

Smartphone-Based Virtual Agents to Help the General Population Concerned by Sleep Complaints During COVID-19 Confinement: A Feasibility Study

Pierre Philip, Lucile Dupuy, Charles M. Morin, Etienne de Sevin, Stéphanie Bioulac, Jacques Taillard, Fuschia Serre, Marc Auriacombe, Jean-Arthur Micoulaud-Franchi

Submitted to: Journal of Medical Internet Research
on: September 11, 2020

Disclaimer: © The authors. All rights reserved. This is a privileged document currently under peer-review/community review. Authors have provided JMIR Publications with an exclusive license to publish this preprint on its website for review purposes only. While the final peer-reviewed paper may be licensed under a CC BY license on publication, at this stage authors and publisher expressly prohibit redistribution of this draft paper other than for review purposes.

Table of Contents

Original Manuscript..... 5

Supplementary Files..... 21

 Figures 22

 Figure 1..... 23

 Figure 2..... 24

 Figure 4..... 25

 Figure 5..... 26

 Figure 3..... 27

Smartphone-Based Virtual Agents to Help the General Population Concerned by Sleep Complaints During COVID-19 Confinement: A Feasibility Study

Pierre Philip^{1,2} Prof Dr; Lucile Dupuy¹ PhD; Charles M. Morin^{3,4} PhD; Etienne de Sevin¹ PhD; Stéphanie Bioulac^{1,2} MD, PhD; Jacques Taillard^{1,2} PhD; Fuschia Serre¹ PhD; Marc Auriacombe¹ Prof Dr; Jean-Arthur Micoulaud-Franchi^{1,2} MD, PhD

¹USR CNRS 3413 SANPSY University of Bordeaux Bordeaux FR

²Clinique du Sommeil University Hospital of Bordeaux Bordeaux FR

³Ecole de psychologie Université Laval Québec CA

⁴Centre d'étude des troubles du sommeil Institut universitaire en santé mentale de Québec Québec CA

Corresponding Author:

Lucile Dupuy PhD
USR CNRS 3413 SANPSY
University of Bordeaux
Hopital Pellegrin 13th Fl.
Place Amélie Raba Léon
Bordeaux
FR

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.

Objective: This paper describes the feasibility study of this application, during the context of COVID-19 confinement in France.

Methods: 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.

Results: 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 one found that their insomnia complaints (mean scores: baseline ISI: 18.56; ISI after step one: 15.99; P<.001) and nocturnal sleep improved significantly after one week. Subjects who completed step 2 also showed an improvement compared to the initial measure (mean scores: baseline ISI: 18.87; ISI after step two: 14.68; P<.001). The most severely affected subjects (ISI >21) did not respond to either intervention.

Conclusions: 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.

(JMIR Preprints 11/09/2020:24268)

DOI: <https://doi.org/10.2196/preprints.24268>

Preprint Settings

1) Would you like to publish your submitted manuscript as preprint?

✓ Please make my preprint PDF available to anyone at any time (recommended).

Please make my preprint PDF available only to logged-in users; I understand that my title and abstract will remain visible to all users.
Only make the preprint title and abstract visible.

No, I do not wish to publish my submitted manuscript as a preprint.

2) If accepted for publication in a JMIR journal, would you like the PDF to be visible to the public?

✓ **Yes, please make my accepted manuscript PDF available to anyone at any time (Recommended).**

Yes, but please make my accepted manuscript PDF available only to logged-in users; I understand that the title and abstract will remain visible to all users.

Yes, but only make the title and abstract visible (see Important note, above). I understand that if I later pay to participate in <http://www.jmir.org/preprint/24268>



Original Manuscript

Smartphone-Based Virtual Agents to Help the General Population Concerned by Sleep Complaints During COVID-19 Confinement: A Feasibility Study

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.

Objective: This paper describes the feasibility study of this application, during the context of COVID-19 confinement in France.

Methods: The virtual agent is an AI program using decision tree architecture, and interacting through natural body motion and natural voice. 2,069 users 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 insomnia 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.

Results: 80% of users who downloaded the app ($N=1,574$) completed the screening interview with the virtual agent. The virtual agent was well accepted by the 431 users who answered acceptance and trust questionnaires, regarding its usability, satisfaction, benevolence, and credibility. Of the 773 screened subjects who reported sleep complaints ($ISI > 14$), 166 of them followed the first step of the intervention (21.5%). Of these, 47 (28.3%) followed the second step. Users who completed step one found that their insomnia complaints (mean scores: baseline ISI: 18.56; ISI after step one: 15.99; $P < .001$) and nocturnal sleep improved significantly after one week. Subjects who completed step 2 also showed an improvement compared to the initial measure (mean scores: baseline ISI: 18.87; ISI after step two: 14.68; $P < .001$). The most severely affected subjects ($ISI > 21$) did not respond to either intervention.

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

Keywords: COVID-19; virtual agents; sleep disorders; technology acceptance

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.[1] However, as reviewed recently,[2,3] confinement may induce several negative psychological effects including post-traumatic stress symptoms, anxiety, depression, anger, and insomnia. Notably, Voitsidis[4] 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.[5]

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. Innovative

solutions are therefore 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[6,7] and governmental authorities,[1] 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 [8] for an overview). However, apps and technologies addressing psychosocial stress induced by COVID-19 crisis and confinement are less numerous,[9–11] and to our knowledge, none has focused on insomnia complaints, despite the evidence that digital behavioral therapies are efficient to treat insomnia.[12–14]

Very shortly after the beginning of confinement in France on 17 March, we launched a first 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 deliver a clinical interview to diagnose not only sleep complaints but also addiction and depression in an autonomous, reliable, valid, and acceptable way,[15–19] by fostering empathy and facilitating disclosure of negatively connoted topics. In addition, based on existing tools and knowledge on digital therapies for insomnia,[14] 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

KANOPEE is implemented using the same architecture as our previous ECAs [15–19], in C# in Unity 3D software (Unity-Technologies). The virtual agent, named Louise, interacts through natural body motion (3D animations are based on Motion Capture technologies) and natural voice recorded from an actress. The interaction scenario is pre-defined, using decision trees to adapt to the user's answers.

