Smartphone-Based Virtual Agents Can Help The General Population Concerned By Sleep Complaints: A Proof Of Concept Study During Covid-19 Confinement

Pr. Pierre Philip 1, 2, Ph.D. Lucile Dupuy1, 2,\*, Pr. Charles M. Morin 3, 4, Ph.D. Etienne de Sevin 2,

M.D.Ph.D. Stéphanie Bioulac, 2, Ph.D. Jacques Taillard 2, Ph.D. Fuschia Serre 2, Pr. Marc Auriacombe

2, M.D.Ph.D. Jean-Arthur Micoulaud-Franchi 1, 2

1 - Clinique du sommeil, Services d'explorations fonctionnelles du système nerveux, CHU de Bordeaux,
Place Amélie Raba-Leon, 33076 Bordeaux, France.

2 - USR CNRS 3413 SANPSY, CHU Pellegrin, Université de Bordeaux, France.

École de psychologie, Université Laval, Québec, QC, Canada

«Centre d'étude des troubles du sommeil, Institut universitaire en santé mentale de Québec, Québec,

QC, Canada G1A 0A6

\* Corresponding author:

Lucile DUPUY

USR CNRS 3413 SANPSY, CHU Pellegrin, Université de Bordeaux, France, Clinique du sommeil, Services d'explorations fonctionnelles du système nerveux, CHU de Bordeaux, Place Amélie Raba-Leon, 33076 Bordeaux, France.

Email: Lucile.dupuy@u-bordeaux.fr

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### Abstract

**Background:** The COVID-19 crisis induces psychosocial stress and sleep complaints that require early management. KANOPEE is a smartphone-based application, providing an interaction with a virtual agent dedicated to screen and deliver behavioral interventions to fight sleep disorders. This paper describes the feasibility study of this application, during the context of COVID-19 confinement in France.

**Method:**, 2,069 users of aged 18 years and over downloaded the app during the inclusion period (between 22 April and 5 May 2020). Users first answered a screening interview based on the insomnia severity index (ISI) that was conducted by the virtual agent. If participants were positive for insomniac complaints (ISI > 14), they could join a two-stage intervention program: a) complete an electronic sleep diary for one week, and b) follow personalized sleep recommendations for 10 days. Measures collected included socio-demographic information, ISI and sleep/wake schedules; and acceptance and trust of the agent.

**Findings:** Of all participants, 80% (n=1,574) completed the screening interview with the virtual agent. The virtual agent was well accepted by users regarding its usability, satisfaction, benevolence, and credibility. Of the 773 screened subjects who reported sleep complaints (ISI>14), 214 of them followed the first step of the intervention (34%). Of these, 47 (31%) followed the second step. Users who completed step 1 found that their insomnia complaints (p > .001) and nocturnal sleep improved significantly after one week. Subjects who completed step 2 also showed an improvement compared to the initial measure (p < .001). The most severely affected subjects (ISI >21) did not respond to either intervention.

**Interpretation:** These preliminary results show that KANOPEE is a promising solution to screen populations for sleep complaints, and that it provides practical and effective behavioral advice for subjects reporting moderately severe insomnia.

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#### **Research in context**

**Evidence before this study:** COVID-19 crisis and the resulting confinement induce negative psychosocial effects, including sleep disorders. Digital health technologies have been used to track contaminating subjects to prevent the diffusion of clusters during the pandemic. Previously to the current COVID-19 crisis, several studies showed the effectiveness of digital technologies to deliver digital Cognitive Behavioral Therapy (d-CBT) to treat insomnia. These technologies can be used remotely and do not require human intervention to deliver healthcare. Virtual agents have the ability to foster empathy and motivation, promoting technology acceptance, which is a major challenge to make efficient d-CBT. Added value of this study: In this feasibility study, we tested a new app, providing screening and behavioral intervention through an interaction with a virtual agent, available for the general population, could deliver a screening and a simple behavioral intervention on sleep complaints were reported. Our results show the benefits of computerized behavioral intervention on sleep hygiene and on sleep complaints. We also show that the virtual agent was well accepted by its users, in terms of usability, satisfaction, credibility and benevolence.

**Implications of all the available evidence:** Virtual agents delivered on smartphone apps are promising empathic tools to provide psychological and behavioral support in patients reporting sleep complaints, notably in the context of COVID-19 pandemic.

