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Sleep Disorders and Quality of Life of Women in Menopausal Transition and Postmenopausal Assisted in Primary Health Care: A Cross-Sectional Observational Study Protocol

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Authors' contributions

This work was carried out in collaboration among all authors. All authors contributed to the conception and design of the study. Authors LVSR, LTP and NSFJ wrote the article. Authors NSFJ and LTP done the critical review of the manuscript. Authors LVSR, NSFJ and LTP wrote the protocol paper with assistance from all co-authors. All authors read and approved the final manuscript.

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Study Protocol

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ABSTRACT

Aims: The objective of the study will be to evaluate the presence of sleep disorders, sleep quality and life of women in the menopausal transition and postmenopausal assisted in primary health care (PHC) in Divinópolis/MG.
Study Design: Cross-sectional observational.
Place and Duration of Study: PHC in the municipality of Divinópolis, Minas Gerais, Brazil, between January and December 2023.
Material and Methods: The present study will be carried out by professors and students of the University of the State of Minas Gerais (UEMG), Divinópolis Unit, with women recruited from PHC in the municipality of Divinópolis/MG, after consenting to participate in the study, by signing the Informed Consent Form (ICF). The sample will be consecutive and of convenience and then stratified according to sociodemographic variables, presence or absence of sleep disorders, sleep quality, quality of life and other variables pertinent to the study.
Discussion: Due to the lack of professional performance in primary care for sleep disorders, it is necessary to study the concomitant changes between the menopausal transition and postmenopausal processes. Given the aspects related to these disorders, there is a need for a more in-depth look at the factors that can interfere with sleep quality during this transition.
Conclusion: This study protocol aims to investigate sleep disorders and the quality of sleep and life in women during the menopausal and postmenopausal transition phases. The research seeks to identify data demonstrating the changes that occur during these phases.

Keywords: Primary health care; sleep wake disorders; Postmenopause; climateric.

1. INTRODUCTION

According to the Brazilian Institute of Geography and Statistics, there has been a growing increase in population ageing in Brazil, especially among women, in which life expectancy has shown an average of 80.5 years [1]. Women's health undergoes specific changes with aging, especially during the menopausal transition, the period that precedes menopause and the endocrinological, biological and clinical changes of the approach to menopause begin, varying according to the age and specificity of each woman [2]. Menopause is recognized as the loss of ovarian follicular activity and non-reproductive state and is recognized after twelve consecutive months of absence from menstrual cycles, without pathological or physiological causes [3].

During the menopausal transition, the final phase of the fertile period, where irregular menstrual cycles begin until menopause, various signs and symptoms of vasomotor, psychological and cognitive origin may manifest, such as hot flashes, palpitations, mood swings, depression, irritability, anxiety, sleep disorders, memory problems, concentration, and atrophic effects, such as vaginal atrophy and bladder irritability [4].

Women in the menopausal transition and postmenopausal are more likely to experience sleep disturbances, probably due to the physiological changes of these phases [5]. The prevalence of sleep disorders varies according to the stage: from 16% to 42% in premenopausal, from 39% to 47% in perimenopausal, and from 35% to 60% in postmenopausal [6]. The factors that cause these disorders are not completely clear and vary depending on the specific symptoms. However, some contributing factors may include menopause itself, vasomotor symptoms, depression, ageing, anxiety, cardiovascular and endocrine diseases, medication use, and psychosocial factors [7-10].

Sleep is a state of minor sensorimotor activity, muscle relaxation, and a cyclical process with defined neurological and cardiorespiratory patterns. It is divided into two phases: NREM (non-rapid eye movement) sleep and REM (rapid eye movement) sleep. NREM sleep has subphases that vary according to the depth of sleep: stage 1 (falling asleep), stage 2 (light sleep), and stage 3 (deep sleep). REM sleep is the deepest phase, characterized by rapid eye movements, dreams, and information storage [11]. Good sleep quality is essential for human life, ensuring restorative, protective, immunological and energy-conserving functions. Sleep deprivation impairs mental and physical well-being by affecting functionality [12]. Sleep problems negatively impact quality of life, increasing the risk of accidents and decreasing productivity [13].

Insomnia is a sleep disorder characterized by difficulty in initiating or maintaining sleep, or in waking up earlier than desired, compromising the quality of the day. Globally, the prevalence of insomnia symptoms is approximately 30 to 35%, with an annual incidence between 7 and 15% [14-16]. Women are 1.41 times more likely to develop sleep disorders and 1.3 to 1.8 times more likely to have insomnia compared to men [17,18]. The incidence of insomnia increases in women in the transition from menopause to women in the reproductive phase, and worsens with age, with personal health perception being an important determinant of sleep quality [19,20].

