Delivering digital cognitive behavioral therapy for insomnia at scale: does using a wearable device to estimate sleep influence therapy?

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INTRODUCTION

Cognitive Behavioral Therapy (CBT) received renewed attention when it was recommended recently as the treatment of choice for insomnia by the American College of Physicians. The publication of these guidelines, however, also attracted comments in relation to a number of substantial implementation challenges, such as the scalability of the treatment. Part of the solution to the challenge of disseminating CBT more widely could be the introduction of digital CBT (dCBT) where CBT is provided by digital means, such as a mobile application or computer. A number of such programs has been developed in the last decade (for example), and a recent meta-analysis concluded that the effects of dCBT are in the range of the effect sizes for face-to-face CBT. Direct comparisons suggest that face-to-face CBT is superior to dCBT, however, there was no difference between group CBT and dCBT in a small trial.

In addition to the emergence of digital therapy, the ubiquitous nature of commercially available wearable devices brings fresh challenges and opportunities. Evidence on how well these wearables estimate sleep in healthy persons is mixed. Furthermore, the validity of wearable devices in insomnia is largely unknown; although certain accelerometers may estimate sleep quite reliably, suggesting they might be a useful tool for treatment. For decades, sleep has been assessed with a daily paper-and-pen sleep diary (e.g.) and the consensus diary is now recommended as a valid tool in those suffering from insomnia. This “traditional” approach, however, can be burdensome for many patients and can result in levels of missing or, at best, estimated data. Perhaps, wearable devices offer a user-friendly way to track sleep as part of insomnia treatment. A program used in this evaluation, can integrate wearable data, there may be potential to tailor the dCBT treatment to the patient’s sleep. However, it is not known if or how the use of a wearable estimating sleep during dCBT affects therapy outcomes. As insomnia is based on subjective criteria it might be that the self-assessment of sleep in a sleep diary is integral to the treatment, and that wearing a device potentially takes away this self-assessing component. On the other hand, measuring sleep data objectively might force reflection on the objective components of sleep and not only subjectively experienced sleep.

First, we assessed the effectiveness of a dCBT for insomnia in a real-world sample of persons who completed Sleepio, a program which has been found to be effective in formal RCTs in improving insomnia. We expected to confirm that dCBT can successfully improve insomnia and related well-being constructs in an evaluation of an ongoing service, similar to the previous evidence from RCTs. However, our main research aims were to (1) assess what characterizes those users who connected a wearable device to the program to estimate sleep diary variables, (2) assess whether connecting a wearable device affected insomnia
symptom improvement and improvement on related well-being factors, and (3) assess whether connecting a wearable device affected the interaction with the program compared to those who did not connect a wearable device. In an effort to identify the effect of using a device in the optimized treatment situation, we only focus upon those who completed treatment, to ensure that participants had actually utilized their sleep diary data on a regular basis, including throughout the core component of CBT for insomnia, sleep restriction, which extends from session three through to the final session six. The essential difference of interest, therefore, was between those whose diary was self-completed throughout (the default state of the Sleepio program) and those who connected a device to automatically fill the diary throughout. Reporting upon completers also provides us with the best comparison between these sub-groups because the program routinely incorporates a post-test after the sixth session. We expected improvement on insomnia symptoms and well-being irrespective of connecting a device. As there is limited to no evidence on the use of wearable devices in behavior change programs, we did not specify a direction of possible differences in treatment effect between those connecting a device to the dCBT program to estimate diaries and subjectively completing diaries.