#### Introduction

The current COVID-19 crisis has led to massive public health interventions resulting in the confinement of almost the entire human population on earth. However, as reviewed recently,<sup>1,2</sup> confinement may induce several negative psychological effects including post-traumatic stress symptoms, anxiety, depression, anger, and insomnia. Notably, Voitsidis<sup>3</sup> showed in a panel of 2,363 Greek subjects that almost 38% of them reported insomnia complaints during the confinement related to COVID-19, and these complaints were associated with a higher rate of depression. COVID-19 was also shown to increase the use of tobacco and alcohol in association with depression and stress symptoms.<sup>4</sup>

All these findings confirm that the COVID-19 crisis has produced major psychosocial stress and that prolonged confinement is potentially an aggravating factor for sleep complaints and insomnia. While the early detection of psychosocial stress can help in promoting simple behavioral techniques, innovative solutions are needed to track and help individuals at risk of psychosocial stress due to the large number of affected persons and the limited number of available healthcare professionals during the crisis.

In this context of pandemic and overwhelmed healthcare services, digital technologies have a major role to play. As mentioned by many researchers<sup>5,6</sup> and governmental authorities,<sup>7</sup> technologies such as social media, smartphone applications, telehealth technologies, and big data analyses have great potential to disseminate information, screen, and remotely monitor the general population, including infected COVID-19 patients. Several apps have been deployed to manage the fight against COVID-19 (*e.g.*, STOP COVID in France; see <sup>8</sup> for an overview). However, apps and technologies addressing psychosocial stress induced by COVID-19 crisis and confinement are less numerous,<sup>9–11</sup> and to our knowledge, none has focused on insomnia complaints, despite the evidence that digital behavioral therapies are efficient to treat insomnia.<sup>12–14</sup>

Very shortly after the beginning of confinement in France on 17 March, we launched a social media campaign with our hospital and our university through major national radios and newspapers on the risk of insomnia and the way to evaluate and correct inappropriate sleep hygiene practices during confinement. In addition to social media campaigns, we developed a free smartphone application to help people with sleep problems in the context of the COVID-19 crisis.

Named KANOPEE, the program is based on our previous research on embodied conversational agents (ECAs) (also called Virtual Agents), which may be defined as animated characters able to engage in face-to-face dialogue through verbal and nonverbal behavior. Our team previously demonstrated that ECAs can diagnose not only sleep complaints but also addiction and depression in an autonomous, reliable, valid, and acceptable way,<sup>15–19</sup> by fostering empathy and facilitating disclosure of negatively connoted topics. In addition, based on existing tools and knowledge on digital therapies for insomnia,<sup>14</sup> we developed a digital sleep diary to automatically quantify daily sleep patterns and sleep duration, and to establish personalized sleep interventions guided by the data collected through the app.

We hypothesized that a virtual agent made available via a smartphone app would be efficient and acceptable not only in providing autonomous screening for insomnia complaints but also in establishing digital behavioral interventions to help the population during the COVID-19 crisis. We therefore launched a proof-of-concept study during the confinement to test our hypothesis.

### Methods

## **Description and implementation of KANOPEE**

After KANOPEE was made freely available on Google Play Store on 22 April (see Figure 1), we launched a second media campaign presenting it and showing how it could help the French population to self-evaluate their sleep and provide practical solutions to manage insomnia.

## FIGURE 1 ABOUT HERE

During the screening interview (interview 1), users answered the Insomnia Severity Index scale<sup>20</sup> administered via a virtual agent called Louise (see **Figure 2**, left screen). Then, depending on the score  $> \text{ or } \le 14$ )<sup>21</sup>, users were provided with simple sleep hygiene recommendations (respect usual wake up time, get exposed to the light in the morning, sleep in silent and dark room...) or could enter the intervention program. They initially entered the "first step" of the intervention program with instructions to complete a sleep diary for one week in order to have a better understanding of their sleep patterns and to collect data about sleep indicators. Every morning after filling in their sleep schedule, they received visual feedback on their sleep, *e.g.* time spent in bed, total sleep time and sleep efficiency (see **Figure 2**, middle screen). After completing the sleep diary for seven days, they received a follow-up interview with Louise (interview 2) in which they learned about their sleep indicators in the previous week. Then they took the ISI for the second time. Next, they could enter the "second step", during which they were provided with personalized sleep recommendations for ten days based on the sleep diary data and their answers on the ISI (see **Figure 2** right screen). For details of conditions for personalizing

recommendations, see **Table 1** in Appendix. Thereafter, they could access another follow-up interview (interview 3) and take the ISI a third time. Depending on that ISI score, they could continue to use the app autonomously, or if their sleep complaint persisted (ISI score over 21), be referred to a sleep specialist in our hospital.

