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A randomized controlled trial comparing guided internet-based multi-component treatment and internet-based guided sleep restriction treatment to care as usual in insomnia

Tobias Krieger[1±*], Antoine Urech[1,2±], Simone B. Duss[3], Larissa Blättler[1], Wolfgang Schmitt[3], Heidemarie Gast[3], Claudio Bassetti[3+], Thomas Berger[1+]

[1] Institute for Psychology, University of Bern, Bern, Switzerland

[2] Neurorehabilitation Dept. of Neurology, Hospital, and University of Bern, Riggisberg, Switzerland

[3] Sleep-Wake-Epilepsy-Center, Department of Neurology, Inselspital, Bern University Hospital, University Bern, Bern, Switzerland

[±] These authors share first authorship

[+] These authors share senior authorship

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*Address for correspondence

Dr. phil. Tobias Krieger

Department of Clinical Psychology and Psychotherapy

University of Bern

Fabrikstrasse 8

3012 Bern, Switzerland

E-mail: tobias.krieger@psy.unibe.ch

Abstract

Background: Internet-based cognitive behavioral treatment (iCBT-I) for insomnia comprising different sleep-related cognitive and behavioral interventional components has shown some promise. However, it is not known which components are necessary for a good treatment outcome.

Method: People suffering from insomnia (*N* = 104) without any other comorbid psychiatric disorders were randomized (2:2:1) to two guided internet-based self-help interventions for insomnia (multi-component cognitive behavioral self-help intervention [MCT]; sleep restriction intervention for insomnia [SRT]), and care as usual [CAU]. In all three conditions, additional care or treatment was allowed. The primary outcome was insomnia severity measured with the insomnia severity index (ISI) at eight weeks. Furthermore, the two active conditions were compared regarding sleep efficacy from daily diary data over the eight weeks, and other measures from the daily protocols. Secondary outcomes included sleep quality, depressive symptoms, dysfunctional beliefs, and quality of life at post-treatment (eight weeks) and follow-up (six months after randomization).

Results: Both conditions were more effective than CAU at post-treatment, with medium to large between-group effect sizes on the primary outcome (ISI; MCT: Cohen's *d* = -1.15; SRT: *d* = -0.68) and small to medium between-group effect sizes for secondary outcomes. Treatment gains were maintained at 6-month follow-up. Active conditions did not differ from each other on all measures from pre to post, except for dysfunctional beliefs about sleep, and sleep protocol data throughout the intervention. Participants in MCT were significantly more satisfied with the intervention than participants in SRT.

Conclusions: Results of the present study indicate that CAU + MCT and CAU + SRT are both effective compared to CAU. There were no statistical differences regarding efficacy between the two active conditions, but participants in MCT reported to be more satisfied with the intervention.

Keywords: insomnia, online intervention, internet-based intervention, cognitive behavioral treatment, sleep restriction

1. INTRODUCTION

Insomnia is a significant public health problem, with one-third of the adult population reporting symptoms of insomnia, and approximately 10% meeting diagnostic criteria for an insomnia disorder (Ohayon, 2002, Simon and VonKorff, 1997, Morin and Jarrin, 2013). Problems related to sleep, affect daily cognitive performance as well as mood, which in turn affect quality of life as well as work productivity (Walsh, 2004). Insomnia has been proposed to be a contributory causal factor in the occurrence of many mental health disorders (Harvey et al., 2011). As a consequence, insomnia is responsible for high social costs and the economic burden of insomnia is very high, with the largest proportion of all expenses attributable to insomnia-related work absences and reduced productivity (Daley et al., 2009).

Cognitive-behavioral therapy for insomnia (CBT-I) is a psychological treatment that targets the maladaptive behaviors and dysfunctional thoughts that perpetuate sleep problems. CBT-I is one of the most effective treatments for insomnia (Trauer et al., 2015, van der Zweerde et al., 2018). A so-called multi-component therapy consisting of several aspects is recommended by the current guidelines of both the American and European sleep societies (Riemann et al., 2017, Schutte-Rodin et al., 2008). Typically, CBT-I consists of several components such as stimulus control, sleep restriction, sleep hygiene, relaxation techniques, and cognitive restructuring (Perlis et al., 2010, Morin et al., 2006, Okajima et al., 2011). Of note, CBT-I has also shown to have considerable treatment effects for depression comorbid with insomnia (Cunningham and Shapiro, 2018, Wu et al., 2015).

