Effects of Yoga-Like Exercises on Mild and Moderate Alzheimer Disease: A Randomized Controlled Trial Protocol

Effets des Exercices de Type Yoga sur la Maladie d'AlzheimerlLégère et Modérée: Protocole d'Essai Contrôlé Randomisé

Rihab Moncer[1,2], Habib Hajji[1,2], Salma Naija[2,3], Sana Ben Amor[2,3], Sonia Jemni[1,2], Helmi Ben Saad[4,5,6]

1. Physical and rehabilitation department, Sahloul Hospital of Sousse, Tunisia
2 . Faculty of medicine of Sousse, University of Sousse, Tunisia
3. Neurology department, Sahloul Hospital of Sousse, Tunisia
4. Laboratory of Physiology and Functional Explorations. Farhat HACHED Hospital. Sousse, Tunisia
5. Laboratory of Physiology. Faculty of Medicine of Sousse. Street Mohamed KAROUI. Sousse 4000. Tunisia
6. Heart Failure Research Laboratory (LR12SP09), Farhat HACHED Hospital, University of Sousse, Sousse, Tunisia.

Abstract

Background: While aerobic exercises have demonstrated efficacy in slowing cognitive decline and improving psychological symptoms associated with cognitive impairments, they may not be feasible due to multiple disabilities. Other gentle exercises with mindful approaches, such as "Yoga-like", have been explored but lack clear evidence.
Aim: To assess the efficacy of a "Yoga-like" intervention on cognitive and psychological features in patients with mild to moderate Alzheimer Disease (AD).
Methods: We propose a randomized controlled trial design. Patients with mild to moderate AD who are able to undergo neurocognitive assessment and do not have conditions contraindicating deep breathing or extreme postures will be randomly assigned to an intervention group (IG: Yoga-like) or a control group (CG: no intervention). The 'Yoga-like' intervention consists of 30 minutes of exercises combining breathing, postures, concentration, and meditation, conducted three times a week over eight weeks. Both groups will undergo neuropsychological tests at baseline and after eight weeks, including attention, problem-solving, visuospatial abilities, mood and neuropsychiatric symptoms.
Expected results: It is anticipated that the breathing, concentration, and meditation components of the intervention will improve attention, problem-solving abilities and behavioral symptoms. The postural components are expected to enhance visuospatial control and balance.
Trial registration: PACTR202407721329710 (https://pactr.samrc.ac.za/TrialDisplay.aspx?TrialID=30602)

Key words: Aging, Mind-Body therapies, Neurocognitive Disorder, RCT

Résumé

Contexte: Bien que les exercices aérobiques aient démontré leur efficacité pour ralentir le déclin cognitif et améliorer les symptômes psychologiques associés aux déficits cognitifs, ils peuvent ne pas être réalisables en raison de multiples handicaps. D'autres exercices doux avec des approches conscientes, tels que le "Yoga-like", ont été explorés mais manquent de preuves claires.
Objectif: Évaluer l'efficacité d'une intervention "Yoga-like" sur les caractéristiques cognitives et psychologiques chez des patients atteints de la maladie d'Alzheimer (MA) légère à modérée.
Méthodes: Nous proposons un essai contrôlé randomisé. Les patients atteints de MA légère à modérée capables de subir une évaluation neurocognitive et ne présentant pas de conditions contre-indiquant la respiration profonde ou les postures extrêmes seront assignés aléatoirement à un groupe d'intervention (GI: "Yoga-like") ou à un groupe témoin (GT: pas d'intervention). L'intervention "Yoga-like" consiste en 30 minutes d'exercices combinant respiration, postures, concentration et méditation, effectués trois fois par semaine pendant huit semaines. Les deux groupes subiront des tests neuropsychologiques au départ et après huit semaines, y compris l'attention, la résolution de problèmes, les capacités visuospatiales, l'humeur et les symptômes neuropsychiatriques.
Résultats attendus: Il est prévu que les composantes de respiration, de concentration et de méditation de l'intervention améliorent l'attention, les capacités de résolution de problèmes et les symptômes comportementaux. Les composantes posturales devraient améliorer le contrôle visuospatial et l'équilibre.
Enregistrement de l'essai: PACTR202407721329710 (https://pactr.samrc.ac.za/TrialDisplay.aspx?TrialID=30602)

Mots clés: Vieillissement, thérapies corps-esprit, trouble neurocognitif, ECR

Correspondance
Rihab Moncer
Physical and rehabilitation department, Sahloul Hospital of Sousse, Tunisia
Email: rihabmoncer@hotmail.com

