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Protocol

Effect of mind sound resonance technique on physiological and psychological parameters among geriatric population: a structured study protocol for a randomized controlled trial

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ABSTRACT

Background: Aging involves physical, psychological, and social changes, including chronic non-communicable pathologies and HPA axis dysfunction. Yoga can manage these issues, while mind sound resonance technique (MSRT) can alleviate stress, anxiety, and improve psychomotor function. This study aims to report the methodology for three months of MSRT sessions and their impact on physiological and psychological parameters in the geriatric population.
Methods: A randomized controlled trial will involve 80 participants aged 60-75 years, divided into an intervention group and a control group. The intervention group will receive 45 minutes of MSRT sessions daily for 90 days, while the control group will not receive any intervention. Post-intervention assessment will be taken and compared with the control group after 90 days.
Conclusions: MSRT, having a dual benefit as meditative and relaxation component, has been shown to improve the physiological and psychological well-being of the geriatric population, with expected outcomes including improved cardio-autonomic, pulmonary, neurocognitive, and psychological functions and changes in serum stress markers.
Trial registration (CTRI): CTRI/2024/02/062308

Keywords: MSRT, Geriatrics, Physiological and psychological functions, DHEA-S

INTRODUCTION

Aging is a natural part of all living lives. It is a complex process of physical, psychological, and social change, and it is linked to a variety of medical disorders, primarily due to depleted physiological reserves and compromised immunological processes.[1] China, India, and Indonesia are expected to have the greatest number of

senior people by 2025. India's old population is anticipated to increase from 7.6 million in 2001 to 137 million by 2021.[2] Chronic non-communicable diseases such as diabetes, hypertension, ischemic heart disease, and arthritis, as well as a high prevalence of psychiatric disorders such as depression and dementia in the elderly ranging from 9% to 35%, have been reported in epidemiological and population aging studies. Furthermore, chronic distress increases the risk of mild cognitive impairment, resulting in a higher risk of dependency, and its prevalence increases with age.[2-6] Furthermore, sleep disturbances can affect daytime function by the incidence of excessive daytime sleepiness, insomnia, night time awakenings, snoring, restlessness, all of which are strongly associated with respiratory symptoms, physical disabilities, and poorer self-perceived health, as well as dysfunctions of the hypnosis system. Several studies suggest that reducing DHEA(S) can induce heart difficulties, abnormal weight gain, diabetes, poor immunity, and an increased risk of cancer.[2,7] It is therefore essential to establish interventions that promote healthy aging, prevent disability onset, and enhance life quality, while also selecting practices that the elderly can easily implement.[6,8]

Yoga is an ancient traditional science of holistic living that includes the practice of specific postures, regulated breathing, and meditation.[8] It influences both the physiological and psychological aspects of ageing and helps to achieve control over the mind's modifications and thus balance the lifestyle, reduces sympathetic tone, and induces a state of parasympathetic dominance.[8,9] They have also been shown to help restore autonomic homeostasis yoga relaxation practices have demonstrated numerous health benefits, including the ability to improve selective attention, concentration, visual scanning abilities, speed of information processing, and a repetitive motor response, thereby preventing cognitive impairments and clearly reducing anxiety symptoms. yoga has also been shown to treat HPA axis dysfunction.[10,11]

Mind sound resonance technique (MSRT) is an advanced relaxation yoga technique developed by SVYASA, Bengaluru.[12] It uses mantra to generate resonance, which primarily acts through the Manomaya Kosha to induce deeper relaxation for both the mind and the body. MSRT can be done supine or sitting to improve well-being, concentration, willpower, and relaxation. An increase in gamma brain wave coherence (a manifestation of deep relaxation). This strategy also resulted in improved pain, discomfort, disability, and state anxiety reduction in patients with chronic neck pain.[9] MSRT has been shown in clinical and non-clinical populations to improve stress, anxiety, sadness, self-esteem, blood pressure, and heart rate. It has also been shown to enhance psychomotor performance.[10] They gain effective control over body movements, emotional control, and the will to cope with ageing, and as a result, yoga and meditation interventions have been found to promote psychological well-being and decrease anger, anxiety, and depression.[12,13] Similarly, this study is designed to determine and prove the beneficial effects of MSRT on physiological and psychological functioning in the geriatric population.