The app was made freely available on Google Play Store on 22 April (see Figure 1), and after its launch we organized a second media campaign presenting KANOPEE 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

Figure 1 Label: 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

The interaction scenario is made up as follows: first, during the screening interview (interview 1), Louise presents herself and administers the Insomnia Severity Index scale[20] (see **Figure 2**, left screen). Then, depending on the score $>$ or ≤ 14 [21], users are 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

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.

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.[22]

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

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

Measures

Clinical measures

The ISI[20] 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.[21] 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 [23,24] throughout the program. The following dependent variables were derived from daily sleep diaries completed by the subjects: sleep onset latency (SOL, i.e., how many minutes it takes to fall asleep, starting from the moment of intention to fall asleep), number of awakenings (NWAK), terminal wakefulness (TWAK, i.e., amount of awake time between the final Wakefulness awakening and the time of getting out of bed), wake after initial sleep onset (WASO, i.e., total amount of time awake during the night, excluding SOL and TWAK), total time spent in bed (TIB, i.e., time starting from the moment of intention to fall asleep and concluding with the final arising), total sleep time (TST, i.e., actual time slept, calculated from other self-reported variables (TIB–SOL–WASO–TWAK)), and sleep efficiency (SE, i.e., percent of time in bed spent asleep, calculated from other self-reported variables: TST/TIB x 100).

Addictive behaviors (alcohol and cigarette consumption) were evaluated through a clinical interview based on the CAGE[25] and CDS-5.[26]

Acceptance and trust questionnaires

After the interviews with the virtual agent, users could complete two scales on the app: the French version of the Acceptability E-scale (AES) [27,28] 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),[18] 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 χ^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

Characteristics of users

2,069 users over 18 years old downloaded KANOPEE and answered socio-demographic information (**Table 1**). 76% (N = 1,574) 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 healthcare professionals 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). We can see that compared to users who answered the screening interview for sleep, users who chose not to were significantly older (P = .016) and more likely to be male (P = .001). Other factors remained non-significant between the two groups.

Table 1. Characteristics of KANOPEE users depending on their use of the app

Characteristics	Answered screening interview for sleep (N = 1,574)	Did not answer screening interview for sleep (N = 495)	Group comparison	P values
Age (M(SD))	43.11 (13.78)	44.83 (14.37)	t (2067) = 2.40	P=.016
[18-30] years old (%)	21.5	20.0		
[31-50] years old (%)	48.5	44.4		
[51-65] years old (%)	23.3	26.5		
> 65 years old (%)	6.8	9.1		
Gender (% females)	67.0	59.0	χ^2 (1) = 10.71	P=.001
Educational level:				
Middle school (%):	20.2	16.8	χ^2 (2) = 5.690	P=.128
High school (%):	19.6	23.8		
University degree (%):	60.2	59.4		
Healthcare professionals (%)	5.7	5.7	χ^2 (1) = 0.000	P=.997
Confined due to COVID-19 lockdown (%)	76.2	74.9	χ^2 (1) = 0.343	P=.558

Users who answered the screening interview for sleep disorders (N = 1,574) were divided in two subgroups based on their ISI score: ≤ 14 considered as “with subclinical insomnia”, >14 considered as “with moderate-to-severe insomnia” (**Table 2**).

Table 2. Characteristics of users depending on their sleep complaints

Characteristics	ISI ≤ 14 (individuals with subclinical insomnia) (N = 801)	ISI >14 (individuals with moderate to severe insomnia) (N = 773)	Group comparison	P values
Age (M(SD))	44.1 (14.3)	42.0 (13.1)	t (1576) = -3.03	P=.002
[18-30] years old (%)	20.7	22.3		
[31-50] years old (%)	46.3	50.6		
[51-65] years old (%)	24.2	22.3		
> 65 years old (%)	8.7	4.9		
Gender (% females)	60.5	73.9	$\chi^2 (1) = 31.91$	P<.001
Educational level:				P=.007
Middle school (%):	18.6	21.7	$\chi^2 (2) = 12.14$	
High school (%):	17.5	22.0		
University degree (%):	63.9	56.2		
Healthcare professionals (%)	6.6	4.7	$\chi^2 (1) = 2.75$	P=.097
Confined due to COVID-19 lockdown (%)	73.0	79.4	$\chi^2 (1) = 8.86$	P=.003
ISI score (M (SD)):	10.02 (3.42)	18.2 (2.74)	t (1572) = 52.12	P<.001
No clinically sig. insomnia (ISI ≤ 7) (%)	22.5	0		
Subthreshold insomnia (ISI [8-14]) (%)	77.5	0		
Clinical insomnia - moderate (ISI [15-21]) (%)	0	86.9		
Clinical insomnia - severe (ISI ≥21) (%)	0	13.1		
CDS-5 (M(SD))	4.53 (6.93)	6.45 (8.30)	t (734) = 3.41;	P=.001
Daily amount of cigarettes (M(SD))	3.09 (6.40)	5.33 (8.68)	t (734) = -4.03;	P<.001
CAGE (M(SD))	0.65 (0.97)	0.78 (1.12)	t (734) = 1.66	P=.097
Daily amount of drinks (M(SD))	1.34 (2.09)	1.66 (3.18)	t (734) = -1.62	P=.105