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Introduction

Increased life expectancy has led to a rise in cognitive impairments (CI), with Alzheimer's disease (AD) being the most prevalent cause [1, 2]. Initially, the disease was diagnosed based on the impairment of episodic memory but research has shown that numerous symptoms precede memory loss, including attention deficits, executive dysfunction, processing speed decline, language impairments, and visuospatial skills [2]. Additional symptoms are associated with the disease including anxiety, loss of self-image, and aggression [3]. CI in the elderly were related to many risk factors including educational level, occupational and social activities, sedentary lifestyle, cardiovascular risk factors, depression and genetic predisposition [4, 5]. The current (ie; year 2024) pharmacological treatment of AD focuses on symptomatic management [6, 7]. While these medications can provide some relief from symptoms, they do not slow or prevent the progression of AD [8], are expensive and may have side effects [6- 9].

Non-pharmacological interventions were based first on occupational therapy, but some researchers reported a positive correlation between increased physical activity and improve symptoms in patients with AD [10, 11]. Those exercises are more efficient when having multisensory stimulation [13-16]. Mind-body exercises, such us Yoga is one of the integrative exercises that has been introduced in the management of CI in the elderly [14, 17-20]. It is a multi-component mind-body practice, which combines physical postures, breathing exercises, and meditation [21]. Yoga can enhance the density of gray matter in areas of the brain that are linked to memory and emotional regulation [22-25]. However, existing studies, limited in patient numbers, do not provide sufficient evidence of Yoga efficacy in AD [14]. Additionally, the details of Yoga interventions are often inadequately reported [19, 20] and many Yoga interventions exclude the spiritual aspects (ie; meditation) of the practice that could have positive effects on concentration and memory [20]. Classical Yoga, originating thousands of years ago in India, includes eight pillars: physical postures (asanas), breathing exercises (pranayama), and meditation practice [19, 21, 25-27]. Those pillars could be a good solution for cognitive decline, anxiety and aggressively [27] but it may not be suitable for older adults with motor disorders and polyarthritis, conditions affecting 40% of the elderly in low- and middle-income countries [18]. “Chair Yoga” (ie; “Yoga-like”), a modified form designed for those unable to practice Yoga on the floor, is a safe and effective alternative for older adults with motor disorders and polyarthritis [28].

The aim of the present randomized clinical trial (RCT) protocol comprising two groups [Intervention group (IG): Modified Yoga, and control group (CG): no intervention] will be to examine the effects of a modified Yoga intervention program (ie; “Yoga-like”) on neuropsychological assessment (ie; primary outcome), memory, executive function, visuospatial skills, problem-solving, and depression in patient with mild to moderate AD. The “Yoga-like” program will be deemed clinically effective if it produces a change in neuropsychiatric inventory questionnaire (NPI-Q) exceeding the recommended minimal clinically important difference (MCID) of two [29, 30].

Methods

Study setting

This monocentric, prospective, RCT was designed in accordance with the guidelines of the SPIRIT (for standard protocol items: recommendations for interventional trials) [31]. Patients will be recruited during a 10-month period (ie; September 1, 2024, to June 1, 2025) from the Physical and Rehabilitation and Neurology departments (Sahloul Hospital, Sousse, Tunisia). The study protocol received an ethical approval from the ethical committee of faculty of medicine of Sousse, Tunisia (Approval N° 244/ 2024). Each patient’s tutor will be informed about the study aims and will receive a report of the patient’s explorations. A written informed consent will be obtained from the patient’s tutor. Participation in the study will be free of charge.

Data collection will be pseudonymised. Collected data will be stored electronically on a password-protected computer. The study was registered in the Pan African Clinical Trial Registry within the number PACTR202407721329710 (https://pactr.samrc.ac.za/TrialDisplay.aspx?TrialID=30602).

Recruitment method, study population, and inclusion, non-inclusion, and exclusion criteria

Patients will be recruited by two ways. First, from the patient database of the fore mentioned Neurology department, which includes patients/tutors' phone numbers and those of their tutors. Second, from patients consulting the outpatient Neurology department, for cognitive disorder during the study period. The information sheet of these patients includes systematically the telephone contact of the patients/tutors. If a patient/tutor cannot be reached after three phone calls over one week, the patient will not be included in the study.

