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Research Protocol

Nursing Section

Comparing the Combination of Banana Consumption and Deep Breathing Exercises with Banana Consumption alone and Deep Breathing Exercises alone in the Management of Sleep Deprivation, Anxiety, and Depression among Postmenopausal Women: A Research Protocol

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ABSTRACT

Introduction: Sleep disturbances are associated with increased healthcare costs and negative health outcomes. Oestrogen levels decrease after menopause, which may also be accompanied by deterioration in cognitive function along with the symptoms of depression and depressive disorders.

Need of the study: The need of the study is evident in postmenopausal women, where physiological changes lead to a decline in vital hormones such as oestrogen and melatonin, contributing to anxiety, depression, and obstructive sleep apnoea. Consuming fruits rich in tryptophan which is a precursor of melatonin and serotonin can reduce sleep disorders and enhance sleep quality. Fruits containing tryptophan and melatonin can improve the sleep quality of healthy adults when consumed for seven days. Bananas are the prime example of nutritious food which enhances the mood-boosting benefits of serotonin. Deep breathing exercises are effective in reducing menopausal symptoms and help to manage stress related to life and menopause.

Aim: To evaluate and compare the efficacy of a combination of banana consumption and deep breathing exercises with banana consumption alone and deep breathing exercises alone for managing sleep deprivation, anxiety, and depression among post-menopausal women.

Materials and Methods: A random 3-arm parallel intervention study will be carried out at Acharya Vinoba Bhave Rural Hospital, Sawangi Meghe Wardha, and Near Mai Hospital, Gandhi Nagar Arvi Naka Wardha, Maharashtra, India. The study will be conducted from May 2023 to May 2026. A random sampling technique will be used to select the sample. A total of 135 post-menopausal women, meeting the inclusion criteria will be chosen for the study. The Pittsburgh Sleep Quality Index (PSQI) will be used to evaluate sleep deprivation, the self-rating anxiety and depression scale will be used to assess depression and anxiety, and serum magnesium tests along with demographic variables will be recorded. Statistical analysis will be performed using Analysis of Variance (ANOVA), among the outcome variables between the three groups. A p-value less than 0.05 will be considered as statistically significant.

Keywords: Amenorrhoea, Cheerlessness, Pittsburgh sleep quality index, Relaxation technique

INTRODUCTION

Menopause is a normal condition involving the permanent end of menstrual cycles due to the cessation of the production of reproductive hormones from the ovaries for at least 12 consecutive months [1]. Menopausal signs and symptoms include the onset of irregular menstruation, hot flushes, and nocturnal sweats. Other behavioural changes and altered biological processes, such as anxiety and sleep difficulties, have also been linked to menopause. Following menopause, oestrogen levels falls; which could result in loss of cognitive ability [2]. Distinguishing between menopausal symptoms and age-related ones can be difficult, because several of the clinical aspects highlighted so far are linked to normal aging [3]. According to the Study of Women's Health Across the Nation (SWAN), the prevalence of sleep disturbance increases with age and varies between 16% and 42% in the pre-menopausal age group, between 39% and 47% in peri-menopausal women, and between 35% and 60% in postmenopausal females [4]. Sleep issues in menopausal women have been associated with a number of factors, including age-related physiological changes, poor health perception, symptoms of the condition, anxiousness, stress, mood symptoms (such as despair and anxiety), and co-existing chronic health conditions [5]. The consumption of fruits with high tryptophan and melatonin content can help in resolving the sleep disorders [6]. Bananas are one of the fruits that contain melatonin, tryptophan, vitamin B6, and magnesium, all of which are great for producing serotonin and thus, helps in sleep by reducing the stress hormone cortisol, increasing a sleep-promoting hormone called melatonin and regulating the neurotransmitters in Central Nervous System (CNS) [7].

To confirm whether sleep deprivation, anxiety, and depression have been reduced or not, a serum magnesium test is a more

cost-effective option than melatonin. In a previous study, researchers measured the amount of melatonin [6]. There had been previous study regarding benefits of eating banana before sleep to improve the circadian rythm [7]. Sleeping disorders may cause several health problems. People can experience changes in the quality of sleep, along with age. Sleep disorders in the elderly occur due to changes in the circadian rhythm of normal sleep. Along with age, one may experience a reduction in the amplitude of circadian oscillations in all physiological parameters, including the level of melatonin. The changes in the elders can cause difficulty in maintaining deep sleep (deep maintenance problem), sleep onset problems, and Early Morning Awakening (EMA) with the difficulty of going back to sleep [8].Hormonal changes witnessed in women of the post-menopausal age group can be linked to have the adverse effects on mental health. Post-menopause, there is a gradual reduction in the levels of oestrogen due to a reduction in the synthesis and release of oestrogen by the ovaries. Oestrogen has a synergistic action over serotonin; therefore, reduced levels of oestrogen can be associated with depression [9]. Researchers have found that deep breathing exercises are effective in reducing menopausal symptoms. Deep breathing exercises predominantly help to improve mood, combat depression, and reduce anxiety [10]. Hence, the purpose of this study is to examine whether banana consumption with deep breathing exercises is as effective as banana consumption alone and deep breathing exercises alone in the management of sleep deprivation, anxiety, and depression among post-menopausal women.