RESULTS

Descriptives

Of a total of 3551 dCBT completers in this report, 378 users connected a wearable device to the program (10.6%). A similar number of people connected a Fitbit® (N = 183) or a Jawbone UP™ (n = 195). The full sample comprised more women (63%), had a mean age of 44.5 years, 70% of users were employed full-time and 6.8% of the sample reported to be a shift worker. About 35% perceived themselves as overweight, 52% used alcohol for more than once a week and 73% reported the use of caffeine at least once a day. Only 11% reported as smokers while a large majority exercised for 30 min at least once per week. Persons who connected a device to the program did not differ from those who did not connect a device (see Table 1), except for the amount of

Table 1. Demographics and baseline lifestyle descriptives for the full sample, users who have not connected a device and who have connected a device

|                     | All users (n = 3551) | No device users (n = 3173) | Device users (n = 378) | Test-statistic | p     |
|---------------------|----------------------|-----------------------------|------------------------|----------------|-------|
| Female (yes)        | 2233 (62.9%)         | 2010 (63.3%)                | 223 (59.0%)            | χ²(1) = 2.835  | 0.092 |
| Age (years)         | 44.50 ± 14.78        | 44.47 ± 14.93               | 44.71 ± 13.56          | F(1) = 0.089   | 0.766 |
| Employed (yes)      | 2496 (70.3%)         | 2221 (70.0%)                | 275 (72.8%)            | χ²(1) = 2.314  | 0.128 |
| Shift worker (yes)  | 243 (6.8%)           | 219 (6.9%)                  | 24 (6.3%)              | χ²(1) = 0.002  | 0.963 |
| Self-rated overweight (yes) | 1245 (35.1%) | 1104 (34.8%) | 141 (37.3%) | χ²(1) = 1.612 | 0.204 |
| Alcohol usea        |                      |                             |                        | χ²(4) = 5.001  | 0.287 |
| Never               | 616 (17.4%)          | 549 (17.3%)                 | 67 (17.7%)             |                |       |
| Less than once a week | 1085 (30.6%)      | 985 (31.1%)                 | 100 (26.5%)            |                |       |
| Once a week         | 616 (17.4%)          | 553 (17.4%)                 | 63 (16.7%)             |                |       |
| 2–3 times a week    | 799 (22.5%)          | 705 (22.2%)                 | 94 (24.9%)             |                |       |
| >4 times a week     | 434 (12.2%)          | 380 (12.0%)                 | 54 (14.3%)             |                |       |
| Caffeine usea       |                      |                             |                        | χ²(4) = 5.345  | 0.254 |
| Never               | 379 (10.7%)          | 343 (10.8%)                 | 36 (9.5%)              |                |       |
| Less than once a day| 585 (16.5%)          | 533 (16.8%)                 | 52 (13.8%)             |                |       |
| Once a day          | 1056 (29.7%)         | 941 (29.7%)                 | 115 (30.4%)            |                |       |
| 2–3 times a day     | 1200 (33.8%)         | 1056 (33.3%)                | 144 (38.1%)            |                |       |
| >4 times a day      | 330 (9.3%)           | 299 (9.4%)                  | 31 (8.2%)              |                |       |
| Tobacco useb        |                      |                             |                        | χ²(4) = 2.433  | 0.657 |
| Never smoked        | 3162 (89.1%)         | 2831 (89.2%)                | 331 (87.6%)            |                |       |
| Rarely              | 239 (6.7%)           | 213 (6.7%)                  | 26 (6.9%)              |                |       |
| 1–10 times a day    | 107 (3.0%)           | 92 (2.9%)                   | 15 (4.0%)              |                |       |
| 10–20 times a day   | 32 (0.9%)            | 28 (0.9%)                   | 4 (1.1%)               |                |       |
| >21 times a day     | 10 (0.3%)            | 8 (0.3%)                    | 2 (0.5%)               |                |       |
| Exercising > 30 minb |                      |                             |                        | χ²(4) = 11.676 | 0.020 |
| Never               | 178 (5.2%)           | 166 (5.4%)                  | 12 (3.3%)              |                |       |
| Less than once a week | 452 (13.1%)      | 407 (13.2%)                 | 45 (12.2%)             |                |       |
| Once a week         | 591 (17.1%)          | 530 (17.2%)                 | 61 (16.6%)             |                |       |
| 2–3 times a week    | 1227 (35.5%)         | 1110 (36.0%)                | 117 (31.8%)            |                |       |
| >4 times a week     | 1007 (29.1%)         | 874 (28.3%)                 | 133 (36.1%)            |                |       |
| Sleep medication (yes) | 813 (22.9%) | 712 (22.6%) | 101 (27.5%) | χ²(1) = 4.472 | 0.034 |

SD Standard deviation
a Missing n = 1
b Missing n = 46
exercising and use of prescribed sleep medication. Those who connected a device were more likely to exercise more $\chi^2 (4) = 11.676, p = 0.0201$ and use medication than those who did not connect a device ($\chi^2 (1) = 4.47, p = 0.034$).