Only patients diagnosed with mild to moderate stages of AD according to recommendations from the national institute on aging Alzheimer’s [32], having normal or corrected-to-normal vision and color perception, able to sit on a chair, and who don’t practice regular physical activity during the study period will be included in the protocol.

The following non-inclusion criteria will be applied: presence of cardiovascular or orthopedic conditions that could affect the ability to perform the proposed intervention tasks; heart or respiratory diseases that do not allow physical activity; severe cognitive disorders or severe psychiatric diseases; medications that affect posture or the ability to perform exercises.

Files of patients who do not complete the intervention (for the IG) or the final neuropsychological assessments (for both groups), or have missing data, will be excluded

from the final analysis.

Sample size

The sample size was estimated using the formula [33]:
$N = ((r+1)(Z_{\alpha/2} + Z_{1-\beta})^2\delta^2)/MCID^2$, where
• "**N**" is equal to $n_1 + n_2$ (ie; sample sizes for the IG and CG);
• "**$Z_{\alpha/2}$**" is the normal deviate for type I error(fixed at 5%, $Z_{\alpha/2} = 1.96$);
• "**$Z_{1-\beta}$**" is the normal deviate for type II error (fixed at 80%, $Z_{1-\beta} = 0.84$);
• "**r**" (equal to n_1/n_2) is the ratio of the sample size required for the two groups (here, r = 1 gives a sample size distribution of 1:1 for the IG and CG);
• "**δ**" and "**MCID**" are the pooled standard deviation(SD) and the MCID of the main outcome (ie; NPI-Q score). Given the pioneering nature of this study at the time of its realization, "δ" and "MCID" values were fixed at two in NPI-Q score [30, 34].

Inserting the aforementioned data into the formula resulted in a sample size of 16 patients in each group. Considering a potential power loss of 10% due to possible adverse effects, the revised sample size was calculated to be 20 patients in each group [18 = 16/(1-0.10)].

Study protocol and procedures, and randomization

The procedures will consist of four visits (V1 to V4) described in Box 1.

Box 1. Schedule of enrolment, interventions, and assessments.

	Study period and visits (V)						
	Enrolment	**Allocation**	**Post-allocation**				**Close-out**
Time point**	**-V_1**	**0**	**V_1**	**V_2**	**V_3**	**V_4**	***Vf***
Enrolment:							
Eligibility screen	X						
Informed consent			X				
List other procedures	X						
Allocation		X					
Interventions:							
Intervention group							
Control group					⟷		
Assessments:							
List baseline variables	X	X					
List outcome variables			X	X		X	X
List other data variables			X	X	X	X	X

-V1: Before patient recruitment. **Vf**: Final visit, one week after the last intervention.

Visit 1 (V_1)

All patients consulting for CI will undergo neuropsychological evaluation. Those diagnosed with mild or moderate AD will undergo an interview (in the presence of their tutors) regarding the study, assessment, intervention, duration, and aims. Once all inclusion and non-inclusion criteria will be met, the date for the assessment visit (V2) will be scheduled. Any questions or concerns will be discussed by three physicians (RM, SN, and HH in the authors' list). Subsequently, both the physician and the patient's tutor will sign an informed consent form officially admitting the patient to the study. A neurologist (SN in the authors' list) will establish mild to moderate AD diagnosis during the expected period.

Visit 2 (V_2)

DuringV_2, patients will assess neurocognitive tests with a trained neurologist at baseline.

Visit 3 (V_3)

During V_3, patients will be randomly assigned to receive their first intervention, either IG or CG. Randomization will be conducted by one investigator using a random list generated online through PubMed's random group generator (available at http://www.pubmed.de/tools/zufallsgenerator/?no_cache=1). A randomization schema determined the assignment of patients to IG or CG. A list was created with a chronological sequence to ensure clear assignment of each patient to one of the two groups. The physicians responsible for randomization (HH in the authors' list) entered each new patient's name, along with the time, date, and randomized number, into the patient's folder. Due to economic considerations, the physicians were not blinded. Once randomization is completed, the physician will schedule the first day of intervention.

Visit 4 (V_4)

V_4 will occur after the intervention, when patients will have final neurocognitive tests with one investigator (SN in the authors' list).

Data collection

Data will be collected via a questionnaire consisting of two parts. The total duration of the questionnaire is estimated to be 40 minutes (ie; ten minutes for the first part, 30 minutes for the second part). If any patient could not complete the assessments due to attention problems, the neuropsychological tests will be divided in two visits (V_{2a} and V_{2b}) separated by a 24-36 hours.