Participants with moderate-to-severe insomnia were younger ($t (1576) = -3.03$; $P=.002$), more educated ($\chi^2 (2) = 12.14$; $P=.007$), and more likely to be female ($\chi^2 (1) = 31.91$; $P<.001$) compared to those “with subclinical insomnia”. Interestingly, more users who reported being in confinement were found in the “moderate-to-severe insomnia” group ($\chi^2 (1) = 8.86$; $P=.003$) but we did not find evidence of a higher prevalence of insomnia in healthcare professionals. Users with moderate-to-severe insomnia smoked more cigarettes ($t (734) = -4.03$; $P<.001$) and obtained a higher score on the screening questionnaire for addiction to cigarettes ($t (734) = 3.41$; $P=.001$) compared to those in the other group.

Trust and acceptance of virtual agent

431 users answered the acceptance and trust questionnaires (**Figure 4**). 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 virtual agent more than 3 out of 5 for satisfaction. Regarding trust (ETQ score), Louise was perceived as trustworthy to perform medical 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

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).

We found a negative correlation between age and credibility sub-score on the ETQ ($r = -.102$; $P=.034$) suggesting that older individuals found Louise less credible than the younger ones. Age was not correlated with other dimensions of trust and acceptance. Similarly, gender and educational level of the users was not correlated with their attitude towards Louise. Regarding insomnia severity, there was a positive relationship between the severity and credibility of Louise ($r = .125$; $P=.009$) 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 ($r = .109$; $P=.024$), more satisfactory ($r = .128$; $P=.008$) and more benevolent ($r = .117$; $P=.015$).

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

Among the 166 users who completed the first step of the intervention (i.e., fill a sleep diary for one week and answer the ISI for the second time), the total ISI score (**Figure 5**) decreased compared to baseline ($t(165) = 7.88$; $P<.001$) with 36.7% of users obtaining an ISI below a clinically significant level (i.e., ≤ 14), either corresponding to “no insomnia” (4.8%) or to “subthreshold insomnia” (31.9%). For the 47 users who completed the step 2 of the 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

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

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, among the $N = 166$ users who completed the step 1 (i.e., filling in the sleep diary). Mean analyses (see **Table 3**) suggest a reduction in TIB, SOL, and TWAK, and an increased sleep efficiency among this subgroup.

Table 3. Nocturnal sleep indicators of users completing step 1 ($N = 166$)

	M(SD)	t-test	P value
--	-------	--------	---------

Time in bed (hh:mm:ss)	First two nights (1 & 2)	08:56:45 (01:34:22)	t(165) = 2.17	P=.032
	Last two nights (6 & 7)	08:40:27 (01:29:27)		
Total Sleep Time (hh:mm:ss)	First two nights (1 & 2)	06:04:32 (01:56:47)	t (165) = -1.88	P=.061
	Last two nights (6 & 7)	06:21:30 (01:37:33)		
Sleep efficiency (%)	First two nights (1 & 2)	67.60 (20.25)	t(165) = -4.25	P< .001
	Last two nights (6 & 7)	73.82 (17.33)		
Sleep onset latency (hh:mm:ss)	First two nights (1 & 2)	01:31:38 (02:39:11)	t(165) = 2.78	P=.006
	Last two nights (6 & 7)	00:58:37 (01:26.00)		
Number of nocturnal awakenings	First two nights (1 & 2)	1.89 (1.57)	t(165) = 1.81	P= .072
	Last two nights (6 & 7)	1.67 (1.32)		
Wake after initial sleep onset (hh:mm:ss)	First two nights (1 & 2)	00:48:57 (00:55:48)	t(165) = 1.27	P=.207
	Last two nights (6 & 7)	00:42:01 (00:52:58)		
Terminal wakefulness (hh:mm:ss)	First two nights (1 & 2)	00:58:11 (01:09:42)	t (165) = 3.31	P=.001
	Last two nights (6 & 7)	00:39:43 (0:39:57)		

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 4**) that WASO, NWAK, and TWAK decreased after step 2, while TIB, TST, SE increased.

Table 4. Nocturnal sleep indicators of users completing step 2 (N = 47)

	M(SD)	t-test	P value
Seven nights before	07:56:45 (01:18:51)	t (46)= -5.35	P<.001

Time in bed (hh:mm:ss)	Seven nights after	08:37:45 (00:50:21)		
	Seven nights before	06:00:05 (01:24:29)	$t(46) = -2.02$	$P = .047$
Total Sleep Time (hh:mm:ss)	Seven nights after	06:13:26 (01:30:16)		
	Seven nights before	68.47 (14.75)	$t(46) = -3.18$	$P = .002$
Sleep efficiency (%)	Seven nights after	72.36 (16.76)		
	Seven nights before	00:59:22 (00:53:41)	$t(46) = -1.01$	$P = .317$
Sleep onset latency (hh:mm:ss)	Seven nights after	01:08:50 (01:25:02)		
Number of nocturnal awakenings	Seven nights before	1.77 (1.24)	$t(46) = 5.24;$	$P < .001$
	Seven nights after	1.35 (0.97)		
Wake after initial sleep onset (hh:mm:ss)	Seven nights before	00:55:26 (00:52:03)	$t(46) = 3.57;$	$P = .001$
	Seven nights after	00:35:58 (00:32:57)		
Terminal wakefulness (hh:mm:ss)	Seven nights before	00:51:59 (00:42:15)	$t(46) = 3.04;$	$P = .003$
	Seven nights after	00:41:17 (00:32:22)		

