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STUDY PROTOCOL

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Cross-sectional observational study of the sleep disorders in subjects assisted in the Basic Health Units and Family Health Program in Divinopolis, Brazil – a protocol study

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ABSTRACT

Introduction: Sleep disorders have a high prevalence in the general population being currently considered as a major public health problem. In the last four decades, scientific interest in sleep patterns has steadily grown. Such studies may contribute to a better understanding of the clinical course to explore potential therapeutic interventions. This study will aim to verify the prevalence of sleep disorders in subjects assisted at the Basic Health Units (UBS's) and Family Health Program (PSF's) in Divinópolis, MG, Brazil. **Methods**: This research will be an observational, cross-sectional study carried out by professors and students from the University of State of Minas Gerais - UEMG, Divinópolis Unit, with subjects recruited from the UBS's and PSF's in Divinópolis-MG, between March 2016 and December 2017. These subjects will be assessed clinically and respond to the Pittsburgh Sleep Quality Index (PSQI), Epworth Sleepiness Scale (ESS), Berlin Questionnaire, SF-36 Quality of Life Questionnaire, evaluating the quality of sleep, presence of sleep disorders, excessive daytime sleepiness, risk for obstructive sleep apnea and quality of life. **Discussion**: Recently, sleep disorders were considered a global public health problem, affecting the quality of life of the population and influencing morbidity and mortality. The results of epidemiological studies are not only applicable in clinical practice but also in the planning and implementation of public policies and programs aimed at controlling sleep disorders and their impact on individuals and societies.

Keywords: Disorders of Excessive Somnolence; Sleep; Sleep Apnea Syndromes.

INTRODUCTION

The sleep is defined as restorative and healthy state, compared with resting and inactivity, pleasant and naturally restorative, necessary to recover the common physical exhaustion to human experience due to the constant alert state and energy expenditure [1].

The consideration that at least one third of our life happens sleeping associated with the clinical observation that there is a high incidence of cardiovascular events at night, are a motive of growing interest in the effects of the sleep on the cardiovascular system, humoral and night hemodynamic, related to the sleep phases. [2]

Normal sleep in humans consists of two well defined stages based on physiological parameters - non-rapid eye movement (NREM) sleep and rapid eye movement (REM) - which alternate cyclically and differ from each other. The sleep starts in stage NREM conventionally divided into stages 1, 2 and 3, followed by the first episode of REM sleep, which occurs approximately 80 to 100 minutes later.[3, 4]

The classification of the sleep disturbances is necessary for the discrimination and to facilitate the understanding of the symptoms, etiology, pathophysiology and treatment. The third version of the International Classification of Sleep Disorders (ICSD-3), published in 2014, lists the sleep disorders presented in detail, including specific diagnostic criteria.[5]

The ICSD-3 has seven main categories: insomnia, sleep-related respiratory disorders, central hypersomnia disorders, circadian rhythm sleep-wake disorders, parasonias, sleep-related movement disorders, and other sleep disorders.

Sleep-related respiratory disorders are subdivided into obstructive sleep apnea (OSA), central sleep apnea, sleep-related hypoventilation disorders, and sleep-related hypoxemia disorders.

OSA include those in which there are recurrent collapse, partial or complete, of the upper airway during sleep.[6] These events are often associated with reduction in oxyhemoglobin saturation and it is possible to occur an excessive daytime

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sleepiness (EDS), or insomnia.[3] EDS, verified by Sleepiness Scale Epworth (SSE), is a widespread problem which clinicians find frequently in their practice, highly prevalent, affecting up to 30% of the general public, and is it associated with significant personal, occupational and public safety. [7]

Several risk factors have been identified that contribute to the presence of sleep-related hypoxemia disorders, which include alterations in the upper airway anatomy, mechanical and tissue characteristics, neuromuscular function and instability of the sleep-wake ventilation control, in which these factors predominate in individual cases producing different OSA "phenotypes" [8]. The main associated with OSA are age, male gender, body mass index (BMI), a measurement of the neck circumference and craniofacial modifications [4]. There is a clear relationship between OSA and cardiovascular risk, neuropsychological problems, reduced quality of life and consequent increased use of health resources [9].