Obstructive sleep apnea (OSA) is a common public health disorder characterized by repeated episodes of upper airway collapse during sleep [21]. According to some studies, the incidence of OSA in women increases after menopause, and it is estimated that the prevalence of this condition among women in the sixth or seventh decade of life ranges from 4% to 22%, depending on the definition used and the population examined [22,23].

Excessive daytime sleepiness (EDS) is characterized by the inability to remain awake and/or alert during the day due to poor sleep quality, medication use and comorbidities [24]. It presents itself as a common complaint in the population, which has been associated with hypertension, diabetes, allergies, depression, anxiety, and muscle contractures. In addition to these factors, others such as lifestyle habits, alcoholism, sedentary lifestyle and insufficient sleep can predispose to such a framework [25,26]. Women tend to be more affected due to the accumulation of domestic responsibilities directed at them, such as looking after the home and children [27].

Among the levels of health care in Brazil, Primary Health Care (PHC) refers to the first level of health care, which contributes to the care of the most common needs of individuals [28]. According to the Pan American Health Organization/World Health Organization (PAHO/WHO), PHC is defined as the patient's first contact, and this care is comprehensive and of community standard. At this level of health care, if necessary, the patient's demand for other areas is screened according to their complexity. Services are offered aimed at promotion, prevention, protection, diagnosis, treatment, rehabilitation, harm reduction, palliative care and health surveillance [29].

During the phases of menopause, it is essential that women receive adequate care through PHC so that their complaints are attended to with attention and care, and their doubts are clarified [30]. Considering that many women report changes in sleep and quality of life during the menopausal transition and postmenopausal, qualified care by health professionals is essential. These professionals should guide them in an understandable, objective and competent manner about the common clinical implications in this period [31]. PHC enables more humanized and informative care, offering comprehensive support to the needs of these women.

2. MATERIALS AND METHODS

2.1 Study Design and Ethical Considerations

The present study will be of the cross-sectional observational type, carried out by professors and students at the University of the State of Minas Gerais (UEMG), Divinópolis Unit, with women recruited from PHC in the municipality of Divinópolis/MG. The study design follows the norms of the Strengthening the Reporting of Observational Studies in Epidemiology (STROBE) statement [32,33] and is by the ethical standards established in the Declaration of Helsinki 1961 and in the Guidelines and Regulatory Standards for research involving human beings of the National Health Council of the Ministry of Health of Brazil, resolutions 466/2012, 510/2016 and 580/2018 (Fig. 1).

The present study was approved by the Human Research Ethics Committee of UEMG, number 6.125.104/2023, together with the Term of Consent of the Municipal Health Department of Divinópolis-MG. All patients involved will be given an Informed Consent Form (ICF) and leave of absence will be allowed at any time without any charge.

2.2 Sample Description

Women assisted in PHC, through Basic Health Units and Family Health Strategy, in the municipality of Divinópolis/MG, Brazil, will participate in the study, after consenting to participate in the study, by signing the informed consent form. The sample will be consecutive and convenient and then stratified according to the variables, sociodemographic, presence or absence of sleep disorders, sleep quality, quality of life and other variables pertinent to the study.