Part 1: Socio-demographic and medical history

The following socio-demographic and medical history, which are identified as risk factors of CI [4, 5] will be evaluated: age (years), sex (male/female), origin (rural/urban), family (live alone/ with family), profession and leisure activities (sports, gardening, dance), cardiovascular diseases(yes/no), history of depression (yes/no) and anxiety (yes/no), and family history of dementia (yes/no).

Part 2: Neurocognitive tests

MMSE Arabic version will be applied to all patients at baseline. MMSE is a simple evaluation containing 11 questions that provides an overview of cognitive function with a maximum score of 30 [35, 36]. Scores between 26 and 30 indicate normal cognitive function, between 20 and 25 mild and 10 to 19 moderate cognitive disorder [36] (Box 2).

Box 2. Summary of different tests that will be used for patient's neuropsychological assessment.

Test	Normal scores/values	Interest
Mini mental state examination [35, 36]	.Score varies from 0 to 30 .26-30: Normal cognitive function .20-25: Mild cognitive impairment .10-19: Moderate cognitive impairment .0-9: Severe cognitive impairment	.Screening test and diagnostic tool used as a baseline for neuropsychological assessment
Tower of Hanoi Test [37]	.Total number of moves .Total time spent .Number of rule violations .Lower score: Better planning and problem solving skills	.A well-known problem with several possible solutions that examines how a problem's presentation affects the patient's strategies and problem solving skills
Stroop color and word test [38-39]	.Number of correct answers .Time spent to complete the test .MCID varies from 5.4 to 30.6 seconds	.A neuropsychological test that is often used to evaluate the capacity to prevent cognitive interference, also known as the Stroop effect, which happens when processing one sensory attribute interferes with processing another
Neuropsychiatric inventory questionnaire [29, 30]	.Normal populations had a score of zero .People with dementia had a mean score ranging from 10 to 30 .MCID varies from 2 to 3	. A test that assess a wide range of neuropsychiatric symptoms and behavioral in individuals with cognitive impairments.
15-item geriatric depression scale [40]	.Score varies from 0 to 15 .0-5: Normal .5-9: High probability of depression .≥10: Presence of depression	.A short form of the geriatric depression scale used to screen and evaluate depression in the elderly

MCID: Minimal clinically important difference.

The following neurocognitive tests will be performed in this order (Box 2, Figure 1): Tower of Hanoi test [37], Stroop color and word test [38, 39], NPI-Q [29, 30], and 15 item of geriatric depression scale (GDS-15) [40]. Problem-solving skills will be assessed using the Tower of Hanoi test [37]. This task involves transferring disks among three pegs to recreate a pyramid pattern, considering the number of moves and time taken. A five-disk variant will be used, and the test theoretically lasts 10 minutes [37]. Attention will be assessed using the Arabic version of the Stroop color and word test [38, 39]. Over five minutes, patients will respond to stimuli presented on a computer screen across four phases. They will identify shapes' colors, read color names in black ink, read color names in matching colors, and name the ink color of words printed in mismatched colors [39]. The MCID of Stroop test is 5.4 to 30.6 seconds [39]. This test lasts approximately five minutes. NPI-Q [30] is a comprehensive tool used to assess a wide range of neuropsychiatric symptoms in individuals with dementia and other neurological conditions [29]. It evaluates behaviors and psychological symptoms including delusions, hallucinations, agitation, depression, anxiety, euphoria, apathy, disinhibition, irritability, aberrant motor behavior, and sleep and appetite disturbances. The NPI-Q typically takes about five to 10 minutes to administer, involving detailed input from a caregiver or informant. A change of approximately 2 to 3 points on the total NPI-Q score is often considered MCID, reflecting a meaningful shift in symptom severity [30]. Mood will be assessed using the GDS-15 [40]. The latter is widely used in clinical and research settings among the geriatric population to screen for mood disorders and depression. Scores of 0 to 5 are regarded as normal; those of 5 to 9 suggest a high probability of depression; and scores of 10 and more indicate the presence of depression. This test last theoretically 10 minutes [40].