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 assistance to the subjects through behavioral interventions. E-health is growing very quickly and numeric solutions are particularly adapted to conditions such as confinement where human contacts must be limited. Several mobile applications used text-based chat-bots for medical interviews but virtual agents (interacting through natural body motion and natural voice) are still sparse, and we believe that these new empathic Human-Machine Interfaces can reinforce acceptance of E-health solutions. 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.[29] This confirms the potential of digital technologies to provide access to clinical screener and behavioral intervention for insomnia for the general population.[30] Out of 2,069 subjects who downloaded KANOPEE, 1,574 (76%) used it to self-evaluate their sleep. We noted that users who decided not to answer the screening interview for sleep were older and more likely to be male. This result might reflect more specific populations to target like young women, a group well known to report high levels of sleep complaints[31]. While the stress related to confinement could explain why we obtained such a high download rate, another potential explanation is the attractiveness of virtual agents to engage in digital interactions. Even individuals without significant sleep complaints (about 50% of the sample) used our app and were interested in completing a sleep evaluation, this is a very positive signal to develop apps for normal sleepers who want to improve their sleep hygiene. It should be interpreted as a positive signal for future sleep health 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.[18] 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. This is also a positive message to reinforce usage of virtual agents in E-health technologies, a growing field of interest for medicine.

Regarding the intervention program, 21.5% of the patients reporting significant sleep complaints ($ISI > 14$) accepted to fill out a daily sleep diary for more than seven days and to answer the Interview 2 (i.e., completed step 1); and 28.3% of these followed behavioral interventions and completed the sleep diary for 10 more days. 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.[32]

Nevertheless, this study suffers from limitations. First, the very peculiar period of recruitment, during the COVID-19 confinement, which makes our results preliminary. Future work needs to confirm in a more “normal period of time” the fact that KANOPEE can help the subjects improve their insomnia complaints and their sleep hygiene.

Second is a quite big drop-out rate. We do not have a proper idea why users did not follow the program until the end, and further study is therefore needed for a precise examination of usage (e.g., frequency of use, errors made) and qualitative interviews with users to unveil the reasons why users decided to drop-out of KANOPEE.

Another limitation is related to the fact that we could not improve the most severe patients, which shows the limits of non-human interventions. Because we did not explore all the possible comorbidities we might have proposed to some subjects a solution unsuitable to their health problems. Future studies could use detailed interviews that could help select precisely the ideal population to receive the interventions and address the others subjects directly to sleep centers.

Considering the above limitations, we believe that KANOPEE is a new promising tool in the field of E-health that could limit the number of subjects asking for consultations to general practitioners for moderate sleep complaints. Indeed, we believe it can help both by identifying individuals with insomnia complaints and by providing brief and practical behavioral interventions. Further research is needed to test this app apart from the COVID-19 confinement and on more selected subjects.

Acknowledgments

We thank Yannick Levavasseur and Emeric Labbé for developing the app. This project was supported by the grants LABEX BRAIN (ANR-10-LABX-43), EQUIPEX PHENOVIRT (ANR-10-EQPX-12-01) and funding from the Region Nouvelle-Aquitaine (IS-OSA project, N° of contract: 18000389).

Conflict of interest

Authors declare no competing interest.

Appendix

Table 1: Personalized sleep recommendations and conditions for personalization

Personalized sleep recommendations	
<ol style="list-style-type: none"> 1. Try to get up at the same time every day, even during the week-end, to train your biological clock. 2. Stay in bed for reasonable time in order to reinforce association bed-sleep: if you don't sleep, get up! 2bis. If you are awake for more than 15min, get up; and get back to bed only when you feel sleepy. 3. In the morning expose yourself to sunlight or to other source of bright light (luminotherapy, screen) to improve functioning of your biological clock. 4. Physical activity will help to stabilize your biological clock. Ideally, do some sport 1h in the morning, and do not exercise 3 to 4 hours before going to bed. 5. Try to not change your sleep schedule, and do not stay in bed even if you experienced a bad night. 6. Moderate your consumption of stimulating beverages (coffee, sodas, energizer drinks): no more than 4 cups a day, and not after 2pm. 7. Go to bed only when you feel sleepy. Try not to read or eat in bed 8. In the evening, do not skip your meal, but avoid fat-rich dishes and favor starch foods, which help not feeling hungry at night. 9. Do not use your electronic devices (smartphone, TV, tablet) 1 to 2 hours before going to bed. 10. Accommodate your bedroom in conditions conducive to sleep: dark, quiet, and room temperature from 18°C to 20°C. 11. Be careful! You might be experiencing sleep deprivation, try to sleep at least 7h per night. 12. Before going to bed, try exercising abdominal breathing. 	
Conditions for personalization	
If item 1 of ISI (falling asleep) = severe or very severe	Give recommendations 2, 3, 7, 12
If item 2 of ISI (staying asleep) = severe or very severe, or if duration of nocturnal awakening ≥ 15 min	Give recommendations 2bis, 4, 5, 6, 10
If SE > 85% and TST > 7h	Give recommendations 1, 3, 4, 5
If SE > 85% and TST < 6h and ISI total score > 21	Give recommendation 11
Else	Give recommendations 1, 2, 3, 4, 6, 8, 9, 10