METHODS

Study design

The present study, which will be a randomized controlled trial, which will be conducted on participants from govt. yoga and naturopathy medical college (GYNMC), Chennai. The study is planned to start from May 2024 and to complete by April 2025. Institutional ethical committee (IEC) approval has been given, vide letter numbers "RES/IEC-GYNMC/2023/195" (from GYNMC), and "MMCH&RI IEC/PhD/01/OCT/23" (Meenakshi academy of higher education research), Chennai. The registration in the clinical trials registry-India (CTRI) is done; the CTRI number: CTRI/2024/02/062308. Outcome variables will be performed at baseline and after 90 days as depicted in Figure 1.

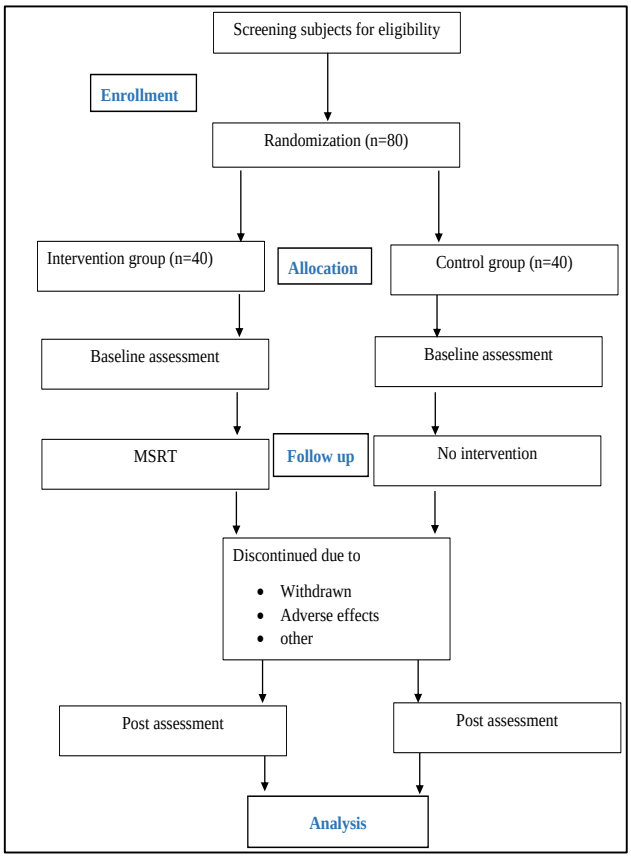

Figure 1: Trail profile.

Sample size

Based on the article the "effect of MSRT on quality of sleep in geriatric population" (Dhanjani et al.[12] The

sample size is calculated on the findings of mean and SD of both the group samples of this article with 95% confidence and 90% power, the sample size is fixed as 80 (40 in each group).

Randomization and blinding

After screening the subjects (n=80) they will be recruited to intervention group (n=40) and control group (n=40) after randomization by random table generator method the baseline assessment will be taken for both the groups, then for intervention group MSRT will be given for 45 mins a day for a total period of 90 days and control group will not get intervention during the study period. After 90 days intervention post assessment will be taken for both the groups and analyzed statistically.

Selection of participants

Inclusion criteria

Individuals who give a willing consent to participate with the age limit between 60 years to 75 years which includes both genders and primarily intervention will be instructed in regional language (Tamil) and English, so they should be knowing these languages were included in study.

Exclusion criteria

The individuals with neurological and psychiatric conditions, also physical disability, disease or injury that could interfere physical activity and Patient with cognitive deficit (e.g. Dementia), mental illness (e.g. psychosis or bipolar disorder), dysfunctions of vital organs, Individuals currently enrolled in any other research study.[2,3,5] These category participants will be excluded from the study after screening them via consultation, investigation reports and analyzing the vital data.

Intervention details

Components of the intervention

The procedure (Table 1) used for MSRT session will be adapted from the book MSRT.[14] MSRT is one of the advanced guided yoga relaxation techniques that can be practiced in supine or sitting posture for achieving the goal of positive health, will power, concentration and deep relaxation, This tool was developed using the concepts from traditional texts that talk about the power of Om (Mandukya Upanishad) and Nadanusandhana (Hatha yoga Pradipika) for achieving internal mastery over the modifications of the mind (Patanjali's definition of yoga), the internal vibrations and resonance developed while chanting the syllables A, U, M, Om and Maha mrityunjaya mantra (MMM) sounds.[1,8]

Sequences of specific classes

The session will begin with a prayer and the sequence of events outlined in Table 1. The instructor will address the concerns of the participants prior to the commencement of the session and will also check on each participant's physical condition during and after the session is concluded. The intervention's goal is to improve both the physiological and psychological functions of the older population. The current technique and procedure have been chosen to create an easy and comfortable practice for the elderly.