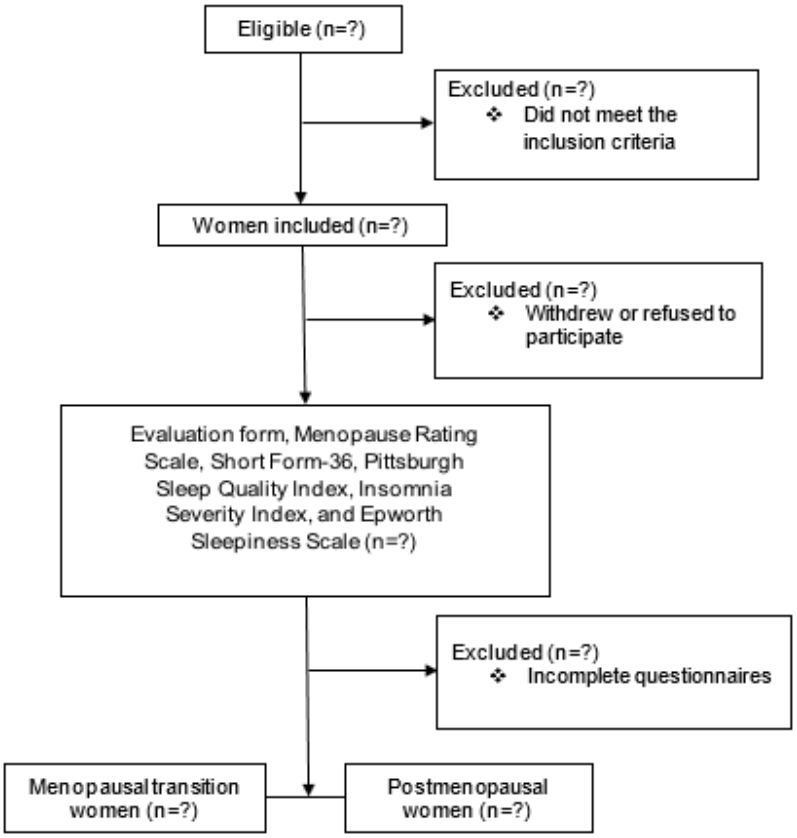

Fig. 1. Flowchart of the study

2.3 Inclusion Criteria

Women over 18 years of age in the menopausal transition or postmenopausal period assisted at PHC in the city of Divinópolis/MG, agreed to participate in the study, signing the informed consent form.

2.4 Exclusion Criteria

Women with a clinical diagnosis of cancer, using hormone replacement therapy, who have undergone surgical removal of the ovaries (oophorectomy) or total hysterectomy and presence of incomplete answers in the questionnaires.

2.5 Study Protocol

2.5.1 Clinical evaluation Form and sociodemographic questionnaire

The evaluation of the patients will be carried out at the PHC of Divinópolis-MG, where personal, clinical, and sociodemographic data will be collected, and, through self-report, if the woman is in the menopausal transition or postmenopausal, presenting symptoms from the physiological changes of these phases. Systemic blood pressure will be measured after the individual remains seated at rest for 10 minutes, using the auscultatory method. The evaluation of weight and height will be carried out using an electronic scale (model 200/5, Welmy Indústria e Comércio Ltda, São Paulo, Brazil). Body mass index (BMI) calculation will be performed using the WHO BMI Classification [34]. Neck circumference will be measured with the individual in a sitting position, at the level of the anterior border of the cricoid cartilage, both using a non-elastic tape measure with an accuracy of 1 millimeter [35]. The waist circumference will also use a non-elastic tape measure for its measurement. It will be measured at the midpoint between the lower margin of the last rib and the iliac crest, in a frontal view, on the right or left side [36].

2.5.2 Pittsburgh Sleep Quality Index (PSQI)

The PSQI was developed in 1989 and is a self-administered questionnaire that evaluates sleep quality and possible disturbances in the last month [37], validated for the Brazilian population

in 2011 [38]. The questionnaire aims at the possibility of reliable and standardized measurement, leading to the differentiation of individuals with restful sleep from those with disorders that affect sleep quality [39]. This questionnaire assesses sleep quality and the presence of sleep disturbances over one month. The instrument contains nineteen self-report questions and five questions directed to the room companion. The questions are divided into seven components: subjective sleep quality, sleep latency, sleep duration, habitual sleep efficiency, sleep changes, use of sleep medications, and daytime sleep dysfunction. Adding the values of the seven components, the total score can range from 0 (zero) to 21 (twenty-one), and the higher the number, the worse the quality of sleep. A total score higher than five suggests insufficient sleep [38].

2.5.3 Insomnia Severity Index (IGI)

To measure the presence and severity of insomnia, the IGI, developed in 2001, will be used [40]. This is a brief and simple questionnaire that assesses the presence and severity of insomnia observed by the individual in the last two weeks. Validated for the Brazilian population in 2011 [41], the GII is composed of seven items that investigate difficulty in initiating sleep, staying asleep and waking up, satisfaction with the current sleep pattern, interference with daily functioning, perception of impairment due to sleep problems, and degree of distress or worry caused by insomnia. The items are classified into five alternatives ranging from "not at all" to "very dissatisfied." The cut-off points for the classification of insomnia are: absence of significant insomnia (0 to 7), lower limit for insomnia (8 to 14), moderate clinical insomnia (15 to 21) and severe clinical insomnia (22 to 28).

2.5.4 Epworth Sleepiness Scale (ESS)

When assessing the propensity to daytime sleep, the ESS is a self-assessment instrument composed of eight items that refer to everyday situations. The responses for each item range from 0 (zero) to 3 (three), indicating the probability of falling asleep during a specific activity (0 = never, 1 = low probability, 2 = moderate probability, 3 = high probability) [42]. This scale has been validated for Brazilian culture [43], where a total score equal to or greater than 10 suggests the presence of EDS.

2.5.5 Berlin quiz

To determine the risk for OSA, an individualized clinical questionnaire called the Berlin Questionnaire will be applied [44]. This questionnaire has 10 items organized into three categories as follows: apnea and snoring, daytime sleepiness systemic arterial hypertension, and obesity. All positively marked responses are considered risk factors for OSA. Patients will be classified as either high-risk or low-risk for OSA. A patient is considered at high risk for OSA if two or more of the three categories are positive.