#### FIGURE 2 ABOUT HERE

Throughout the process, all procedures and tools (questionnaires, sleep diary) were introduced by the virtual agent in order to facilitate the understanding of users and increase their engagement. A demo of Louise can be found here: <u>https://youtu.be/y3QfgNvQfr0</u>\_\_\_\_\_

## Socio-demographics and clinical characteristics of users

For the purpose of this study, users were selected for analysis if they met the following inclusion criteria: being aged 18 years old and over, and having downloaded the app before 5 May, in order to have access to the one-week intervention before the end of confinement in France, *i.e.* 11 May. Their use of the app was recorded from 22 April until 26 May. After getting approval by the University and Hospital scientific committees, we obtained authorizations to be registered on the University Hospital register for GDPR approval by the French authorities (CNIL). Informed consent was obtained from all persons downloading the app according to the General Data Protection Regulation and CNIL regulations. Subgroups of participants were then selected for more detailed analyses (see **Figure 3**): those who answered the screening interview for sleep disorders were examined further to determine their eligibility for the next step of daily sleep monitoring. Users who reported suffering from insomnia (ISI score > 14) entered the intervention program and were included in the analyses of outcomes and feasibility.

#### **FIGURE 3 ABOUT HERE**

#### Measures

### 1. Clinical measures

The ISI<sup>20</sup> is a 7-item self-report questionnaire that provides a global measure of perceived insomnia severity (range from 0-28: 0-7 (no clinical insomnia), 8-14 (sub-threshold insomnia), 15-21 (insomnia of moderate severity), and 22-28 (severe insomnia)). The ISI has been validated and has proven sensitive to changes in insomnia severity with treatment.<sup>21</sup> The ISI was used as a screening tool for assessing insomnia severity and as the primary outcome measure of treatment efficacy after the intervention. Participants who obtained an ISI score over 14 used the app to complete a daily sleep diary<sup>22,23</sup> throughout the program. The following dependent variables were derived from daily sleep diaries completed by the subjects: sleep onset latency (SOL), number of awakenings (NWAK), wake after initial sleep onset (WASO), terminal wakefulness (TWAK), total time spent in bed (TIB), total sleep time (TST), and sleep efficiency (SE).

Addictive behaviors (alcohol and cigarette consumption) were evaluated through a clinical interview based on the CAGE<sup>24</sup> and CDS-5.<sup>25</sup>

## 2. Acceptance and trust questionnaires

Users could complete two scales on the app: the French version of the Acceptability E-scale (AES) <sup>26,27</sup> to measure acceptance of the KANOPEE app by two sub-scores (usability *i.e.*, the perceived ease of using the system; and satisfaction *i.e.*, the perceived enjoyment of the use and usefulness of the system); and the ECA Trust Questionnaire (ETQ),<sup>18</sup> which measures trust in a virtual agent by two sub-dimensions: perceived credibility (*i.e.*, perception that the agent has the ability and the expertise to conduct a medical intervention) and benevolence (*i.e.*, perception that the agent is well-intentioned and will accurately take one's interests into account). Familiarity with technologies was also evaluated by a single question: "how familiar are you with computer technologies?" with three choices: No/Moderately/Yes, that we scored between 0 to 2, higher scores corresponding to more familiarity with technologies.

## Statistical analyses

Quantitative variables were expressed with means (M) and standard deviations (SD), and qualitative variables were expressed using percentages. To compare two groups of users (*e.g.* with subclinical insomnia *vs.* with moderate-to-severe insomnia) we performed Student t-tests for continuous variables (*e.g.*, age, CDS score, cigarettes smoked), and  $\chi^2$  tests for categorical variables (*e.g.* gender, educational level, healthcare professional, users following the confinement). The data collected during the program was described using means and standard deviations, and evolution of the measures over time was analyzed using repeated t-tests. Acceptance (usability and satisfaction sub-scores of the AES), and trust (credibility and benevolence sub-scores of the ETQ) data was expressed using distributions and percentages. To investigate factors associated with acceptance and trust, we conducted univariate analyses with Pearson correlation analyses between two continuous variables (age, insomnia severity, familiarity with technologies), and performed mean comparisons (t-test or ANOVAs) to analyze the variation of AES and ETQ regarding categorical variables (gender, educational level). All analyses were performed using SPSS software (version 26, PASW Statistics).