Table 1: Detailed procedure of MSRT.

Steps	Practice	Duration
Step 1: Prayer	Maha Mritunjaya Mantra: Oṃ tryambakaṃ yajāmahe| Sugandhiṃ puṣṭivardhanam. Urvārukamiva bandhanāt| Mṛtyormukṣīya māmṛtāt Rig Veda 7.59.12	2 mins
Step 2:	A) Ahata-Loud chanting of A, U, M and AUM (3 rounds). Feel completely body resonance. B) Anähata-Mental phase of A, U, M and AUM (3 rounds). Feel resonance even with anahata phase.	40 mins
Step 3:	Ahata-Loud chanting of MMM Resonance (3 rounds) Anähata-Mental phase of MMM (3 rounds)	
Step 4:	Anähata-AUM (9 rounds)-feel resonance waves	
Step 5:	Ajapa-japa AUM to Silence (9 rounds). Feel the resonant waves of Om coming up and spreading throughout the body and diffusing into silence (9 rounds)	
Step 6:	Stay in silence	
Step 7:	Resolve	2 mins
Step 8:	Prayer-MMM, om shathi shanthi shanthih |	1 min

*MMM- Maha mrityunjaya mantra.

Selection and instructors

Yoga trainers who are skilled and registered are confirmed based on their expertise in teaching yoga to the people with chronic diseases when necessary and required. The chosen instructor will be directed to teach the participants.

Measurement of intervention fidelity over time

To document the practice session, a manual checklist will be created for the participants and will be entered in excel sheet.

Intervention group

The group will be performing MSRT technique for 45 minutes for the duration of 90 days (weekly thrice). Before starting the session, the subjects will be informed with all the details regarding the study and intervention.

Control group

This group will not perform any practice during the intervention period for 90 days.

Outcome variables

Quantitative outcome variables

The quantitative outcome measure is done for assessing the cardio autonomic function, pulmonary function, neuro-cognitive function, and serum stress marker (DHEA-S).

The systolic blood pressure (SBP) and diastolic blood pressure (DBP) will be measured with a Sphygmomanometer (Diamond dial deluxe apparatus) with a comfortable free size cuff and stethoscope (Auscultatory method). To determine variability, it is measured in both sitting and supine positions; measured every day before and after the intervention.

Heart rate variability

The apparatus used to measure heart rate variability (HRV) will be manufactured by Mavom lab in Bangalore. All subjects will be instructed to maintain their normal sleep pattern, refrain from consuming coffee or alcohol, and refrain from engaging in physical activity 24 hours before the evaluations. This test will take 2 hours in the morning. Following a light breakfast. Before the recording begins, subjects will be encouraged to urinate. After 15 minutes of supine relaxation on a couch, an electrocardiogram (ECG) with regular breathing will be recorded for 5 minutes. The task force on HRV's recommendation for recording short-term HRV will be followed. During rest in supine posture, limb Lead II ECG will be collected at a rate of 8000 samples/second using an ECG analogue to digital converter (AD).[15]

The data extraction of HRV will be done as; the ectopic and artifacts will be removed from the recorded ECG after manual checking in offline mode. Thus, HRV data will be excluded when recordings have more than 10% of beats are premature, or artifact time exceeded 5% of recorded time. Raw R-R interval data will be obtained from simple analog-digital (A-D) converter will be stored in the system separately and HRV analysis will be done using kubios HRV analysis software version 2.2 (Bio-signal analysis group, Finland). Linear model heart rate variability analysis will be carried out in this study, analyzed in the time and frequency domain. In the time domain, the standard deviation of the NN interval (SDNN), the square root of the mean squared differences of successive NN intervals (RMSSD), the number of interval differences of successive NN intervals greater than 50 ms (NN50), and the proportion derived by dividing NN50 by the total number of NN intervals (pNN50) will be used. In frequency domain power spectral density (PSD) analysis in non-parametric method (fast Fourier transform) will be used. They are low frequency (LF, 0.04-0.15 Hz) and high frequency (HF, 0.15-0.40 Hz) power expressed in normalized units (LF nu and HF nu, respectively), and LF/ HF ratio.[15]

