Study Protocol

Cross-Sectional Observational Study of the Influence of Insomnia on the Functional Capacity of Patients Assisted in the Basic Health Units of Divinopolis, Brazil - A Protocol Study

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Abstract

Insomnia is seen as one of the most common sleep disorders, characterized by difficulty in initiating and / or maintaining sleep and by daytime symptoms that impair the occupational functioning, interfering in the daily activities of the individuals, and may even cause physical incapacity. Therefore, the need to evaluate such repercussions becomes important in the search for further clarification on the subject, and the 6-Minute Walk Test (TC6M) is a good evaluation tool. The study will aim to evaluate the functional capacity in adult patients with insomnia assisted in Basic Health Units (BHU) of Divinópolis. The study will be cross-sectional observational, carried out with a consecutive and convenience sample, recruited from BHU in the city of Divinópolis, being approved by the Ethics Committee in Research with Human Beings of the university, protocol number 1,475,521/2016. All patients will be submitted to the 6MWT after being clinically evaluated and responding to the Insomnia Severity Index, requiring the presence of insomnia to perform the same. The 6MWT is a good alternative in the evaluation of functional capacity because it is easy to apply and low cost.

Introduction

Sleep is defined as a restorative and healthy state, compared to rest and inactivity, necessary to recover physical exhaustion due to constant alertness and energy expenditure [1]. During the same period different stages are characterized by well-defined neurophysiological and cardiorespiratory patterns [2].

The observations on sleep began in the 19th century due to the concern that it covered a large part of the human species [3]. In 1963, Frei Snyder proposed two characteristic and distinct organic states, REM (Rapid Eye Movement) and NREM (Non-Rapid Eye Movement) sleep [1].

A sleep cycle lasts for about 90 to 110 minutes and repeats 3 to 5 times during the night. Sleep begins in the NREM stage, consisting of 3 stages. Stage 1 occurs between 1 and 7 minutes from sleep onset being the moment of transition from wake-solo. Stage 2 continues for approximately 10 to 25 minutes and a more intense arousal is needed. Stage 3 lasts approximately 20 to 40 minutes, requiring an even more intense stimulus when compared to the other stages [2].

REM sleep is characterized by electrical desynchronization, episodic jolts of rapid eye movements, and absence of activity on the electromyogram, being constituted by tonic events, represented by muscular and other atonic and phasic events, characterized by cardiac and other changes in heart rate [4].

To encompass the symptoms, etiology, treatment and pathophysiology of disorders, the American Sleep Association's International Classification of Sleep Disorders (AASM) was created in 1997 in association with other societies and reformulated in 2005 [5]. Subsequently, the International Classification of Sleep Disorders (ICSD-3) was published in 2014, which includes an extensive review of the literature to list sleep disorders, as well as the criteria used for diagnosis, divided into 7 categories [6]:

1. Insomnia.
2. Respiratory disorders related to sleep.
3. Central disturbances of hypersomnias.

4. Sleep-wake disorders of the circadian rhythm.

5. Parasomnias.

6. Sleep related movement disorders.

7. Other sleep disorders.

At present, the prevalence of sleep disorders has been increasing in the adult population, reaching from 37.2 to 69.4% of the population. About 16.6% of the population aged > 50 years reported extreme or severe sleep problems [7]. In a study carried out in São Paulo, sleep disturbances occurred in 46.7% of the sample, being more reported in women, older people and with obesity [8].

The standard gold standard for sleep is given through the complete basal nocturnal Polysomnography (PSG), in which it refers to the simultaneous recording of some physiological variables, including electroencephalogram, electrocardiogram, airflow, respiratory effort, pulse oximetry and body temperature [9].

Insomnia is one of the most common sleep disorders, characterized by nocturnal symptoms of difficulty in initiating and / or maintaining sleep, and by daytime symptoms that impair social and occupational functioning. Insomnia can exist alone or associated with medical / psychiatric conditions [10].

Individuals with insomnia present anxiety, mood variability, reduced cognitive ability that is related to concentration, memory and attention [11]. They may also present physical symptoms such as fatigue, depression, reduced functional performance and excessive daytime sleepiness [12]. In addition, symptoms of insomnia and excessive daytime sleepiness are associated with comorbidities and the increased risk of mortality when studying the elderly population [13].