Validity of Yoga concepts in health

The concepts of pranayama [21], Yama, and Niyama [41], Pratyahara [48], Dharana, Dhyana, and Samadhi originate from ancient yogic traditions and have been subjects of interest in various scientific studies [2, 21, 41-48]. Introduced in biomedical sciences and health, yoga has always been interpreted through its philosophy [42], but in the last decade (ie; 2014-2024), studies have shown the physiological effects of these concepts [43, 44]. Physiologic effects due to pranayama are characterized by decreased oxygen consumption, decreased heart rate, and decreased blood pressure, as well as increased theta wave amplitude in electroencephalography recordings, increased parasympathetic activity accompanied by feelings of alertness and reinvigoration [44]. Indeed, this diaphragmatic breathing stimulates the deep fascia of the abdomen and thorax, activates the vagus nerve and solar plexus, and modulates the autonomic nervous system, thereby reducing stress [44, 45]. The research specifically focusing on the clinical validity of Yama and Niyama is sparse. However, these principles are often included as part of comprehensive yoga programs and many studies have proven effects of these concepts to reduce heart rate and improve autonomic regulation [43, 44]. Another pillar, Pratyahara [42], where patients are asked to withdraw their senses, seeks to calm the mind by lessening the influence of sensory stimulation [42]. Dharana, Dhyana, and Samadhi benefit the brain, as shown by electrophysiological and recent functional magnetic resonance imaging studies [43-45]. Overall, electroencephalographic measures indicate slowing subsequent to meditation, with theta and alpha activation related to proficiency of practice [43-45]. Sensory evoked potential assessment of concentrative meditation yields amplitude and latency changes for some components and practices [44]. Cognitive event-related potential evaluation of meditation implies that practice changes attentional

allocation [44-46]. Neuroimaging studies indicate increased regional cerebral blood flow measures during meditation [43-45]. Another critical point in yoga practice in clinical trials is the reproducibility of these concepts and how to ensure the application of meditation. However, some studies have identified how yoga teachers and classes can ensure fidelity to all pillars to achieve yoga benefits [47, 48].

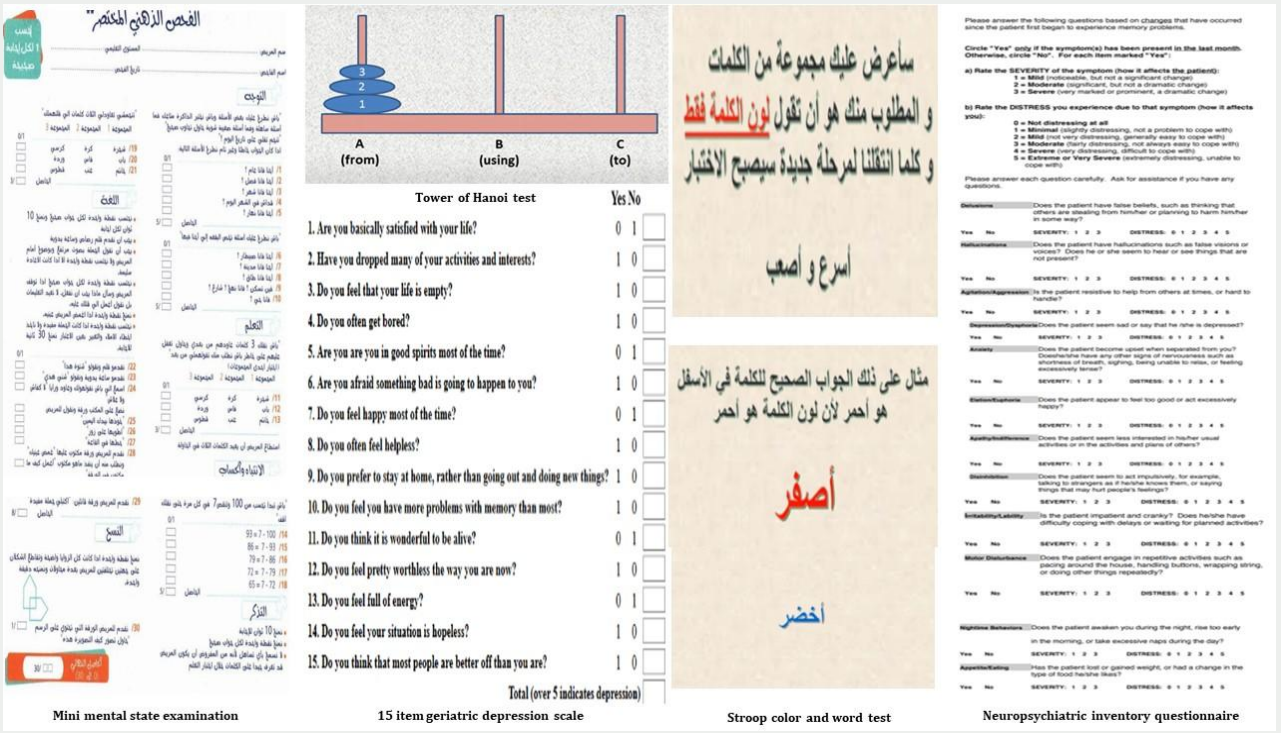

Figure 1. Illustration of the five applied psycho-cognitive tests.