Pulmonary function tests (PFT) will be performed using RMS Helios 401. All subjects will do spirometry while standing, with their noses clipped closed. Each subject completed a minimum of three trials, with the best of the three chosen for use. The following spirometry parameters were measured: forced vital capacity (FVC), forced expired volume in one second (FEV1), FEV1 to FVC ratio (FEV1/FVC), peak expiratory flow (PEF), mean forced expiratory flow during the middle half of FVC (FEF 25-75%), Slow vital capacity (SVC), and Maximum voluntary volume (MVV).[16] The marker is set to zero, and the subject is instructed to sit upright and inhale deeply while holding their breath, a mouthpiece is inserted between their teeth with their lips locked, and they blow the air forcefully. The measured peak flow was the highest value obtained throughout three efforts [17] to determine pulmonary function.

Visual reaction time (VRT) testing is performed by having the subject sit in front of and control component A of the PC 1000 Hz timer device (made by Mavom lab, Bangalore). The examiner will start the stimulation procedure by pressing the start button on component A, and the subject will be instructed to press the stop button with their dominant hand as soon as they see the red light.[17] The number of oscillations produced will be recorded as reaction time with millisecond (ms) accuracy.

Auditory reaction time (ART) will begin when the examiner hit the start button on component A of the device (made by Mavom lab, Bangalore), and ends when the subject clicked the stop button with their dominant hand after hearing the sound through their headphones. For each subject, three trials will be allowed with a one-minute interval for both VRT and ART, and the shortest time recorded will be used for analysis. The time interval between the stimulus presentation and the subject's response will be measured in milliseconds.[17]

Critical flicker fusion frequency (CFFF), this module's system displayed a sequence of red-light stimuli at various frequencies ranging from 12 Hz to 120 Hz (made

by Mavom lab, Bangalore). The examination will take place in a darkly lit room, with the participant made to sit 80 cm away from the module and a 40 W bulb set behind them. The red light will be presented on a white background, and the frequency of the flicker will gradually increase from 12 Hz until the participant claim that the given light is viewed as "steady", "constant", or "fused". The mean value of three descending measures from high to low frequency when the subject stated that the light began to flicker and the mean value of three ascending measures from low to high frequency when the subject reported that the light stopped flickering will be collected for analysis.[18]

Blood biomarkers

Serum levels of DHEA-S (stress marker) will be measured using a chemiluminescent enzyme immunoassay (CLEIA). The procedure last less than 5 minutes for the collection of blood from vein in arm (the visible vein from antecubital fossa-preferably median cubital vein) usually 5 ml of venous blood will be collected and stored in gold top tube and send to a recognized laboratory for analysis. Dehydroepiandrosterone (DHEA) the major secretory product of the adrenal gland, is produced in larger quantity than any other circulating steroid hormone. Levels of DHEA decline dramatically with age, concurrent with the onset of degenerative changes and chronic diseases associated with aging.[7]

Qualitative outcome variables

The qualitative measure is done using a questionnaire assessing depression, anxiety, stress, quality of life, quality of sleep.

Depression anxiety stress scales (DAS-21), will be used to assess the symptoms of anxiety, stress, and depression. It is made up of 21 items, 7 for each of the three subscales: DASS-D (depression), DASS-A (anxiety), and DASS-S (stress). Respondents must rate the extent to which each item applies to them over the previous week on a 4-point Likert scale ranging from 0 (did not apply to me at all) to 3 (applied to me very much).[19]

Older people's quality of life questionnaire (OPQOL-brief), consists of 13 statements, with the participant asked to indicate how much he or she agrees with each statement by selecting one of five possible options ("strongly disagree", "disagree", "neither agree nor disagree", "agree" and "strongly agree", each with a score of 1-5). Higher ratings indicate a higher quality of the life.[20]

Pittsburg sleep quality index (PSQI) is a ten-item, self-reported questionnaire designed to measure sleep quality. Subjective sleep quality, sleep latency, sleep duration, habitual sleep efficiency, sleep disturbances, medication use, and daytime sleepiness are the seven sub-scales.[2]

Statistical analysis

Descriptive statistics such as mean and standard deviation will be used assess the physiological hormonal and psychological variable. Paired t test will be adopted to find out the effectiveness of MSRT on the selected physiological, hormonal and psychological variables. Independent t test will be used to compare the effectiveness of MSRT on physiological, hormonal and psychological variables. Pearson correlation coefficient will be adopted to prove the relationship between physiological, hormonal and psychological variables. Analysis of variance (ANOVA) test and independent t test will be done to association between physiological, hormonal and psychological variables with demographic variables. And the data analysis will be done using appropriate statistical test in R statistical software version 4.0.2.