Treatment outcomes

First, we assessed the effects of dCBT in the full sample (see Table 2), the post treatment test was completed with a median of 42 days (InterQuartile Range (IQR): 37–54) after the start of session 1. The median of completed diaries during this period was 41 (IQR: 36–49). Overall sleep quality on the SCI significantly improved after dCBT for insomnia ($\chi^2(3504) = 83.33, p < 0.001$; Cohen’s $d = 1.45$ [95% CI 1.41–1.50]). Results stratified for the use of prescribed sleep medication can be found in supplementary table 1, suggesting that the change in SCI is larger for those who use medication than those who do not.

Significant reductions in depressive symptoms ($Z = -26.81, p < 0.001$), symptoms of anxiety ($Z = -29.51, p < 0.001$), perceived stress ($Z = -28.69, p < 0.001$), life dissatisfaction ($Z = -19.16, p < 0.001$) and less poor work productivity ($Z = -25.42, p < 0.001$) were observed following dCBT (see Table 2). These results remained similar after the exclusion of shift workers.

The results in Table 3 demonstrate that users with no connected device had a significantly better sleep and less sleep affected work productivity than device users both at baseline (respectively F(1,3532) = 12.94, p < 0.001 and $U = 233095, p < 0.001$) and at post-therapy (respectively, F(1,3521) = 11.84, p < 0.001 and $U = 489106, p < 0.001$). In addition, those who did not connect a device had less depressive symptoms at post-therapy than those who connected a device ($U = 553788, p < 0.001$). Similar to the entire user group, therapy effects were significant for all variables for both those who connected a device and those who did not connect a device (all $p < 0.001$, see supplementary table 2). Further analyses of change scores, i.e. post-treatment scores minus baseline scores, demonstrated that the therapy effect did not differ for change in insomnia between those who connected a device and those who did not. Of the well-being outcomes only the change in work productivity differed between those who connected a device and those who did not, where the decrease was slightly smaller in those who connected a device ($U = 256138, p = 0.0090$). Stratification for medication demonstrated that the difference in work productivity between those who used a device and those who did not was only significant for those who did not use medication ($U = 144305, p = 0.008$).

Program interaction

Interaction with the online program was evaluated by assessing several metrics collected within the program. Users with a device were more likely to view the library (difference: 9.4%, $\chi^2(1) = 16.61, p < 0.001$) and more likely to post in the community (difference 5.5%, $\chi^2(1) = 9.41, p = 0.002$). Although we did not see a difference in the percentage of people who viewed the community ($\chi^2(1) < 0.001, p = 0.983$), we did see that people with a device were viewing the community more often (median difference: $3, U = 538614, p = 0.001$). No difference in number of diaries completed was found.

DISCUSSION

This evaluation suggests that, within a sample of persons who complete dCBT, persons who choose to wear a device to estimate their sleep reported more severe insomnia complaints, more use of sleep medication and more affected work productivity than persons who manually complete sleep diaries users of devices. They did not differ majorly with regards to demographics and lifestyle, although users who connected a device were more likely to exercise more often. Both groups had similar improvements in insomnia and associated well-being, although those who connected a device tended to interact with the program more. In addition, the results lend support to the validity of controlled trial published estimates of how many people own a device.28,29

However, usage of wearable devices is shown to drop by one-third after 6 months of buying a wearable device, and to half after 18 months of buying.30 In addition, not everyone might want to connect their device to the program. Although possible, it seems unlikely that people have specifically bought a wearable device for the dCBT program. This could be due to many reasons such as price, comfort, esthetics or other factors, not necessarily related to the preference of completing diaries online or via a device within a dCBT program. Users that connected a device had poorer sleep at the start of the program and, possibly associated with this, a higher use of sleep medication and reports of poorer work productivity due to sleep. Perhaps observing your device-generated data influences your perspective on your sleep and the need to pursue a sleep intervention. Alternatively, those with more severe sleep problems or more severe daytime effects

