focus on the coldness that had formed over the tongue and mouth roof as they inhaled. The tongue was pulled in, the mouth was closed, and exhalation was performed through the nostrils. At first, breathing took place for 4 seconds, and expiration took place for 6 seconds (4:6) and then gradually raise the counts to 4:8, 5:10, or 6:12 with repetition. This was continued for 5 minutes (min) which was considered as one round of Sheethali pranayama. This was followed by 2min rest. This 5 min Sheetali pranayama was repeated one more time and at the end of this, 3 min rest was followed. Altogether this one round was spanned for 15 min [13].

2.6.2. Sheetkari pranayama

The participants are asked to open the lips and bring the upper and lower rows of teeth together, expand their cheeks then inhale deeply and slowly through the space between the teeth's. The chin was descended to the chest at the conclusion of the inhalation, and the breath was retained for 6 seconds without changing the nature or volume of the exhalation. After retaining for 6 seconds chin was lifted up, and exhalation done slowly through the nostrils. This completes one round. This was repeated for one more round in 15 min duration with 2 mins gap. At the end, breathing was brought back to normal and 3 min rest was followed [13].

2.7. Control group

Control group subjects will be in supine lying position without any intervention for 30 minutes.

2.8. Outcome Variables

2.8.1. Hamilton anxiety scale (HAM-A)

The HAM-A is a 14- item clinician rated instrument designed to assess and quantify severity of anxiety. Each item is rated on a five-point Liker-type scale ranging 0 to 4, with higher scores indicating more severe anxiety. It is comprised of somatic subscale (items 7-13) and psychic subscale (item 1-6 and 14). The somatic component emphasizes features of GAD such as autonomic arousal, respiratory, gastrointestinal and cardiovascular symptoms. The psychic subscale addresses the more subjective cognitive and affective complaints of anxiety (tension, fears, anxious mood, difficulty concentrating). HAM-A is particularly useful in assessing the severity of GAD [14].

2.8.2. Blood Pressure

Blood pressure will be assessed using a non-invasive arm type Omron automatic blood pressure monitor. Make sure the cuff is positioned over your artery and one to two centimetres' away from your elbow when you wrap it around your upper arm. Press the start button and turn on the monitor. The cuff will automatically expand on its own. As the device lets out air, the cuff will gradually loosen and tighten again. Your heart rate as well as your systolic and diastolic blood pressure will be displayed on the display once the measurement is finished. A digital blood pressure monitor measures blood pressure in an artery using an inflated bladder cuff, an air pump that runs on batteries, and a pressure sensor that detects vibrations in the arterial wall. This is known as Oscillo metric methods.

3. Results

Data analysis will be done using the appropriate statistical tests in Statistical Package for the Social Sciences, version, 16. Inferential data of Paired sample 't' test will be used find the probability of within group and Independent 't' test will be used for between group. Mean of the variables will be represented using bar chart.

4. Discussion

The current study is the first study to explore the Immediate effect of Sheetali and Sheetkari pranayama Practice on Generalized anxiety disorder. Previous literature suggests that Pranayama improves the physical and mental well-being but, in addition, sheetali and sheetkari pranayama also cools down the body and the brain by increasing the delta (red bands) and alpha band power (green bands) in the frontal and occipital regions and an increase in theta band power (yellow band) in frontal region with a marked decrease in beta band power (blue bands) indicating that the brain was calm and quiet in relaxed state with less anxiety [15] and also appears to be effective for lowering the systolic blood pressure in individuals with hypertension [16].

In previous literature on bramari pranayama revealed that practice of bhramari pranayama is also beneficial for reducing reduces Heart rate, pulse rate and blood pressure by inducing the parasympathetic dominance and also identified that the EEG waves that dominate after practicing Bhramari are alpha, paroxysmal gamma, and theta waves. Alpha waves are linked to deep relaxation, gamma waves to higher mental activities and perceptual tasks, and theta waves to increased creativity, learning, stress reduction, and stimulation of inner intuitions [17].

According to topographic mapping of the brain activity, Sheetali and Sheetkari pranayamas fall under ideal state of mind which may offer all the main benefits of deep breathing techniques, such as lowering stress, managing rage and irritation, preventing restlessness, and fostering a sense of calm and peace [15].

Deboer and Tobler observed that, as the body temperature drops during sleep, slow frequency waves are generated and the EEG's theta frequency shifts concurrently with the eutermic brain temperature [18]. Sheetali and Sheetkari pranayama generate slow-frequency alpha, theta, and delta waves, which represent a state of calmness and relaxation [19]

5. Conclusion

The present study findings will provide high quality clinical evidence on the efficacy of sheetali and sheetkari on generalized anxiety disorder. if the observations of this study ascertain positive results, it could be recommended as an adjuvant therapy for generalized anxiety disorder subjects along with conventional care.

Compliance with ethical standards

Disclosure of conflict of interest

No conflict of interest to be disclosed.

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