Although a multicomponent cognitive-behavioral therapy has shown to be effective, it is not clear which components of a multi-component therapy are most helpful to treat insomnia successfully. For example, there is empirical evidence that psychoeducation and sleep hygiene are not likely to be effective components of a successful insomnia treatment (Morin et al., 1994).

Several studies have investigated which components specifically contribute to treatment outcome. In dismantling studies in a face-to-face setting, sleep restriction has shown to be one of the most effective of these components (Spielman et al., 1987, Youngstedt and Kripke, 2004, Morin et al., 2006, Harvey et al., 2002, Miller et al., 2014). A recent review concluded that sleep restriction is an effective single behavioral intervention for the treatment of insomnia for sleep diary variables (Miller et al., 2014). Epstein and colleagues (Epstein et al., 2012) conducted a dismantling study in older adults suffering from insomnia to compare

multi-component therapy, sleep restriction alone, and stimulus control alone, to a waitlist control group. They found initial evidence that stimulus control, sleep restriction, and multi-component therapy are equally efficacious. However, multicomponent therapy showed higher remission rates and should, therefore, be recommended. Similarly, a study by Harvey et al. (Harvey et al., 2014) compared cognitive behavioral therapy (CBT) with cognitive therapy (CT) and behavior therapy (BT) in chronic insomnia and showed significant improvements across all three treatment conditions. The authors found the greatest improvement for insomniacs in the CBT group, while improvements in the BT group were faster but less enduring and in the CT group improvements were delayed in action but more sustained.

Unfortunately, the availability of CBT-I is severely limited for many reasons, including lack of trained clinicians, poor geographical distribution of knowledgeable professionals, expense, and inaccessibility to treatment and clinicians (e.g., van Straten and Cuijpers, 2009). Online interventions represent a potential solution to overcome several of the barriers to treatment access (Andersson and Titov, 2014). Several randomized controlled studies of internet-based self-help treatments for insomnia (iCBT-I) have shown its efficacy (e.g., van Straten et al., 2014, Jernelöv et al., 2012, Ritterband et al., 2009), and recent meta-analyses (Seyffert et al., 2016, Zachariae et al., 2016, Ye et al., 2016) show good results with large effects on insomnia severity, and medium effects for sleep efficiency and sleep quality. There is evidence that guided self-help interventions show better results compared to unguided interventions, irrespective of whether it is internet-based or not (Jernelöv et al., 2012, Ho et al., 2014).

Regarding dismantling studies in online interventions, Kaldo and colleagues (Kaldo et al., 2015) compared eight weeks of a guided multi-component iCBT-I with an active internet-based control treatment consisting of components with less empirical support for the treatment of insomnia such as sleep hygiene, relaxation, mindfulness, and general stress management. Notably, these components were only presented in an abbreviated form, and there was no guidance. Multi-component ICBT was significantly more effective after eight weeks. However, the two conditions did not differ anymore after 12 months due to a continuous decrease in ISI among controls. A very recent study showed that a multi-component therapy is more efficacious than online sleep education across a range of demographic groups (Cheng et al., 2018).

In summary, even though a considerable number of studies show positive effects for guided internet interventions for insomnia, there is still a lack of knowledge about which components of a multicomponent treatment are essential for the positive effects, and whether all

components are necessary for an effective treatment. The current study aims to compare sleep restriction, which is one crucial behavioral component of CBT-I, and a multi-component cognitive behavioral treatment with an active waiting list control group. Furthermore, it aims to compare the two active conditions. To our knowledge, this is one of the first studies that compare two different forms of guided iCBT-I and the first study that investigates guided internet-based sleep restriction.

