On Sleeping Aids Usage and… a Potential Way to Reduce It

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Abstract

Insomnia symptoms are prevalent and the usage of over the counter and prescription sleeping aids is high, as access to the first line of recommended treatment, CBT-I, is limited and costly.

This observational study evaluated the change in sleeping aids usage in people with insomnia symptoms who chose to use a mobile app to deal with their sleep difficulties.

The results indicate a decrease in the frequency of reported sleeping pills intake for users who remain engaged with the app. The decrease was from 56% of users reporting sleeping aids usage on their first night session to 39% for those reaching their eleventh session.

The decrease in sleeping aids usage is most probably related to the efficiency of the sleep improvement intervention for users engaged with the app.

1. Background

Difficulties falling asleep, maintaining sound sleep, or waking up not refreshed are frequent [1][2]. Although the first line of recommended treatment is an intervention based on behavioral change and cognitive reframing provided by trained sleep therapists [3], access to that treatment is limited and costly [4], leaving many sufferers to continue with their sleepless nights and/or use sleeping aids or pills [5].

Digital CBTI has proven efficient in improving sleep [6][7][8].

Sleeprate provides a digital intervention for insomnia and poor sleep rooted in the state-of-the-art protocols of CBTI. The solution shows not only significant sleep improvement, but also improvement in productivity, presenteeism, and absenteeism [9].

Sleeping pills help as an adjunct when dealing with chronic insomnia or symptoms of insomnia [10] and are recommended for short-term usage in acute insomnia or transient insomnia. The lack of trained sleep therapists, the availability of many new sleep inducing/maintaining products, the reluctance of people to commit to a time-consuming behavioral change, and their inclination to find an immediate fix remain the main drivers to the extensive use of sleeping pills world-wide and in the US. Reports indicate that as many as 4% of U.S. adults aged 20 and over used prescription sleep aids [11]. As for over the counter (OTC) sleeping aids data are scarce. One study suggests that 10% of adults aged 18–45 years use OTC sleep aids [12].

Yet, the pharmacological intervention has limited effect in the long run and many side effects. Even newer prescription drugs can cause unwanted serious side effects leading initially to a decrease in the indicated dosage of some per the FDA guidance, followed by a mandatory black box warning for some of those products [13][14].

Recently we have updated the self-help Sleeprate app that provides personalized sleep improvement intervention based on state-of-the-art Cognitive Behavioral Therapy for Insomnia. Besides improvements in the app navigation, motivational approach, and new algorithms to allow better personalization of the app guidance, Sleeprate added the capability to acquire reported usage of sleeping aids/pills of any kind. No attempts of guidance to reduce sleeping pills usage are made by the app.

Most published evaluations regarding sleeping pills usage are obtained from consumers, patients, and providers surveys. We present here, for the first time, observational data regarding daily reported sleeping pills usage collected in real time, using a mobile app.

2. Methods

Review and analysis of aggregated and deidentified Sleeprate users' data starting on September 21, 2020 at the release of a new version of the app and ending on April 26, 2021.

Sleeprate provides a personalized behavioral change intervention rooted in the gold standard principles of CBTI. During the app onboarding process potential users answer 9 yes/no questions regarding their sleep. The last question is: "Do you ever use sleeping aids/pills?".

Only after answering those questions people willing to get an understanding of their sleep or to improve it start tracking their nights using subjectively logged data with or without adding a layer of objective sleep measures using a wearable device [15].

The app collects answers to several basic sleep questionnaires and a sleep journal completed daily

regarding sleep timing, sleep latency, time awake at night, sleep satisfaction, daily routines, usage of sleeping pills, social media, daily stress, daytime sleepiness and more. The first seven days of app usage and the initial answers to questionnaires serve for an initial evaluation aimed at detecting sleep problems and the daily routines that need attention and change to deal with the uncovered sleep difficulties. This first week is followed by a few weekly cycles of personalized guidance and training aiming to: (1) realign sleep drive and internal clock so as to allow falling asleep easily at the intended time - namely bedtime restriction and anchoring wake-up time; (2) stimulus control aiming to reduce anxiety around bedtime if detected; (3) cognitive reframing provided by in-context daily messaging and relevant pieces of sleep education; (4) stress-reduction exercises including breathing, mindfulness, strategies to unwind and deal with worries; (5) feedback regarding sleep damaging routines. Previous studies report sleep improvement and a reduction in daytime consequences of insomnia symptoms [9][16].

We selected data for analysis by looking longitudinally into the app usage and reporting between September 21,2020 and April 26, 2021. Fig 1 presents the data acquisition process using the Sleeprate app.
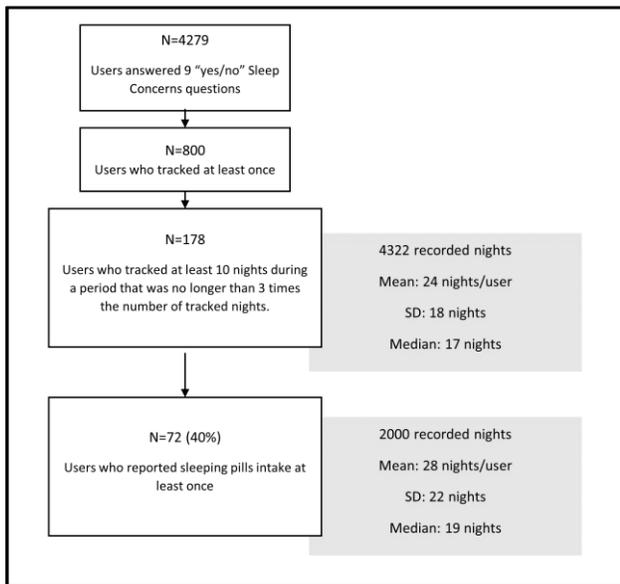