Sleep disorders have high prevalence in the general population and it is currently considered an important public health problem, affecting about 45% of the population.[10] A study published in 1993 demonstrated that the prevalence of disease ranged from 2% to 3% in women and 4% to 5% in men.[11] In young adults in the Western world, OSA affects 3-7% of the male population and 2.5% of women.[12] A study of a representative population in the São Paulo City demonstrated that 24.8% of men and 9.6% of women had OSA.[13]

The gold standard for the diagnosis of sleep disorders the full-night polysomnography (PSG). This refers to the simultaneous recording of some physiological variables during the sleep: Electroencephalogram, electrooculogram, electromyogram, electrocardiogram, airflow, respiratory effort, other body movements, pulse oximetry, heart rate and snoring sensor.[6]. However, to conduct this examination, a location with adequate physical structure and human resources with specific training is required, which demand a high financial investment and restricts its availability in some centers of the country. Thus, subjective instruments have been used both in clinical routine and in research protocols in the world scientific community, such as the Pittsburgh Sleep Quality Index (PSQI), a combination of quantitative and qualitative information of the sleep.[14,15]

The aim of this study will be to verify the prevalence of sleep disorders in subjects assisted in the Basic Health Units (UBS's) and the Family Health Program (PSF's) in Divinópolis city.

METHODS

STUDY DESIGN AND ETHICAL CONSIDERATION

This study will be an observational, cross-sectional, conducted by students and professors from the University of the State of Minas Gerais - UEMG, Divinópolis Unit, with individuals recruited from UBS's and PSF's of Divinópolis-MG, between March 2016 and December 2017.

The study design will follow the rules of Strengthening the Reporting of Observational Studies in Epidemiology (STROBE)[16,17] (Figure 1) and agree with the ethical standards set in the Declaration of Helsinki in 1961 and in the Guidelines and Regulatory Standards Research involving human beings of the National Health Council of the Brazilian Ministry of Health, resolution 196/96 updated by 466/2012.

This study was approved by the Ethics Committee on Human Research of the University of the State of Minas Gerais, under protocol number 1,475,521/2016 authorized by the Municipal Health Secretary of Divinópolis. The patients enrolled will sign the Statement of Consent Form, including signing of responsible relatives for those under 18 years, and allowing the removal at any time at no cost.

Lectures and guidelines on sleep quality will be offered to the participants. Subsequently, a new research and extension project will be elaborated, proposing treatment for eventual disorders found, as well as guidelines.

SUBJECTS

Will participate in this study, subjects assisted in UBS's and PSF's of Divinópolis-MG, of both genders, over 18 years after agreeing to participate in the study by signing the informed consent, without cognitive impairment that disturb the understanding to respond to questionnaires. Those who do not agree to participate in study and having comorbidities

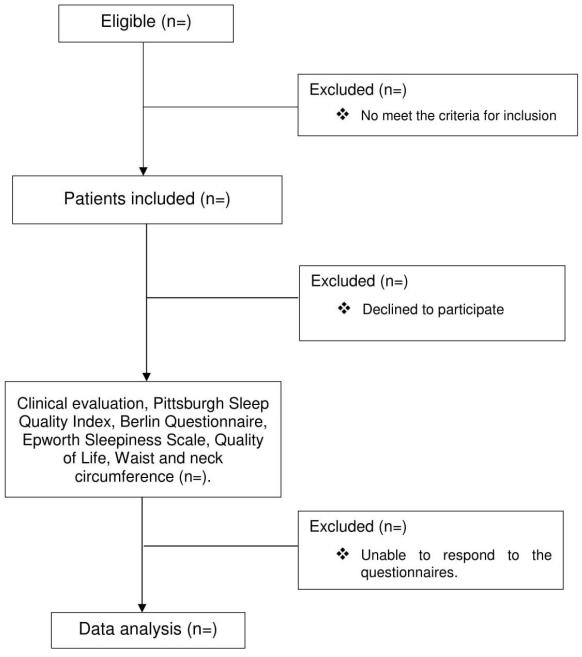

Figure 1: Flowchart of the study

that is possible to influence the evaluations, diagnosis and/or prognosis of disease outcome, will be removed. This sample will be consecutive and of convenience and later stratified as to the socio-demographic variables, comorbidities, presence or not of sleep disorders and other variables pertinent to the study.