References

1. World Health Organization. Responding to community spread of COVID-19: interim guidance. 2020; .
2. Brooks SK, Webster RK, Smith LE, Woodland L, Wessely S, Greenberg N, Rubin GJ. The psychological impact of quarantine and how to reduce it: rapid review of the evidence. *The Lancet* 2020; 395:912–920.
3. Morin CM, Carrier J. The acute effects of the COVID-19 pandemic on insomnia and psychological symptoms. *Sleep Med* 2020; .
4. Voitsidis P, Gliatas I, Bairachtari V, Papadopoulou K, Papageorgiou G, Parlapani E, Syngelakis M, Holeva V, Diakogiannis I. Insomnia during the COVID-19 pandemic in a Greek population. *Psychiatry Res* 2020; 289:113076.
5. Stanton R, To QG, Khaledi S, Williams SL, Alley SJ, Thwaite TL, Fenning AS, Vandelanotte C. Depression, Anxiety and Stress during COVID-19: Associations with Changes in Physical Activity, Sleep, Tobacco and Alcohol Use in Australian Adults. *Int J Environ Res Public Health* 2020; 17:.
6. Fagherazzi G, Goetzinger C, Rashid MA, Aguayo GA, Huiart L. Digital Health Strategies to Fight COVID-19 Worldwide: Challenges, Recommendations, and a Call for Papers. *J Med Internet Res* 2020; 22:e19284.
7. Inkster B, O'Brien R, Selby E, Joshi S, Subramanian V, Kadaba M, Schroeder K, Godson S, Comley K, Volmer S, Mateen B. Digital health management during and beyond the COVID-19 pandemic: Opportunities, barriers, and recommendations (Preprint). 2020; .
8. Sarbadhikari S, Sarbadhikari SN. The global experience of digital health interventions in COVID-19 management. *Indian J Public Health* 2020; 64:117.
9. Geoffroy PA, Le Goanvic V, Sabbagh O, Richoux C, Weinstein A, Dufayet G, Lejoyeux M. Psychological Support System for Hospital Workers During the Covid-19 Outbreak: Rapid Design and Implementation

- of the Covid-Psy Hotline. *Front Psychiatry* 2020; 11:.
10. Taylor CB, Fitzsimmons-Craft EE, Graham AK. Digital technology can revolutionize mental health services delivery: The COVID-19 crisis as a catalyst for change. *Int J Eat Disord* 2020; 53:1155–1157.
 11. <https://www.wysa.io/>. Wysa - Your Safe Space This Difficult Time 2020; .
 12. Ritterband LM, Thorndike FP, Gonder-Frederick LA, Magee JC, Bailey ET, Saylor DK, Morin CM. Efficacy of an Internet-Based Behavioral Intervention for Adults With Insomnia. *Arch Gen Psychiatry* 2009; 66:692–698.
 13. Espie CA, Kyle SD, Williams C, Ong JC, Douglas NJ, Hames P, Brown JSL. A Randomized, Placebo-Controlled Trial of Online Cognitive Behavioral Therapy for Chronic Insomnia Disorder Delivered via an Automated Media-Rich Web Application. *Sleep* 2012; 35:769–781.
 14. Zachariae R, Lyby MS, Ritterband LM, O'Toole MS. Efficacy of internet-delivered cognitive-behavioral therapy for insomnia – A systematic review and meta-analysis of randomized controlled trials. *Sleep Med Rev* 2016; 30:1–10.
 15. Philip P, Bioulac S, Sauteraud A, Chaufton C, Olive J. Could a Virtual Human Be Used to Explore Excessive Daytime Sleepiness in Patients? *Presence Teleoperators Virtual Environ* 2014; 23:369–376.
 16. Philip P, Micoulaud-Franchi J-A, Sagaspe P, de Sevin E, Olive J, Bioulac S, Sauteraud A. Virtual human as a new diagnostic tool, a proof of concept study in the field of major depressive disorders. *Sci Rep* 2017; 7:42656.
 17. Auriacombe M, Moriceau S, Serre F, Denis C, Micoulaud-Franchi J-A, de Sevin E, Bonhomme E, Bioulac S, Fatseas M, Philip P. Development and validation of a virtual agent to screen tobacco and alcohol use disorders. *Drug Alcohol Depend* 2018; 193:1–6.
 18. Philip P, Dupuy L, Auriacombe M, Serre F, de Sevin E, Sauteraud A, Micoulaud-Franchi J-A. Trust and acceptance of a virtual psychiatric interview between embodied conversational agents and outpatients.

Npj Digit Med 2020; 3:1–7.