Figure 1. Data collection flow

We chose to analyze data only for users who tracked at least 10 nights in the app during a period that was no longer than 3 times the number of tracked nights. Sleep sessions not in line with this criterion were not considered. 178 users met those criteria, and out of those 40% reported at least on one occasion the intake of a sleeping aid or pill. Out of a total of 4322 nights recorded by eligible users, 984 (23%) contained reported intake of sleeping aids or pills.

We checked the connection between the answers to the initial sleeping pills/aids question and the nightly reported aids intake. Out of a total of 4279 available answers, 1378 (32%) people answered "Yes" to the "*Do you ever use sleeping aids/pills?*" question. Only 78% of the users who reported intake of sleeping pills at least once during the night sessions also answered "Yes" to the relevant question during onboarding. On the other hand, 8% of those who never reported pills intake answered "Yes" to the same question.

Regarding demographics of the 178 users for whom we have enough data of interest, the majority were women, and most were 25-45 years of age, see Fig. 2.

Figure 2. Age and gender distribution of 178 users included in the sleeping pills intake analysis.

3. Results

This is an observational study, and our data indicates that sleeping pills usage is higher in women, with 42% of women and 37% of men reporting sleeping pills intake at least once.

The age-related sleeping pills usage is high in the very old, as expected. There were only 6 users older than 80 and 83% reported sleeping pills intake at least once, while 44% of users aged 25-45, the largest subgroup of our observational study population, reported pills intake at least once.

The trends regarding the frequency of sleeping pills intake in people engaged with the app, and who reported pills intake at least once are presented in Fig 3. The results indicate a decrease in the frequency of reported sleeping pills intake for users who remained engaged with the app. The pills usage frequency oscillates from night to night and on the eleventh session a very significant decrease is observed. Oscillations may continue, as there are also fluctuations in the sleep latency, sleep efficiency, and time spent wake at night.

4. Discussion

To our best knowledge, this is the first observational study based on real time data acquired using sleep tracking, a

digital sleep journal integrated in a self-help mobile app based on state-of-the art protocols of CBT-I and coaching people on how to improve their sleep.
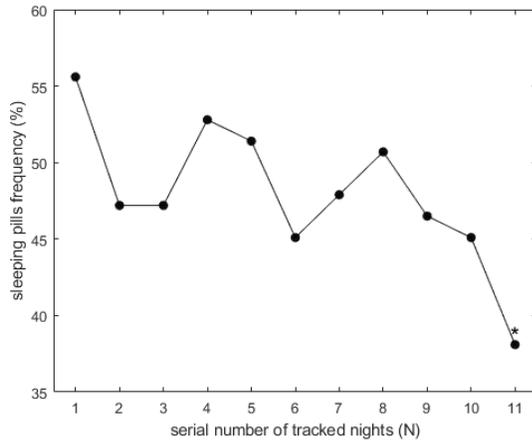

Figure 3. The figure shows the frequency of the nightly reported sleeping pills intake. To show a trend of the frequency of pills usage as a function of the engagement with the app, the chosen x-axis is the serial number of the tracked night for each user. To avoid bias due to the low numbers of users, data points were plotted until the first data point was contributed by less than 60 different users. One can easily see fluctuations in the frequency of pills intake as people remain engaged with the app. Significant decrease appears on session 11 (Chi-square proportion test, $p < .05$). Note: the 11th session maybe in week 2 or later since first tracked night, as the average number of weekly tracked nights per user is 5 (SD 2).

Acquiring daily data regarding sleeping pills intake provides data points as a function of time andhelps overcoming memory issues related to survey data.

The reported sleeping aids usage (over the counter and prescription) in a population of people who chose to engage with a sleep improvement self-help app is relatively higher than the usage in the general population. This is expected as people with sleep problems are looking for a relief to their suffering.

There is an apparent trend of a decrease in sleeping aids usage for those using the app. The app is not making any attempt to provide guidance regarding the use or the reduction of sleeping aids. Thus, it is reasonable to assume that sleep improvement [9][16] related to the engagement with the app leads to the decrease in sleeping pills usage. We do not have yet results regarding users' compliance with the personalized guidance and changes in sleep complaints for the specific time frame and study population. Thus, we are not able to show a correlation between the improvement in sleep complaints and the decrease usage of sleeping aids. Further analysis will help understanding the connection.

The limitations are clear as this is an observational study based on aggregated data and not a clinical controlled study. However, a clinical controlled study should follow to evaluate in detail the efficacy of Sleeprate's application in sleep improvement for those suffering from chronic insomnia, or symptoms of insomnia. A clinical controlled study would throw additional light regarding the efficacy of the app not only regarding sleep improvement, but also helping to reduce sleeping aids usage of any kind.

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