It is known that in the city of São Paulo the prevalence of objective insomnia evaluated by PSG is 32%, while the prevalence of subjective insomnia is 15% [14]. In Poland, the prevalence of insomnia is 58.9% in women and 41.4% in men, being more common in women between 60 and 79 years (74.8%). However, the most common type of complaint among patients, regardless of age and sex, is related to the difficulty of falling asleep (60.2%) [15].

In clinical practice, most of the patients with difficulty in sleep do not present complaints to the physician, and it is necessary to question whether sleep-related diurnal and nocturnal complaints and complaints are reported [16].

Human activities are concentrated in the daytime period, but due to work, exercise and even disturbances or sleep deprivation, changes can occur in this pattern, leading initially to changes in several activities [17].

Among the elderly, studies have shown the association between insomnia and physical disability. Spira and collaborators [18] reported that insomnia symptoms have been associated with reports of limitations in daily activities. Another study reported that from the measurement of the short sleep period, i.e., lower sleep efficiency through pulse actigraphy in older women, a greater risk of difficulty in domestic activities was observed, among other changes [19].

The 6-Minute Walk Test (6MWT), whose purpose is to assess functional capacity and tolerance to physical effort, is commonly chosen because it is easy to use, more tolerated and better reflects daily activities [20,21], and is also valid in the evaluation of the prognosis and response to treatment of a series of cardiorespiratory diseases [22].

The objective of this study will be to evaluate the functional capacity in adult patients with insomnia assisted in Basic Health Units (BHU) of Divinópolis.

Methods

Study design and ethical considerations

This will be a cross-sectional observational study carried out by students from the University of the State of Minas Gerais (UEMG), Divinópolis Unit, with adult patients recruited from the BHU in the city of Divinópolis - MG, between July 2017 and March 2018 (Figure 1).

The design of the study followed the norms of the "Strengthening the Reporting of Observational Studies in Epidemiology (STROBE) statement" [23] and agrees with the ethical standards established in the 1961 Declaration of Helsinki in Hong Kong in 1989 and Edinburgh in Scotland in 2000) and the Guidelines and Regulatory Norms for research involving human beings of the National Health Council of the Brazilian Ministry of Health, resolution 196/96 updated by 466/2012.

The study was approved by the Committee of Ethics in Research with Humans of the UEMG, protocol number 1,475,521/2016. The informed consent term was obtained from all the patients involved, being allowed to be removed at any time without any encumbrance.

At the end of this study, a new research project will be developed, proposing treatment for possible disorders encountered.
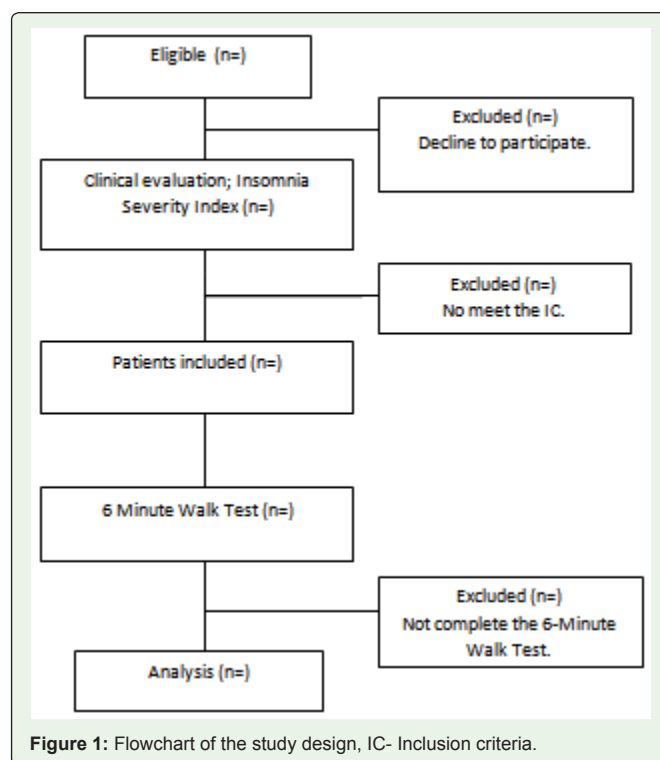

Figure 1: Flowchart of the study design, IC- Inclusion criteria.