Primary objectives:

1. To evaluate the magnesium level.
2. To evaluate and compare the improvement in sleep deprivation, anxiety, and depression after the consumption of two bananas and deep breathing exercises as opposed to banana consumption alone and deep breathing exercises alone.

Secondary objectives:

To correlate the sleep deprivation score, anxiety, and depression scores in all three groups with serum magnesium levels.

Alternate hypothesis: Consumption of bananas along with deep breathing exercises may be significantly efficacious as compared to the consumption of bananas alone or deep breathing exercises alone in the management of sleep deprivation, anxiety, and depression among post-menopausal women.

Null hypothesis: Consumption of bananas along with deep breathing exercises may not be significantly efficacious compared to the consumption of bananas alone or deep breathing exercises alone in the management of sleep deprivation, anxiety, and depression among post-menopausal women.

REVIEW OF LITERATURE

Hachul H et al., found that complaints about sleep were more common in the late post-menopausal group, even though the polysomnography test reveals greater quantities of extended and deep slumber durations in post-menopausal women. It has been noted that post-menopausal women are more likely to report subjectively poor quality sleep than pre-menopausal women. Oestrogen and sleep quality may also be related indirectly, most often via melancholy or a gloomy mood [11]. Chronic sleep problems can make the depression worse. The circadian hypothesis can be used to explain this mechanism. The circadian rhythm, which is regulated in physiology, maintains a 24-hour rhythm by molecular clocks at the supra-chiasmatic nucleus and behaviour [12,13].

Abnormalities in melatonin production can be resulted from age-related and neurodegenerative conditions that affect the biological clock gene's control of sleep/wake cycles, encouraging a rise in insomnia and sadness. The control of sleep and wakefulness is influenced by the serotonergic system and the alteration of the serotonergic system in depressed persons caused by aging or inflammation, alters sleep patterns and causes REM sleep disturbance. The circadian rhythm will vary if fruit consumption is minimal [13]. According to new research in the UK, the quality of sleep is positively correlated with the absence of fruit supply [14]. Serotonin and tryptophan elements found in fruits can help in treating sleep problems and enhance sleep quality. Tryptophan is a metabolite of melatonin and consuming melatonin and tryptophan-containing fruit for seven days can improve the quality of sleep in healthy individuals [15].

One of the most frequent psychological issues seen in post-menopausal women is anxiety, depression, and stress. Due to societal stigmas and lack of information among the older population, women tend to dismiss these symptoms. Post-menopausal women frequently experience difficulties like anxiety and depression. These psychological issues might arise as a result of several circumstances, including decreased Vitamin D and Oestrogen levels, elevated stress, and many more. Although, these issues may not seem to be important to patients, post-menopausal women may experience negative effects on their mental and physical health, which necessitates more patient knowledge [16].

Serotonin is a naturally existent neuro-transmitter (a chemical that transmits messages between neurons in the brain). Although the body can produce serotonin on its own, it may not produce enough quantities to function properly. As one of serotonin's primary functions is to regulate mood, it's likely that people have heard about the connection between serotonin levels and depression. Serotonin is naturally present in several foods and bananas are a nutrient-rich meal that may contribute to elevating one's mood [17]. A deep breath helps to inhale more oxygen and remove carbon dioxide from the blood stream. By reducing tension, anxiety, and other emotional disturbances and encouraging relaxation, deep breathing exercises can help overcoming unfavourable emotional reactions [18].

Further, a research has shown that low levels of magnesium may play a role in sleep disorders [19]. A Research has shown that banana nutrients like melatonin, tryptophan, and other have synergistic effects on sleep disorder scores. A banana contains 8.9±0.3 pg of melatonin per gram of fresh fruit and two bananas, or 190 grams, will boost melatonin levels in the blood by 174 pg/mL [6]. Melatonin can induce relaxation and a decrease in body temperature by activating certain receptors and receptor agonists in the serum and an improvement in sleep quality, total sleep length, and sleep efficiency [20].

Researchers assessed the impact of physical activity on menopausal symptoms and the efficacy of deep breathing exercises. The findings of this study supported the notion that deep breathing techniques and aerobic activity can help in reducing perimenopausal symptoms.

MATERIALS AND METHODS

A random three arm parallel interventional study design will be conducted from May 2023 to May 2026 at Acharya Vinoba Bhave Rural Hospital, Sawangi Meghe Wardha, and Near Mai Hospital, Gandhi Nagar Arvi Naka, Wardha, Maharashtra, India, after obtaining ethical permission (Ref. no: DMIHER (DU)/IEC/2023/924).