Table 2. Sleep, depression, anxiety, perceived stress, overall health, life satisfaction and productivity at baseline and post-treatment for all users (n = 3551)

|                           | Baseline | Post-treatment |
|---------------------------|----------|----------------|
|                           | N        | Mean ± SD/ median (IQR) | N    | Mean ± SD/ median (IQR) | Test-statistic | p |
| Sleep (SCI-7)             | 3533     | 4.25 ± 1.94             | 3522 | 7.15 ± 2.04              | r(3504) = 83.33^b | <0.001 |
| Depression (PHQ-2)        | 3495     | 2 (0–3)                 | 3524 | 1 (0–2)                  | Z = -26.81^c  | <0.001 |
| Anxiety (GAD-2)           | 3495     | 2 (1–3)                 | 3524 | 1 (0–2)                  | Z = -29.51^c  | <0.001 |
| Perceived stress          | 3444     | 2 (1–2)                 | 3524 | 1 (0–2)                  | Z = -28.69^d  | <0.001 |
| Life satisfaction         | 3466     | 7 (5–8)                 | 3523 | 7 (6–8)                  | Z = -19.16^d  | <0.001 |
| Work productivity         | 2460^a   | 2 (1–4)                 | 3444 | 1 (0–3)                  | Z = -25.60^d  | <0.001 |

| SD standard deviation, IQR interquartile range, SCI-7 sleep condition indicator 7 items, PHQ-2 Patient Health Questionnaire 2 items, GAD-2 generalize anxiety disorder 2 items |
|--------------------------------|
| a Baseline work productivity is only assessed in those who were employed, n = 2496 |
| b Paired T-test |
| c Wilcoxon signed rank test, Z-value based on negative ranks |
| d Wilcoxon signed rank test, Z-value based on positive ranks |
Table 3

| Variable                  | No device Mean ± SD | Device Mean ± SD | Test-statistic | p     |
|---------------------------|---------------------|------------------|----------------|-------|
| Sleep (SC-7)              | 4.29 ± 0.97         | 4.16 ± 0.95      | 9.71           | <0.001 |
| Anxiety (GAD-2)           | 17.48 ± 2.89        | 17.14 ± 2.85     | 3.66           | 0.061 |
| Depression (PHQ-2)        | 3.91 ± 1.60         | 3.91 ± 1.62      | 1.0            | 0.365 |
| Perceived stress (PSQI)   | 17.7 ± 3.8          | 17.46 ± 3.6      | 3.86           | 0.126 |
| Life satisfaction         | 17.65 ± 4.7         | 17.53 ± 4.7      | 1.77           | 0.187 |
| Work productivity         | 2.68 ± 2.51         | 2.65 ± 2.51      | 0.04           | 0.887 |

Increased interquartile range indicates a higher generalizability and increased statistical power. Evaluation data of the effects given with emphasis on specific categories. 

Possibly, clinicians could also suggest wearable devices to face-to-face treatment, if the patient prefers to use a wearable device to assess their sleep. Users that connected a device within a dCBT program were more motivated to use the full range of tools available due to more severe sleep problems. 

However, when measurement errors are consistent at each time point, they will have a limited impact on change scores, as the current study is not set up to validate measures. We cannot therefore interpret the lack of difference in treatment outcomes. 

Evaluating data at this large scale comes with advantages such as evidence for the validity of commercially available wearable devices may reduce user burden. As we did not use randomization to estimate sleep diaries independently of user preference. In addition, we found significant differences in interaction with those who connected a device to the program, whereas those who did not use a device. However, this evaluation also has several limitations. First, persons who complete treatment but do not show improvement and therefore do not improve. While we have focused on the second category of user journeys. Persons who complete treatment but do not complete the program as expected. One of the main advantages of dCBT is the ability to collect online diaries, which can be integrated to face-to-face treatment methods. These diaries may reduce user burden. As we did not use randomization to assess the impact of automated diary completion. Choice of additional measurement devices to face-to-face treatment might still have a limited impact on change scores, as the current study is not set up to validate measures. We cannot therefore interpret the lack of difference in treatment outcomes. 