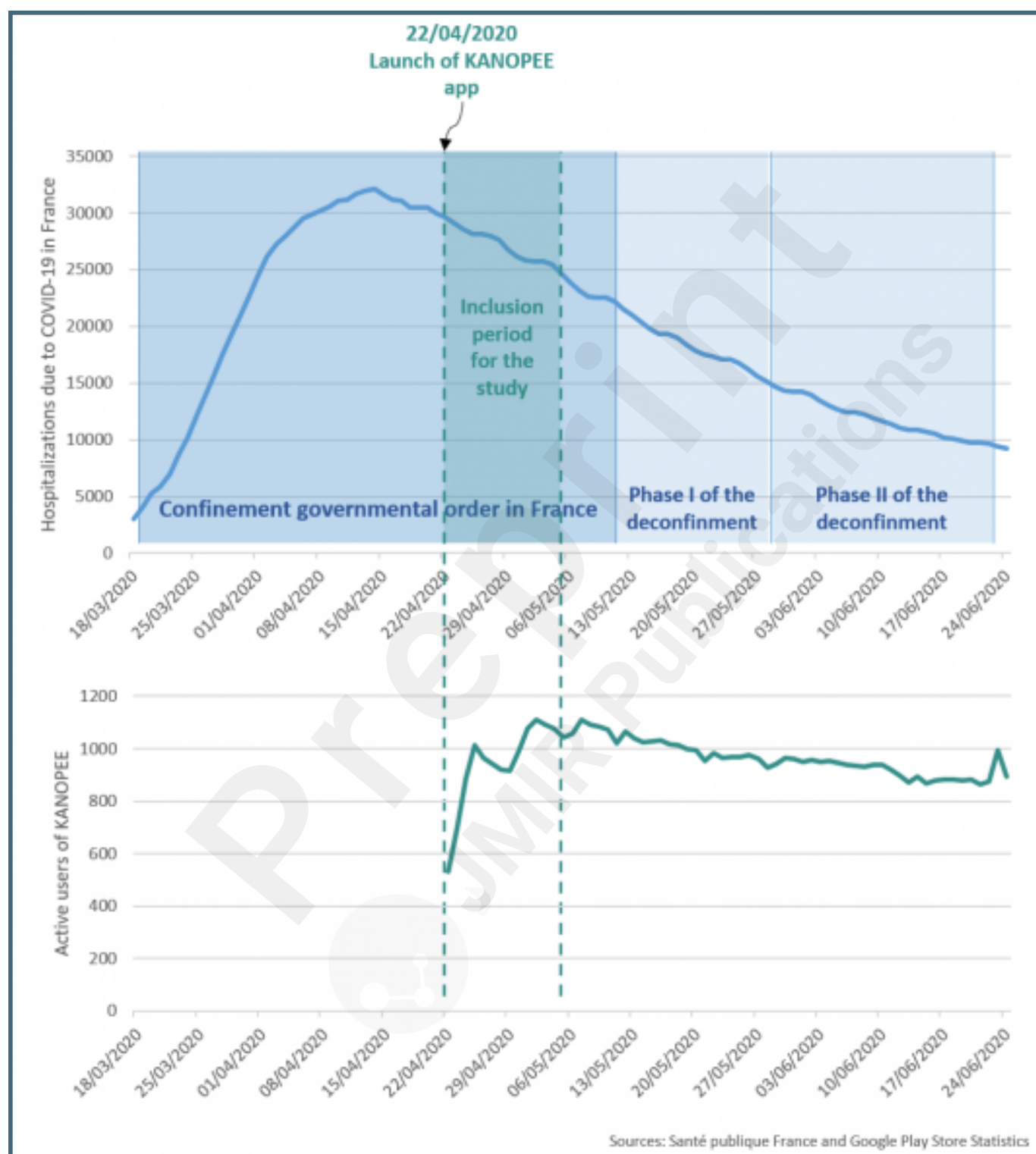
19. Dupuy L, Micoulaud-Franchi J-A, Philip P. Acceptance of virtual agents in a homecare context: Evaluation of excessive daytime sleepiness in apneic patients during interventions by continuous positive airway pressure (CPAP) providers. *J Sleep Res* 2020; e13094:.
20. Bastien CH, Vallières A, Morin CM. Validation of the Insomnia Severity Index as an outcome measure for insomnia research. *Sleep Med* 2001; 2:297–307.
21. Morin CM, Belleville G, Bédard L, Ivers H. The Insomnia Severity Index: psychometric indicators to detect insomnia cases and evaluate treatment response. *Sleep* 2011; 34:601–608.
22. SANPSY L. <https://www.youtube.com/watch?v=y3QfgNvQfr0&feature=youtu.be>. 2020; .
23. Morin CM. *Insomnia: Psychological assessment and management*. New York, NY, US: Guilford Press; 1993.
24. Buysse DJ, Ancoli-Israel S, Edinger JD, Lichstein KL, Morin CM. Recommendations for a Standard Research Assessment of Insomnia. *Sleep* 2006; 29:1155–1173.
25. Ewing JA. Detecting Alcoholism: The CAGE Questionnaire. *JAMA* 1984; 252:1905–1907.
26. Etter J-F, Houezec JL, Perneger TV. A Self-Administered Questionnaire to Measure Dependence on Cigarettes: The Cigarette Dependence Scale. *Neuropsychopharmacology* 2003; 28:359.
27. Micoulaud-Franchi J-A, Sauteraud A, Olive J, Sagaspe P, Bioulac S, Philip P. Validation of the French version of the Acceptability E-scale (AES) for mental E-health systems. *Psychiatry Res* 2016; 237:196–200.
28. Tariman JD, Berry DL, Halpenny B, Wolpin S, Schepp K. Validation and testing of the Acceptability E-scale for Web-based patient-reported outcomes in cancer care. *Appl Nurs Res* 2011; 24:53–58.
29. Espie CA, Emsley R, Kyle SD, Gordon C, Drake CL, Siriwardena AN, Cape J, Ong JC, Sheaves B,

- Foster R, Freeman D, Costa-Font J, Marsden A, Luik AI. Effect of Digital Cognitive Behavioral Therapy for Insomnia on Health, Psychological Well-being, and Sleep-Related Quality of Life: A Randomized Clinical Trial. *JAMA Psychiatry* 2019; 76:21–30.
30. Insel TR. Digital Phenotyping: Technology for a New Science of Behavior. *JAMA* 2017; 318:1215–1216.
31. Zhang B, Wing Y-K. Sex differences in insomnia: a meta-analysis. *Sleep* 2006; 29:85–93.
32. Berry SM, Connor JT, Lewis RJ. The Platform Trial: An Efficient Strategy for Evaluating Multiple Treatments. *JAMA* 2015; 313:1619–1620.