## Results

#### 1. Characteristics of users

2,069 users over 18 years old downloaded KANOPEE (**Table 1** in **Appendix**). 76% of users answered the screening interview for insomnia disorders. Most users were between 31 and 50 years old (Mean: 43.52; SD = 13.94) and had a university degree. Most were confined, and 5% were professional health workers involved in the fight against COVID-19. About half of the users who answered the screening interview for sleep disorders obtained an ISI score over the clinical threshold for insomnia (ISI > 14). Users who answered the screening interview for sleep disorders (N = 1,574) were divided in two subgroups based on their ISI score:  $\leq 14$  considered as "with subclinical insomnia", >14 considered as "with moderate-to-severe insomnia" (**Table 2** in **Appendix**).

Participants with moderate-to-severe insomnia were younger (t (1576) = -3.03; p = 0.002), more educated ( $\chi^2$  (2) = 12.14; p = 0.007), and more likely to be female ( $\chi^2$  (1) = 31.91; p < 0.001) compared to those "with subclinical insomnia". Interestingly, more users who reported being in confinement were

found in the "moderate-to-severe insomnia" group ( $\chi^2(1) = 8.86$ ; p = 0.003) but we did not find evidence of a higher prevalence of insomnia in healthcare workers. Users with moderate-to-severe insomnia smoked more cigarettes (t (734) = -4.03; p < 0.001) and obtained a higher score on the screening questionnaire for addiction to cigarettes (t (734) = 3.41; p = 0.001) compared to those in the other group.

#### 2. Trust and acceptance of virtual agent

431 users answered the acceptance and trust questionnaires (**Figure 5**). Acceptance of the overall system (AES score) was rated very positively, with 61.7% of users being "very satisfied" with the usability of the system, and 93.9% of users rating the VMA more than 3 out of 5 for satisfaction. Regarding trust (ETQ score), Louise was perceived as trustworthy to perform clinical interviews. Indeed, 94.1% of patients "somewhat agreed" or "totally agreed" that she was benevolent, and 67.03% of patients had a positive attitude towards her credibility (more than 1 out of 3).

## **FIGURE 4 ABOUT HERE**

We found a negative correlation between age and credibility sub-score on the ETQ (r = -102; p = 0.034) suggesting that older individuals found Louise less credible than the younger ones. Age did not influence other dimensions of trust and acceptance. Similarly, gender and educational level of the users did not influence their attitude towards Louise. Regarding insomnia severity, there was a positive relationship between the severity and credibility of Louise (r = 0.125; p = 0.009) indicating that individuals with more severe insomnia complaints found her more credible. Lastly, we found significant correlations between familiarity with technologies and attitudes towards Louise: individuals more familiar with technologies found her more usable (r = 0.109; p = 0.024), more satisfactory (r = 0.128; p = 0.008) and more benevolent (r = 0.117; p = 0.015).

### 3. Evolution of ISI score and nocturnal sleep indicators during the intervention program

The total ISI score (**Figure 4**) decreased after step 1 intervention (t(165) = 7.88; p < .001) with 36.7% of users obtaining an ISI below a clinically significant level (i.e., < 15), either corresponding to "no insomnia" (4.8%) or to "subthreshold insomnia" (31.9%). After step 2 intervention, ISI score continued to decrease but without reaching a significant threshold (t(46) = 1.42; p = .162), but compared to the initial measure, a significant decrease is observed (t(46) = 4.852; p < .001) and the proportion of users reporting low insomnia complaints increased, with a total of 48.9% of users below a clinically significant level. Of note, 14.9% of users still reported "severe insomnia" after step 2, so they were referred to a sleep specialist.