Importantly, we also avoid measurement bias by using outcomes connected a device in fl. Importantly, connecting a device to dCBT will not affect treatment efficacy. 

The use of wearables in dCBT for insomnia connected a device in fl. Importantly, connecting a device to dCBT will not affect treatment efficacy.
limitations. First, to be able to ensure our research question we assessed a sample of users that had completed a post-therapy survey, making it likely that the cohort comprised motivated individuals. This can have inflated the overall treatment effects.

In line with our research question, we evaluated existing data on a large scale and hence were not able to have a control group such as in a RCT. Current results align however with those suggested from previous controlled trials. Lastly, users who connected a device to the program might have differed on baseline characteristics that we did not measure, and post-therapy outcomes other than the ones we evaluated may have revealed group differences in treatment outcomes. Use of devices within the program was self-chosen, a future RCT in which the use of wearable devices is randomized might give us more insight in non-self-selected use of wearable devices and treatment effects more extensively.

In conclusion, this evaluation confirms that integration of wearable device data may offer new opportunities for dCBT, and although validation of device generated sleep estimates remains elusive, participants in this sample of dCBT completers achieved outcomes comparable to those who did not use wearable devices. In addition, we found some evidence that they were more likely to utilize the full range of options available within the dCBT program.

METHODS

Participants

This is an evaluation of data collected within an online sleep improvement program (Sleepio™, Big Health Ltd., London, UK). All users consent to the anonymized use of their data when they access the program (www.sleepio.com/privacy and www.sleepio.com/terms). In addition, the program is fully HIPAA and HITRUST compliant. As this manuscript presents an evaluation of an ongoing service no approval of a research ethics committee was obtained. Users can be self-referred, referred by clinicians or have access through an employer’s wellbeing offering. For the present report, we selected a cohort of users who completed the program and a recently introduced post-intervention assessment, in an effort to identify the effect of using a device on full treatment outcomes.

Intervention

Sleepio™ is an online, fully automated, dCBT program for insomnia.5 Users receive six weekly sessions from an animated personal therapist in which core behavioral techniques, such as sleep restriction (i.e. reducing the sleep window to enhance sleep consolidation) and stimulus control (i.e., getting out of bed after 15–20 min of being awake), and cognitive techniques, such as thought re-structuring (i.e. targeting unrealistic thoughts about sleep and the effects of sleeping less) and paradoxical intention (i.e. sleeping less) are randomized might give us more insight in non-self-selected use of wearable devices and treatment effects more extensively.

In conclusion, this evaluation confirms that integration of wearable device data may offer new opportunities for dCBT, and although validation of device generated sleep estimates remains elusive, participants in this sample of dCBT completers achieved outcomes comparable to those who did not use wearable devices. In addition, we found some evidence that they were more likely to utilize the full range of options available within the dCBT program.
Wilcoxon signed rank test. Results were stratified for baseline descriptive variables with a significant difference between users who connected a device and users who did not connect a device. IBM SPSS version 22.0 (IBM Corp., Somers, NY, USA) was used to perform all analyses.

Data availability
Data are available on request due to privacy or other restrictions.

AUTHOR CONTRIBUTIONS
All contributed to study design, data analyses and writing/reviewing the manuscript. PFM contributed to data-analyses and reviewing the manuscript, and CAE contributed to study design, data analyses and writing/reviewing the manuscript. All authors have approved the final version of this manuscript and take accountability for all aspects of the manuscript.

ADDITIONAL INFORMATION
Supplementary information accompanies the paper on the npj Digital Medicine website (https://doi.org/10.1038/s41746-017-0010-4).

Competing interests: The position of AIL at the University of Oxford is funded by Big Health Ltd, the company behind the digital CBT program evaluated for this manuscript. PFM is employed by Big Health Ltd. CAE is the clinical and scientific director of Big Health Ltd and holds shares in Big Health Ltd.

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