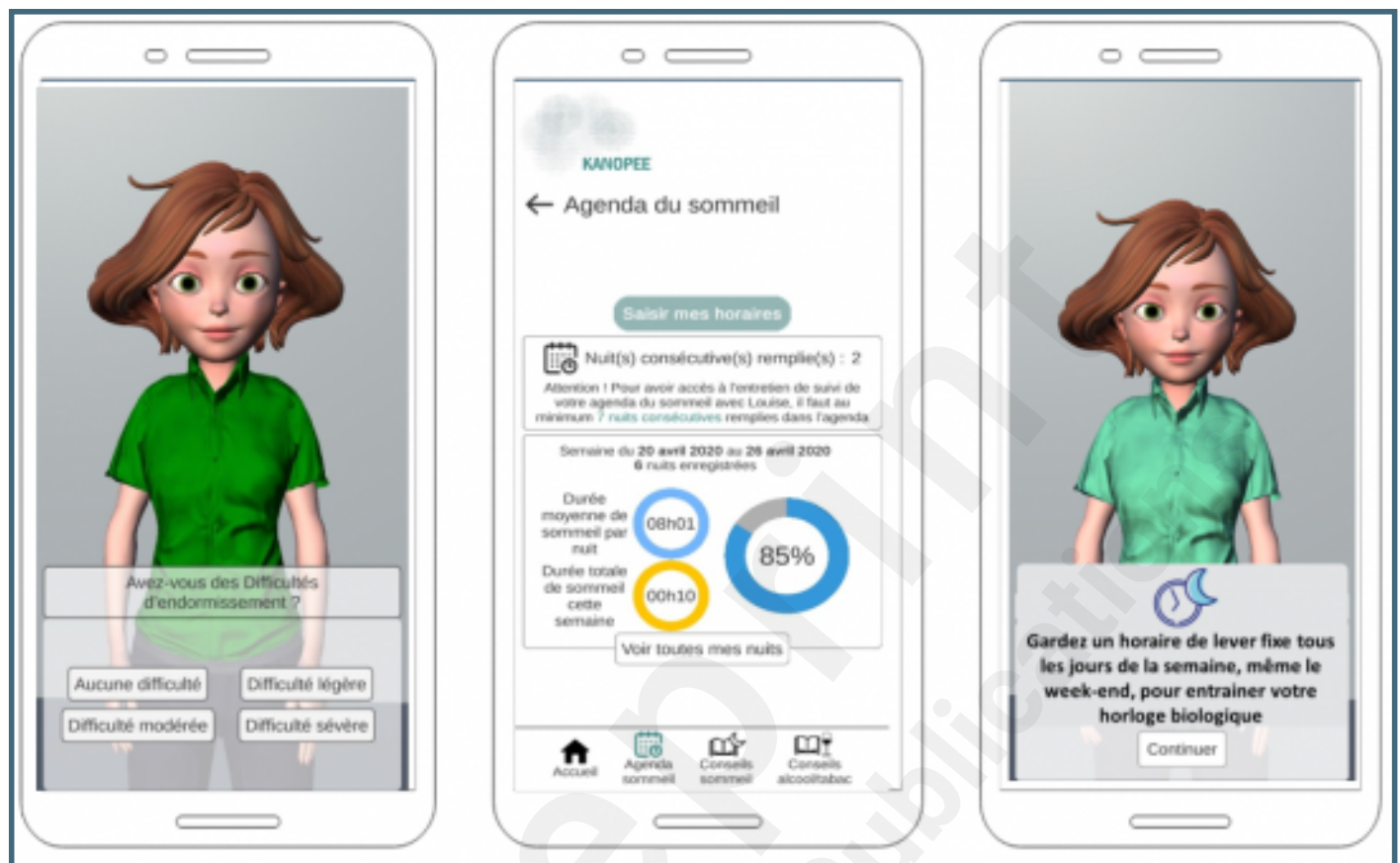
Supplementary Files

Figures

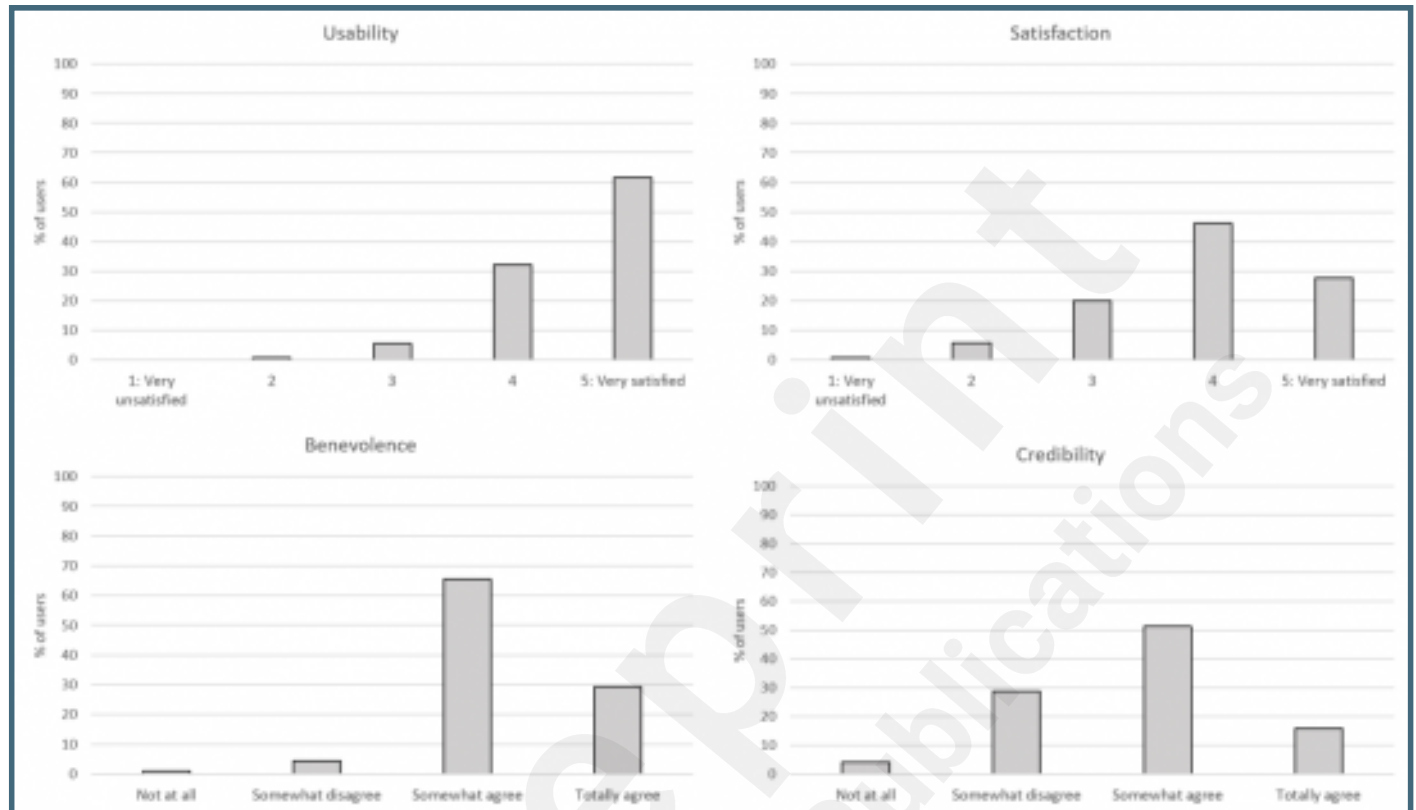
Context of the conception and use of KANOPEE: chronological evolution of hospitalizations due to COVID-19 in France, confinement strategies ordered by the French government, number of active users, and inclusion period for this study.