#### **FIGURE 5 ABOUT HERE**

Regarding nocturnal sleep indicators, we computed the mean of the first two nights completed in the sleep diary and the last two nights before receiving step 2 intervention in order to evaluate the evolution of sleep indicators during completion of step 1 intervention. Mean analyses among the N = 214 users who completed step 1 (see **Table 4** in the **Appendix**) suggest a reduction in TIB, SOL, WASO, NWAK and TWAK, and an increase in TST and SE among the subgroup completing step 1, i.e., filling in the sleep diary. To measure the effect of completing step 2 on sleep indicators, we computed the mean of the seven nights before receiving the personalized sleep recommendations and compared it to the mean of the seven nights after starting step 2. Mean analyses among the N = 47 users who completed step 2 suggest (see **Table 5** in the **Appendix**) that WASO, NWAK, and TWAK decreased after step 2, while TIB, TST, SE increased.

### Discussion

Our results show for the first time the feasibility of using virtual agents in the context of a major health crisis to track insomnia symptoms and deliver behavioral interventions. More than 2,000 people downloaded the app over an 11-day period, with no technical error reported by Google Play store, which

is a higher inclusion rate than the one reported in a previous study proposing online d-CBT for insomnia.<sup>28</sup> This confirms the potential of digital technologies to provide access to clinical screener and behavioral intervention for insomnia for the general population.<sup>29</sup> Out of 2,069 subjects who downloaded KANOPEE, 1,573 (76%) used it to self-evaluate their sleep. While the stress related to confinement could explain why we obtained such a high download rate, another potential explanation is the attractivity of virtual agents to engage in digital interactions. Even individuals without significant sleep complaints (50% the sample) used our app and were interested in completing a sleep evaluation, a possible signal for future sleep hygiene campaigns.

Acceptance of the agent was a major challenge in this specific context and we obtained very good results, similar to those previously obtained in a medical context.<sup>18</sup> Usability and benevolence were very well ranked by the users, which confirms the empathic dimension of our virtual agents even on smaller devices like smartphones.

Regarding the intervention program, 28% of the patients reporting significant sleep complaints (ISI> 14) accepted to fill out a daily sleep diary for more than seven days and 34% of these followed behavioral interventions and completed the sleep diary for 10 more days. These rates are lower than those obtained by Espie et al.,<sup>28</sup> possibly because we did not select the subjects specifically to be enrolled in the intervention. Interestingly, subjects completing step 1 significantly improved their sleep over a short period of time (*i.e.* 7 days). We hypothesize that filling in the sleep diary and receiving a daily feedback on sleep efficiency score helped participants to adjust their sleep schedule autonomously. Another possible explanation is that their insomnia symptoms decreased naturally over time, even though a reduction of time in bed for about half an hour suggests an active change. These findings are very encouraging for the use of electronic sleep diaries to promote sleep hygiene practices, a form of low intensity sleep health intervention that could be beneficial at the more global population level. The lower number of subjects who completed their personalized intervention obtained an improvement in nocturnal sleep with a reduction of nocturnal awakenings and insomnia complaints, so step 2 was beneficial for a subgroup of individuals with more significant sleep complaints. Altogether, with completion rates of 80% for the initial evaluation and 34% for the personalized interventions in a selected population, we believe that our results open interesting perspectives for populational interventions and mirror the proposal of Berry et al. to set up trials in which large-scale interventions are offered simultaneously to different sub-groups of patients.<sup>30</sup>

KANOPEE is thus a promising tool both for identifying individuals with significant insomnia complaints and for providing brief, practical and effective behavioral interventions.

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## Figure legends:

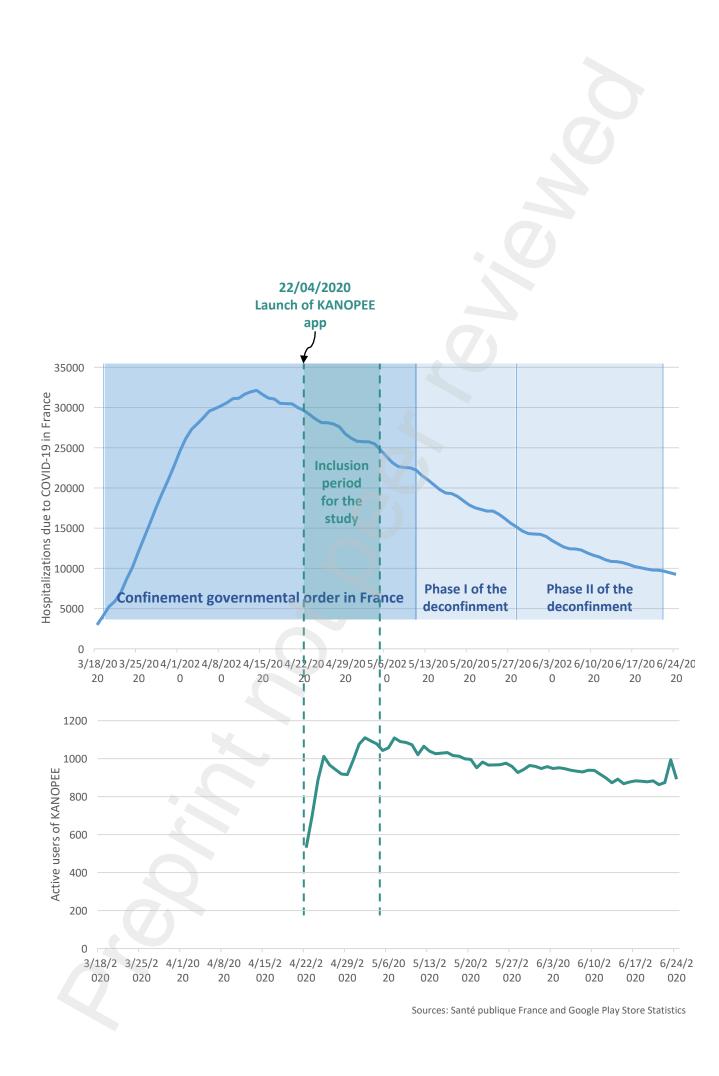
**Figure 1: Context of the conception and use of KANOPEE**: chronological evolution of hospitalizations due to COVID-19 in France, confinement strategies ordered by the French government, number of active users, and inclusion period for this study

**Figure 2: Examples of interfaces of KANOPEE**. From left to right: **1.** Screenshot of Louise questioning the Insomnia Severity Index. **2.** Screenshot of the sleep diary and the visual feedbacks regarding sleep. **3.** Screenshot of a personalized sleep recommendation given by Louise during Interview 3.

# Figure 3. Flowchart of users included in the different steps of analyses

**Figure 4. Distribution of usability, satisfaction, benevolence and credibility perception of the virtual companion for sleep disorders (Louise).** a.: percentage of patients' rating for usability dimension (AES sub-score), b.: percentage of patients' rating for satisfaction dimension (AES sub-score), c.: percentage of patients' rating for benevolence dimension (ETQ sub-score), d.: percentage of patients' rating for credibility dimension (ETQ sub-score).

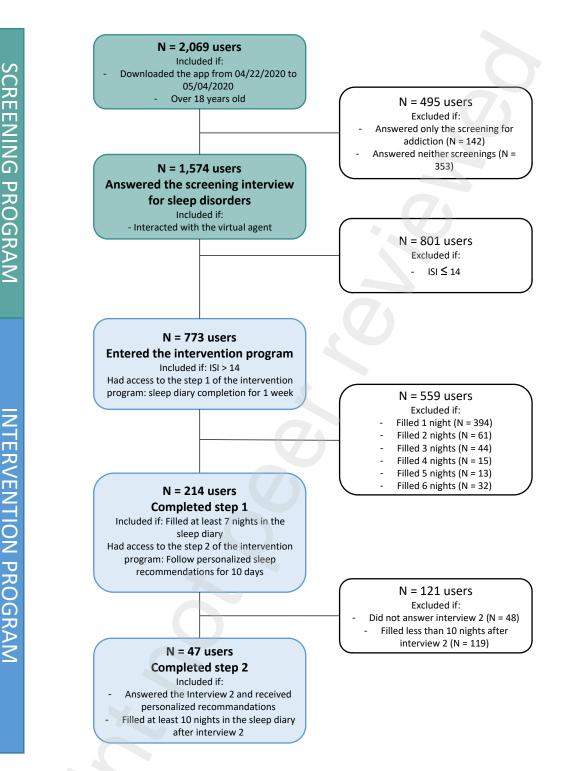
**Figure 5: Distribution of users depending on the severity of their insomnia complaints (ISI score) along the intervention program:** Step 1: sleep diary completion; step 2: follow personalized sleep recommendations













Satisfaction

