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Validation of Self-Quantification Xiaomi Band in a Clinical Sleep Unit †

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Abstract: Polysomnography (PSG) is currently the accepted gold standard for sleep studies, as it measures multiple variables that lead to a clear diagnosis of any sleep disorder. However, it has some clear drawbacks, since it can only be performed by qualified technicians, has a high cost and complexity and is very invasive. In the last years, actigraphy has been used along PSG for sleep studies. In this study, we intend to assess the capability of the new Xiaomi Mi Smart Band 5 to be used as an actigraphy tool. Sleep measures from PSG and Xiaomi Mi Smart Band 5 recorded in the same night will be obtained and further analysed to assess their concordance. For this analysis, we perform a paired sample t-test to compare the different measures, Bland–Altman plots to evaluate the level of agreement between the Mi Band and PSG and Epoch by Epoch analysis to study the ability of the Mi Band to correctly identify PSG-defined sleep stages. This study belongs to the research field known as participatory health, which aims to offer an innovative healthcare model driven by the patients themselves, leading to civic empowerment and self-management of health.

Keywords: sleep; polysomnography; participatory health; Xiaomi Mi Smart Band 5; Internet of Things

1. Introduction

Sleep has considerable implications in our daily life, and it is crucial to effectively accomplish basic vital functions. People whose sleep quality is poor exhibit different sleep disturbances, such as the fragmentation of the different sleep stages, night arousals and a greater will of having diurnal naps. Moreover, in the most serious cases, sleep disorders like insomnia, hypersomnia or sleep apnoea may also appear [1]. Sleep Units are specialised areas for diagnosis and treatment of all these sleep disorders and offer a wide range of diagnostic tests (e.g., PSG or Multiple Latency Test) [2]. Despite providing multiple possibilities, PSG is considered as the most reliable instrument for the measure of sleep parameters by the scientific community. However, PSG also implies high invasiveness and cost, as well as specialised technicians to use it. Hence, different approaches for sleep assessment using wearable devices are being compared with PSG in order to achieve their maximum possible quality for sleep studies, so they can be used as a complementary tool [3]. In this study, the validation of the sleep data recorded by Xiaomi wristbands is assessed to determine whether these measurements are reliable enough for people to evaluate their own sleep. On this matter, previously conducted studies about these type of wearables have shown a high accuracy and sensitivity, a low specificity and a poorly significant and limited estimation of sleep/wakefulness states [4].

2. Methods

2.1. Design of the Study

This is an observational, analytic, longitudinal, pilot study whose aim is to demonstrate that data collecting instruments, along with their management, are viable and effective. Different variables from the population of interest will be observed and recorded without any direct intervention, so as to establish causality associations between these variables. It is considered as longitudinal, since the tracking of the variables will be performed during six months, continually (and occasionally) recording and monitoring sleep quality. A difference of >15 min in deep sleep measures between Xiaomi and PSG will be considered as clinically relevant in this study. Accepting a 0.05 α risk and a 0.1 β risk (statistical power of 90%) in a bilateral contrast, a population of 43 patients is needed to detect a difference that is $\geq$15 min. According to previous studies, a $\pm$30 SD will be assumed. Only patients that perform a medical test at the Sleep Unit from San Rafael Hospital and are >18 years old will be asked to participate. Legal and ethical aspects that guarantee good clinical practice will be followed in this study. Therefore, the informed consent process will be carried out with all participants.

2.2. Data Collection and Analysis

In this study, PSG data in EDF+ format, the most accepted standard to exchange EEG and PSG data [5], will be obtained from patients that undergo a sleep study at the Sleep Unit of San Rafael Hospital. In addition, patients will be given a Xiaomi Mi Smart Band 5 that will measure their sleep along with PSG for one night. By doing so, we will be able to compare both recordings in order to assess if these wearable devices show results in concordance with PSG. Besides, software to obtain data second by second from Xiaomi bands was developed by the TALIONIS Group, since these wearables export daily data by default, which hinder the analysis.

2.2.1. Variables of Interest

Table 1 shows the features that will be extracted from our data. Numeric variables will be shown as mean (M) and standard deviation (SD), including their range, minimums and maximums.

Table 1. Summary of the features of interest for our study

Variable	Description	Dimension
Time in Bed (TIB)	Total time the patient is laying down	min
Sleep Onset Latency (SOL)	Length of time from full wakefulness to sleep	min
Wake After Sleep Onset (WASO)	Periods of wakefulness after defined sleep onset	min
Sleep Efficiency (SE)	Time spent asleep/Time in Bed $*$ 100	%
Light sleep	$N1 + N2$ sleep stages	min
Deep sleep	$N3$ sleep stage	min
REM sleep	-	min

2.2.2. Statistical Analysis

After preprocessing the data (described in Figure 1), and following the analysis performed in the available literature for these validation studies [6], the summary of the aforementioned variables for both the Xiaomi Mi Smart Band 5 and PSG will be compared by using a paired sample *t*-test to study if there are significant differences between the means of each Xiaomi-PSG variable. To evaluate the level of agreement between Xiaomi and equivalent PSG sleep measures, we will use Bland–Altman plots. Since we are interested in the ability of Xiaomi devices to correctly identify sleep stages, Epoch by Epoch (EBE) analysis will be used to calculate the sensitivity (proportion of epochs identified as sleep by PSG that are correctly classified by the device), specificity (proportion of epochs identified as awake by PSG that are correctly classified by the device), agreement between both PSG and Xiaomi device in light sleep (proportion of PSG F1 + F2 epochs identified as light sleep by the device), deep sleep (proportion of PSG F3 + F4 epochs identified as deep sleep by the device) and REM sleep (proportion of PSG REM identified as REM by the device) identification.

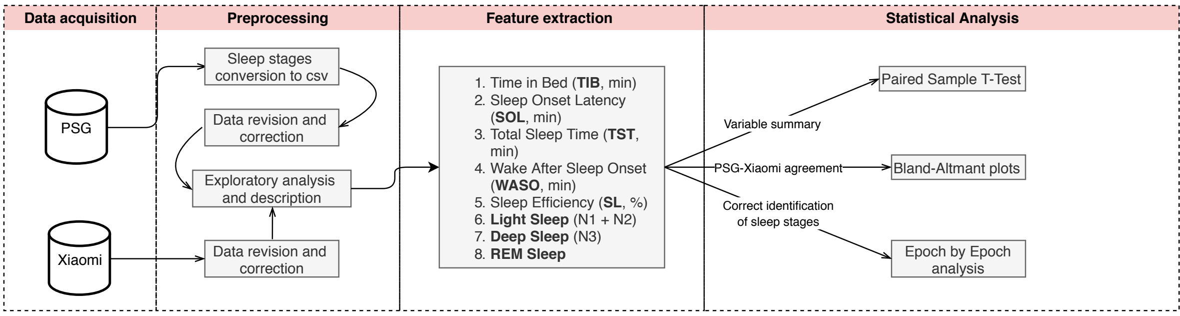

Figure 1. Sleep data validation workflow.

3. Conclusions

This study offers a promising approach to assess whether wearable devices, in our case the Xiaomi Mi Smart Band 5, are able to correctly record our sleep. Even though these devices are not expected to replace polysomnography studies, they may be used as an initial evaluation for users to manage their own sleep quality and, if necessary, visit their doctor or simply change some habits.

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Conflicts of Interest: The authors declare no conflict of interest.

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