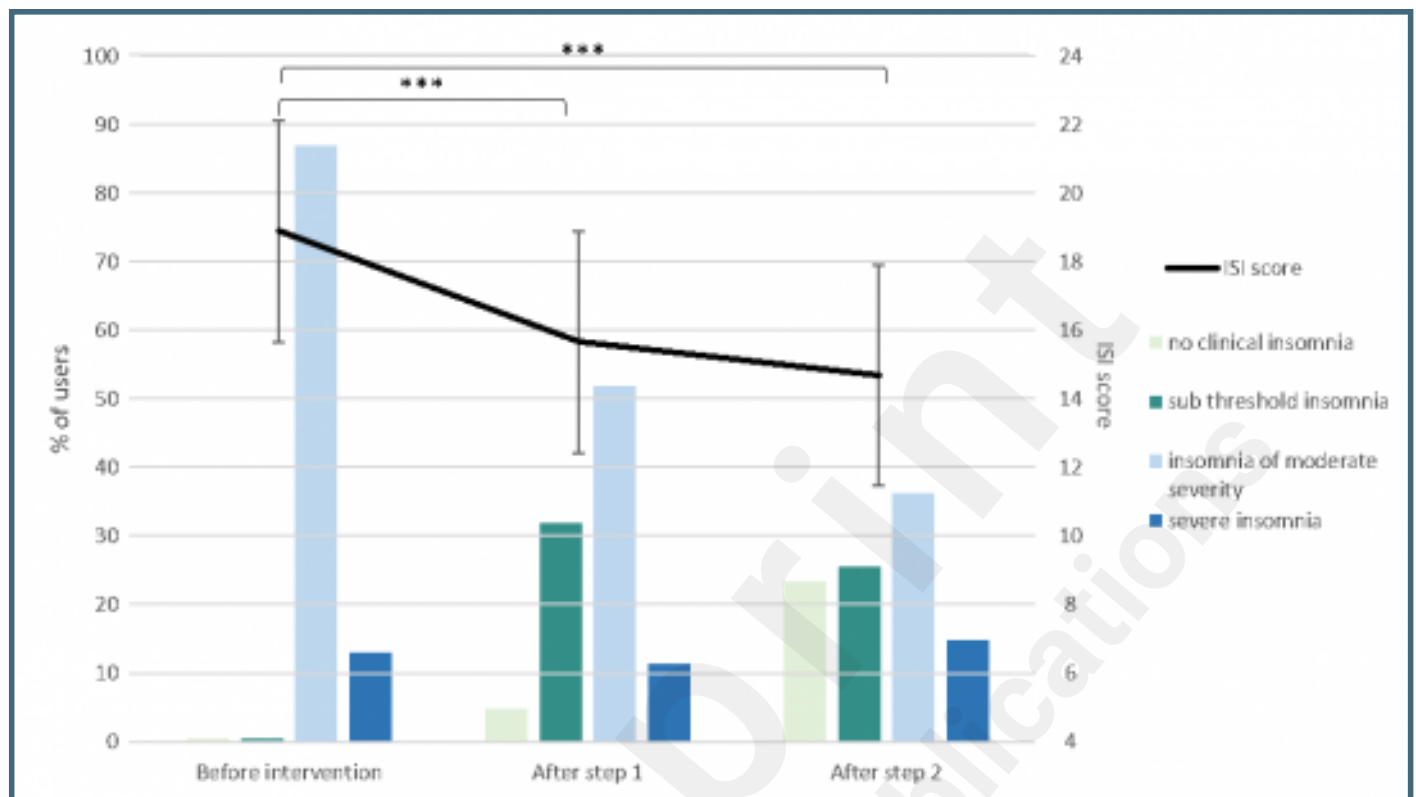
Examples of interfaces of KANOPEE. From left to right: 1. Screenshot of Louise questioning the Insomnia Severity Index. 2. Screenshot of the sleep diary and the visual feedbacks regarding sleep. 3. Screenshot of a personalized sleep recommendation given by Louise during Interview 3.



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).



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.



Flowchart of users included in the different steps of analyses.