2.5.6 Short Form (SF-36)

To assess quality of life, the use of the SF-36 questionnaire is recommended. This instrument, designed for clinical and research use in the United States of America, has demonstrated good sensitivity in several situations, eliminating problems of over distribution in extreme scores such as "excellent" and "very poor" [45]. In 1999, the translated version of the SF-36 was published and adapted to the Portuguese, adapted to the Brazilian culture. This instrument, which is easy and quick to apply, is administered through interviews and considers its measurement properties [46]. The SF-36 contains 36 items, of which 35 are grouped into eight dimensions: functional capacity, pain, physical aspects, emotional aspects, social aspects, mental health, vitality and general health status. The last item evaluates the change in health over time. Each dimension has its items encoded and transformed on a scale from zero (worst health status) to 100 (best health status).

2.5.7 Menopause Rating Scale (MRS)

Quality of life-related to climacteric symptoms will be assessed using the Menopause Rating Scale (MRS). It is a scale that has been validated and translated into 9 languages, one of them in the Brazilian version in Portuguese [47-49]. It has 11 items on a scale of 0 (zero) to 4 (four), indicating the absence of symptoms to severe symptoms, respectively. The score is obtained through the sum of the score, the higher it is, the worse the patient's symptoms and quality of life. It can be divided into MRS domains: score of 0-4 points, indicating absent symptoms, 5-8 points mild symptoms, 9-15 points for moderate symptoms, greater than or equal to 16 points for severe symptoms [49]. The time to answer the

questionnaires and the evaluation form will be approximately 15 minutes.

2.6 Quality Control

The researchers responsible for data acquisition in this study will receive specific training to ensure data quality. Periodic external monitoring will be carried out to verify the correct application of the methodology for the acquisition of information and the performance of the different tests.

2.7 Statistical Analysis

First, a pilot study will be carried out to determine the sample size calculation. The Kolmogorov-Smirnov normality test will be implemented to determine the presence or absence of normality in the data. Numerical data will be presented as mean and standard deviation for variables with normal distribution, and median and interquartile range for those with asymmetric distribution. Categorical data will be described as a percentage of the total and as an absolute number. In the stratification of the sample, the student's t-test will be performed when it is necessary to compare paired samples. For comparisons between quantitative variables, the student's t-test or the non-parametric Mann-Whitney test will be used. When the variables were qualitative, the Chi-square test or Fisher's exact test will be used. Correlations between continuous variables will be performed with Pearson's correlation test or Spearman's correlation test. For the statistical treatment, the statistical software (Statistical Package for Social Sciences SPSS 13.0® (Chicago, IL, USA) will be used. The level of statistical significance will be set at 5% for all tests ($p<0.05$), for a 95% confidence interval.

3. RESULTS

It is expected to find changes in sleep quality and the presence of sleep disorders in both menopausal and postmenopausal women assisted in PHC, which may influence their quality of life. It is pertinent to quantify and analyze the difference between these changes in both groups. This issue is decisive in the inclusion of intervention and treatment programs for sleep disorders. In addition, basal nocturnal polysomnography, the gold standard test to assess sleep, is expensive and difficult to access for patients assisted in PHC, justifying the use of subjective tools such as questionnaires to assess sleep in this population.

4. DISCUSSION

Due to the increase in life expectancy in the world population, and especially the greater predominance of females, it is necessary to understand the phases that these women experience in different periods of their lives. Menopause is a complex period of major changes in a woman's body and understanding its relationship with sleep quality is important to contribute to improving the quality of life for this specific population. And although few studies compare sleep disorders and the quality of life of women in the menopausal transition and postmenopausal, it is an important topic, considering the prevalence of these disorders, which are now considered a public health problem [50,51]. In addition, complete nocturnal polysomnography and actigraphy have a higher cost. Therefore, the use of subjective tools such as questionnaires to assess sleep in this population is justified.

5. CONCLUSION

This study protocol aims to describe the investigation of sleep disorders, as well as the quality of sleep and life in women in the menopausal and postmenopausal transition phases. The research aims to identify data that demonstrate the concomitant changes present in these phases. These findings will contribute to the development of public health policies aimed at improving sleep and, consequently, the quality of life of these women, based on a comprehensive approach to women's health.

DISCLAIMER (ARTIFICIAL INTELLIGENCE)

Author(s) hereby declare that NO generative AI technologies such as Large Language Models (ChatGPT, COPILOT, etc) and text-to-image generators have been used during writing or editing of manuscripts.

CONSENT AND ETHICAL APPROVAL

The present study was approved by the Human Research Ethics Committee of UEMG, under opinion number 6.125.104/2023, together with the Term of Consent of the Municipal Health Department of Divinópolis-MG. All patients involved will be written consent and leave will be allowed at any time at no cost.

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COMPETING INTERESTS

Authors have declared that no competing interests exist.

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