Subjects

Adult patients with insomnia assisted in the BHUs of the city of Divinópolis-MG, over 18 years, of both genders, without cognitive impairment that deficit the understanding to respond the questionnaire, with insomnia (by the ISI questionnaire) and after agreeing to participate in the study, signing the informed consent. Those patients who do not agree to respond to the questionnaire and with diseases and / or comorbidities that may influence the results of the evaluations will be excluded. This sample will be consecutive and of convenience, and later stratified as to the socio-demographic variables and those pertinent to the study.

Study Protocol

Clinical evaluation

The patients' evaluation will performed in the BHUs, where they will collected personal data, evaluation of Heart Rate (HR), respiratory rate, systemic Blood Pressure (BP), weight and height. BP will be measured by the auscultatory method, after the patient remains seated for 10 minutes. The weight and height will evaluated through an electronic scale (model 200/5, Welmy Indústria e Comércio Ltda, São Paulo, Brazil).

Body Mass Index (BMI) will be calculated using the BMI Classification of the World Health Organization [24]. The neck circumference will be measured with the individual in the sitting position, at the level of the anterior border of the cricoid cartilage, both using a non-elastic tape measuring 1 millimeter [25]. The waist circumference will be measured by a non-elastic tape measure, measure at the midpoint between the lower margin of the last rib and the iliac crest [24].

Insomnia severity index

The ISI is a self-administered questionnaire that quantifies the patient's perception of insomnia. It evaluates the subjective symptoms and consequences of insomnia in daily activities, as well as the concerns. The questionnaire consists of seven items that investigate sleep initiation and maintenance, satisfaction with the sleep pattern, interferences in daily activities and degree of concern attributed to problems with sleep. Each item is assigned a value on a scale of 0 to 4 and the total score ranges from 0 to 28, in which a score of 0 to 7 indicates absence of insomnia; 8 to 14 mild insomnia; 15 to 21 moderate insomnia and 22 to 28 severe insomnia [26,27]. The Portuguese version of the ISI was valid and adequate to assess and evaluate these impacts in different contexts [28].

6 Minute walk test

The TC6M will follow the standards established by the American Thoracic Society (ATS), 2002 in which it will carried out in a continuous corridor that could not be smaller than 25 meters, being ideal corridors with length equal or superior to 30 meters. The patient will rested for 10 minutes before the test, and at this time PA, HR and Peripheral Oxyhemoglobin Saturation will be measured.

When the patient stood up, the dyspnea will assessed through the Borg scale and guidelines will given to the patient to perform the test. As soon as the patient started walking the time will checked and standardized phrases of encouragement were said by the applicator every minute. PA, Peripheral Oxyhemoglobin Saturation, HR and the Borg scale were re-evaluated every minute. The number of laps performed by the patient will be recorded. When the patient to discontinue the test, he will stood for 15 seconds at rest and then encouraged to return. In the last 15 seconds of testing, the patient will be advised that the walk will be discontinued [29].

Quality control

The researchers responsible for data acquisition will receive specific training for data security (questionnaires, vital signs, and 6MWT). Periodic external monitoring will be conducted to verify the application of the methodology for acquiring information and different tests.

Statistical Analysis

Numerical data will be known as mean and standard, there are no cases of variables with normal distribution, and median and interquartile range for those with asymmetric distribution. Categorical data will be describe as absolute number and percentage of total.

The Kolmogorov-Smirnov normality test will be performed in order to determine the normality of data. 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 statistical analysis will be used statistical software GraphPad Prism Software Inc., version 5.01 for Windows 2007 (San Diego, CA, USA) was used. The level of statistical significance is set at 5% for all testis ($p < 0.05$).

Discussion

Sleep disturbances are considered a public health problem, most of the time not being detected and treated since they are unknown by the population. Insomnia, one of the most common disorders, causes a series of changes, whether physical or psychological, that can influence the functional capacity of the individual.

The 6MWT is a good alternative in the evaluation of functional capacity because it is easy to apply and low cost. Since the symptoms of insomnia can negatively affect the daily routine of the individual, the need to evaluate such repercussions becomes important in the search for further insights on the influence of insomnia on the functional capacity of the individual.

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