Intervention

The intervention will include the eight pillars of Yoga applied while seated on a chair three times a week for eight weeks, 30 min per session [28]. The rehabilitation area is chosen to ensure concentration and meditation [28]. Chair height will be selected to ensure patient comfort and allow patient to rest their feet on the floor with a backrest that allows the patient to rest their back in an aligned position.

Sessions will be led by one therapist, a yoga teacher, with small group of five patients. The session will begin with slow and deep breathing exercises [21, 28]. The therapist will educate patients on proper breathing techniques, known as Pranayama (Breath control) [21, 25-28]. Pranayama involves regulating the breath to enhance energy flow and mental clarity [21, 25-28]. Patients will be instructed to place one hand on the chest and the other on the abdomen to feel abdominal expansion during inhalation and its contraction during slow exhalation [46]. Simultaneously with deep inhalation, patients will learn to contract their perineal muscles [49].In addition to breathing techniques, the therapist will review two foundational pillars of yoga: Yama (Universal moral observances) and Niyama (Self-discipline) [21]. Throughout the session, the therapist will encourage patients to accept themselves, their limitations, and their values. The session will then progress to a series of chair-based Asanas (Physical postures) for the neck, back, and limbs, synchronized with the same breathing rhythm. This aspect of yoga is widely recognized [14, 19]. To mobilize the cervical spine, patients will be guided to gently tilt their head from side to side and perform slow clockwise and counter-clockwise rotations. Trunk mobility will be addressed by placing one hand on the opposite knee and the other on the chair's back while twisting. For lower limb mobilization, patients will perform seated knee flexion and extension movements and practice maintaining balance in single-leg positions with hands in the air [14, 19, 28].

The last five minutes will include Pratyahara (Sense withdrawal) and Dharana (Concentration) and finished by Dhyana (Meditation) and Samadhi (Absorption) [27, 42]. Samadhi represents a state of profound bliss or enlightenment that promotes self-acceptance and enhances self-esteem [27, 42, 43]. During the meditation phase, patients will be instructed to close their eyes, take deep diaphragmatic breaths, relax their neck, shoulders, hands, and toes, release negative thoughts with each exhalation, and welcome positive thoughts while accepting their illness. Finally, the therapist will prompt patients to acknowledge their accomplishments, express gratitude, and emphasize the importance of self-love [46].

RM and HH will supervise the intervention, the unintended events, and will decide who will stop and continue the intervention.

Statistical methods

Quantitative data distribution will be assessed using the Kolmogorov-Smirnov test. For normally distributed data with equal variances, results will be presented as mean ± SD. Non-normally distributed data will be presented as median (interquartile range). Categorical data will be presented as frequencies and percentages (%).

Student's T-test or Mann-Whitney U test will compare quantitative data between groups, while the Chi-square test will compare categorical data.

The interventional program will be deemed clinically effective if it produces a change in verbal fluency exceeding the recommended MCID of two words in the NPI-Q score compared to the initial assessment [29, 30].

Expected results

The outcomes expected from the results of this protocol are:
i) Enhance number of words due to concentration pillar of "Yoga-like".
ii) Improving execution speed, problem solving, memory and visuo-spatial control due postural pillars and spiritual pillars of "Yoga-like".
iii) Improving mood due meditation parts.

Declaration

The authors wish to disclose that an artificial intelligence tool (ie; ChatGPT 3.5) was utilized to enhance the clarity and coherence of the manuscript' writing. The tool was utilized for language refinement purposes only, ensuring the text was clear and coherent without altering the scientific content or generating any new text [50].

ABBREVIATIONS' LIST

AD: Alzheimer Disease
CI: Cognitive Impairment
CG: Control Group
GDS-15:15-item Geriatric Depression Scale
IG: Interventional Group
MCID: Minimal Clinically Important Difference
MMSE: Mini-Mental State Examination
NPI-Q: Neuropsychiatric Inventory Questionnaire
SD: Standard Deviation

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