Sample size calculation: Using a Random sampling technique, 135 post-menopausal women will be selected based on the calculation.

$$n1=n2=2\frac{(Z_{\alpha}+Z_{\beta})^2\sigma^2}{(\delta)^2}$$

Z_{α}=1.96

α=Type 1 error at 5%

Z_{β}=0.84 at (1-β)=Power -80%

σ=Standard deviation

ε=True Difference in means

Mean±SD. (Before) PSQI score in Aerobics Treatment=19.99±3.69

Mean±SD. (After)=10.23±4.94 (As per the reference article) [21]

Difference in mean=9.76

Clinically accepted 20% margin=((9.76)*20)/100=2.44

Pooled standard deviation=(3.69+4.94)/2=4.315

Minimum sample size $N=2*(1.64+0.84)^2(2.44)^2/(4.315)^2=38$ each in 2 groups.

Considering a 20% drop out, the authors have a sample size of 45 per group.

Hence, the researchers decided to include 135 post-menopausal women:

- 45 post-menopausal women for PI group (banana consumption)
- 45 post-menopausal women for PII group (deep breathing exercise)
- 45 post-menopausal women for PIII group (banana consumption and deep breathing exercise)

Inclusion criteria: Those post-menopausal women who are suffering from sleep deprivation, anxiety, and depression as per the rating scale and willing to participate in the study will be included in the study.

Exclusion criteria: Post-menopausal women who have been taking any type of antidepressant drugs, steroids, afflicted with diabetes mellitus, hyperthyroidism, acute and chronic renal failure, and stroke or those with history of asthma , sinus problems or experiencing cold and cough will be excluded from the study.

The sample will be randomly selected with sleep deprivation, anxiety, and depression level assessment scales using Pittsburgh Sleep Quality Index (PSQI) [22], Zung Self-rating Anxiety [23] and Zung Self-Rating Depression Scale (SDS) [24].

Planned Procedure

The scales for sleep deprivation, anxiety and depression will be used before and after the intervention in all the subjects. Serum magnesium tests will be done before and after the intervention.

Sleep quality index: It is a self-reported 19 item questionnaire with seven subcategories: subjective sleep quality, sleep latency, sleep duration, habitual sleep efficiency, sleep disturbances, use of sleeping medication, and daytime dysfunction and designed to evaluate overall sleep quality in clinical populations. The questionnaire consists of a combination of Likert type and open-ended questions (Scores for each question range from 0 to 3, with higher scores indicating more acute sleep disturbances). The scale has an internal reliability of α=0.83, a test-retest reliability of 0.85 for the global scale, a sensitivity of 89.6%, and a specificity of 86.5% [22].

Zung self-rating anxiety scale: The SAS is a 20-item self-report assessment device built to measure anxiety levels, based on scoring in four groups of manifestations: cognitive, autonomic, motor and CNS symptoms. Each question is scored on a Likert-type scale of 1-4 (based on these replies: “a little of the time”, “some of the time”, “good part of the time”, “most of the time”). The total raw scores range from 20 to 80 [23].

The Zung Self-Rating Depression Scale is a short self-administered survey to quantify the depressed status of a patient. There are 20 items on the scale that rate the four common characteristics of depression: the pervasive effect, the physiological equivalents, other disturbances, and psychomotor activities. Each question is scored on a scale of 1-4 (a little of the time, some of the time, good part of the time, most of the time). The scores range from 25-100, 25-49 normal range, 50-59- mildly depressed, 60-69- moderately depressed and 70 and above- severely depressed [24].

The informed consent form will be accessible to everyone to read and sign. The samples will receive a thorough description of the study’s objectives and the type scale that will be used. Combination therapy of Banana consumption and deep breathing exercise will be given for the PIII Group: 300 gm banana consumption at 4 pm and 7 pm and deep breathing exercise for 10 minutes in the morning for 14 days. Banana consumption and deep breathing exercise will be separately given (300 gm banana consumption for 14 days at 4 pm and 7 pm for PI Group and deep breathing exercise for 10 minutes in the morning for 14 days for PII Group). Proper handling of sample information will ensure that anonymity and confidentiality are upheld. Information will not be used or released in violation of the contract’s conditions.

PSQI scale, Self-rating Anxiety and Self-rating Depression scale, and Serum magnesium test

Data gathering will take place over a 14-day period. After gaining approval from the relevant authorities, this research will be conducted.

STATISTICAL ANALYSIS

The collected data will be coded, tabulated, and analysed using descriptive statistics (mean, percentage, standard deviation) and inferential statistics. The Statistical Package for Social Sciences (SPSS) version 25.0 will be used for statistical analysis. The Pearson Correlation Coefficient test will be used for correlation analysis. Significance differences between pre and post-test readings will be done using a t-test. The association with demographic variables and the comparison between the 3 groups will be done using a one-way Analysis of Variance (ANOVA) test and independent t-test. The p-value of <0.05 will be considered significant.

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