DISCUSSION

This study is planned to explore the effects of MSRT practice on the physiological and psychological functions among the geriatric population; as the elderly needs an easy and feasible practice rather difficult exercises; MSRT is an effective, easy and convenient to follow with the instructions. And it is referred to have a dual benefit as meditative effect along with its relaxation component.[1] According to a systematic review (Moovendhan and Nivethitha 2017) of the scientific literature, regular yoga practice can be regarded as an effective intervention for treating a variety of health-related issues that older adults suffer.[9] In accordance with the study (PS et al), MSRT is a useful non-pharmacological option for maintaining and improving older people's cognitive performance. It is believed that practicing MSRT will increase one's capacity to manage distractions and stay alert without becoming distracted. In addition, talked about numerous studies showed that yoga-based relaxation techniques enhance P300 amplitude instantly following a practice. They also improve motor speed, information processing speed, selective attention, concentration, visual scanning skills, and repetitive motor response, all of which help to prevent cognitive impairments and preventing dementia.[1]

Additionally, by increasing levels of brain-derived neurotrophic factor (BDNF), relaxation may lessen the amount of cortisol secreted during stressful situations, which may have neuroprotective effects. Additionally, GABAergic cortical inhibition, a mechanism connected to better cognitive function and higher emotional regulation, is linked to meditation activities. The prefrontal cortex and right anterior insula, which are involved in attention, interception, and sensory processing, are thicker in those who meditate. Compared to non-meditators, advanced meditators have higher levels of melatonin, which prevents the build-up of beta-amyloid plaque, a characteristic feature of Alzheimer's disease.[1] Subtle yoga poses and deliberate breathing exercises cause the sympathetic nervous system to

become less active, which leads to parasympathetic dominance and physiological stress reactivity.[1] In GAD patients, the MSRT approach can also result in a notable improvement in psychomotor performance. Regarding the mechanism, research indicates that yoga improves autonomic functions by inducing neurohormonal mechanisms that inhibit sympathetic activity by down regulating the hypothalamic-pituitary-adrenal axis. This decreases stress and anxiety. Practices focused on mindfulness may also improve cognitive flexibility, which aids in anxiety management.[8] Additionally, it is well established from meditation that anxiety reduction enhances performance on memory and attention-demanding tasks. Therefore, the decreased anxiety may also have contributed to better performance.[1] Based on the outcomes of a study (Dhanjani et al), individuals overall sleep quality improved and their frequency of sleep disruptions decreased following a 15-day yoga intervention. This higher-quality sleep was consistent with earlier research. As previously mentioned, inactivity that prevents older adults from engaging in physical activity is also linked to sleep disturbance in older adults. Relaxation was significantly enhanced by the MSRT-guided meditation, and the subject's bodies and minds were simultaneously stimulated and comforted resulting in more sound sleep.[12]

Further there were no RCT's done to find the effectiveness of MSRT among the geriatric population, this study plan is done to explore the effectiveness of MSRT on the Physiological functions (Cardi autonomic functions, pulmonary function, Neuro cognitive function and changes in the Serum stress marker level "DHEA-S"); psychological functions (depression, anxiety, stress and quality of sleep, quality of life).

CONCLUSION

The results of the current study are expected to provide impeccable clinical proof of the effectiveness and security of the yoga protocol for the geriatric population. If the findings of this study show that the geriatric population's cardio autonomic, pulmonary, neurocognitive and psychological functions and serum stress marker (biomarker) have improved, then it may be suggested as adjuvant therapy for better patient care and management in addition to conventional care.

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Conflict of interest: None declared
Ethical approval: The study was approved by the Institutional Ethics Committee "RES/IEC-GYNMC/2023/195" (from GYNMC), and "MMCH&RI IEC/PhD/01/OCT/23" (Meenakshi academy of higher education research), Chennai.

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