EVALUATION PROTOCOL

Clinical Evaluation

The evaluation of patients will occur in UBS's and PSF's, which it will be collected the personal data, objective assessment of heart rate, respiratory rate, peripheral blood pressure, weight and height. Systemic blood pressure will be measured by the auscultatory method after the subject remains seated for 10 minutes. The weight and height will be evaluated by an electronic scale (model 200/5, Welmy Indústria e Comércio Ltda, São Paulo, Brazil). The BMI calculation is performed by BMI classification of the World Health Organization.[18] The neck circumference will be measured in the individual in sitting position at the level of the lower border of the cricoid cartilage, both using an inelastic tape with 1mm accuracy.[19] The waist circumference will also use a non-elastic tape measure for its measurement. The waist circumference will be measured at the midpoint between the lower margin of the last rib and the iliac crest.[18]

Pittsburgh Sleep Quality Index (PSQI)

In addition to the previous questionnaires, a PSQI Portuguese version will be applied to evaluate the sleep quality of the individuals. The instrument contains 19 questions divided into 7 areas scored separately. The sum of these points (range: 0-21) provides an overall measure of sleep quality, with high scores indicating insufficient sleep (> 5 is indicative of poor sleep quality). The evaluated areas are related to subjective sleep quality, sleep duration, sleep latency, habitual sleep efficiency, sleep disturbances, use of medications and sleep-related impact of surcharges and daytime dysfunction sleep. [14,15]

Epworth Sleepiness Scale and Berlin Questionnaire

The post clinical evaluation, two specific sleep questionnaires will be applied. To determine the presence of EDS, the ESE Portuguese version will be used.[20,23] This is a simple, self-administered questionnaire, addressing situations involving the occurrence of daytime sleepiness during normal daily activities in adults. Individuals will be instructed to rate their probability to feel the desire to sleep or nap in eight situations on a scale 0-3.

As for determining the risk for OSA, a clinical questionnaire of individualized will be applied, the Berlin Questionnaire.[24] This questionnaire has 10 items organized in three categories as follows: apnea and snoring, daytime somnolence and systemic arterial hypertension and obesity. All positively marked responses are considered risk factors for OSA. Patients will be classified as high risk or low risk for OSA. A patient is considered high risk for OSA if two or more of the three categories are positive.

Quality of Life

To assess the quality of life, it will be used the generic questionnaire SF-36 (Medical Outcomes Study 36 - Item Short-Form Health Survey),[25] the validated version to Brazilian culture.[26] The SF-36 is an instrument of easy administration and understanding, but not so extensive. It 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) and a last item which evaluates health change in the time. For each dimension, the items of the SF-36 are encoded, grouped and transformed into a scale from zero (worst health status) to 100 (best health).

QUALITY CONTROL

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

STATISTICAL ANALYSIS

A pilot study will be performed first to determine the calculation of the sample size. The numerical data will be presented as mean and standard deviation in the case of variables with normal distribution, and median and interquartile range for those with asymmetric distribution. Categorical data will be described as absolute number and percentage of total.

The Kolmogorov-Smirnov normality test will be performed in order to determine the data normality. According to the embodiment of the sample stratification, Student's t-test when comparing paired samples. For the comparisons between variables, for the 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, depending on the case. The correlations between continuous variables will be carried out with the *Pearson* correlation test and Spearman correlation test. The statistical analysis will be used statistical software (Statistical Package for Social Sciences 13.0® SPSS (Chicago, IL, USA). The level of statistical significance is set at 5% for all tests ($p<0.05$).

DISCUSSION

In the last four decades, scientific interest in the sleep patterns has steadily grown. Recently, sleep disorders were considered a public health problem worldwide, affecting the

quality of life of the population and influencing morbidity and mortality. This study aims to determine the prevalence of sleep disorders in subjects assisted in UBS's and PSF's in Divinópolis. The results of epidemiological studies are not only applicable in clinical practice, but also in the planning and implementation of public policies and programs to control the sleep disorders and their impact on individuals and societies.

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AUTHOR'S CONTRIBUTIONS

All the authors contributed to the conception and design the study. CAAS and NSFJ provided idea for the research or article, created the hypothesis, wrote the original proposal and are the guarantor of the paper. NSFJ, LTP, WMS, CAS, IJSC and MEMF significantly contributed to writing this paper, while, MTTS, JA, RJES and CAAS were involved in revising the manuscript critically. This protocol paper was written by NSFJ, LTP and WMS with input from all co-authors. All authors read and approved the final manuscript. All authors contributed equally to this work.

CONFLICT OF INTEREST

None.

AUTHOR DETAILS

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