2. METHODS

2.1 Study design

This study was a three-arm randomized controlled trial (RCT) comparing two immediate treatment groups to an active waiting list control group. All groups had access to CAU and the waiting list control group was enrolled in the iCBT-I program after the active treatment groups had completed the programme (after eight weeks). The immediate treatment group was followed up for six months after randomization. We wanted to be able to detect a standardized between-group effect size (Cohen's *d*) of 0.35. Smaller effect sizes were considered to be irrelevant from a clinical point of view. A power analysis based on an anticipated drop-out rate of 25% revealed that approximately 90 participants were needed per active treatment group to show such an effect with a power (1-β) of .80 compared to the control condition. Furthermore, 40 participants were estimated to be sufficient for the control condition because effect sizes between the control condition and treatment groups were assumed to be largely based on the previous trials, resulting in a sample size of 225 participants. For practicality reasons, we had to finish the recruitment procedure when 104 participants were randomized, therefore limiting our ability to detect small to medium between-group effect sizes.

2.2 Participants and Procedure

Participants were recruited from June 2016 to July 2017 through newspaper advertisements, online postings, flyers, and physician referrals. Inclusion criteria were a) age of 18 years or older, b) meeting criteria for acute or chronic insomnia according to the International Classification of Sleep Disorders (ICSD-3) (American Academy of Sleep Medicine, 2014), c) having access to the internet, d) good knowledge of the German language. Exclusion criteria were a) known organic insomnia (e.g., due to restless legs syndrome, breathing-related sleep disorder, circadian rhythm sleep-wake disorder), b) psychiatric comorbidities according to the

MINI interview (Ackenheil et al., 1999), and c) acute suicidality. After consenting to study participation and meeting the inclusion and none of the exclusion criteria (assessed via the baseline online questionnaire and an interview via telephone), participants were randomly assigned to one of the three conditions (2:2:1). The allocation list was made using a computerized random number generator and was concealed from the investigators and participants. After the randomization, the participants received an email regarding their allocation. All participants in the active conditions were advised to work through one session per week and to start a new session after receiving weekly feedback by their guide. After eight weeks, all participants were asked to fill out the post-assessment questionnaires online and to participate in a second telephone interview to re-evaluate their diagnostic status. The assessors could not be kept blind regarding group allocation because some participants revealed information about the treatment during the interview. Six months after the beginning of treatment, participants were contacted via email and asked to fill out the questionnaires again and to take part in another interview. The trial was registered with www.clinicaltrials.gov (NCT03110263) and was approved by the Ethics Committee of the Canton of Bern, Switzerland (2016-00295).

2.3 Primary outcome measures

The primary outcome of the present study was the Insomnia Severity Index (ISI) for the comparisons between the three conditions. Also, we used sleep efficacy (SE) reported by the participants during the intervention in the morning protocol for the comparison between the two active conditions.

Insomnia Severity Index (ISI). Insomnia severity was assessed with the Insomnia Severity Index (ISI) (Bastien et al., 2001). Participants indicate the severity of sleep onset difficulties, sleep maintenance difficulties, early morning awakening, satisfaction with current sleep, interference with daytime functioning, noticeability of impairment attributed to sleep problems, and degree of distress or concern caused by the sleep problem for the previous week. The German version of the ISI has shown acceptable psychometric properties (Gerber et al., 2016). Higher scores indicate more severe insomnia. Cronbach's alpha at post was .83.

Sleep efficacy (SE). Participants in the two active conditions were asked to fill out an evening and a morning protocol daily during the intervention phase to assess different parameters of their sleep and its consequences. The protocols were in line with the protocols of the German

Association for Sleep Research and Sleep medicine (DGSM). We assessed SE with data from the morning protocol for every night during the treatment period.

2.4 Secondary outcome measures

Secondary outcomes included the following measures: Overall sleep quality was measured with the Pittsburgh Sleep Quality Index (PSQI) (Buysse et al., 1989, Riemann and Backhaus, 1996). To assess maladaptive beliefs in insomnia, we used the 16-item version of the Dysfunctional Beliefs and Attitudes about Sleep (DBAS) scale (Morin et al., 2007, Weingartz and Pillmann, 2009). Depressive symptoms were assessed by the German short version of the Center for Epidemiological Studies Depression Scale (CES-D) (Radloff, 1977), the "Allgemeine Depressions-Skala – Kurzform" (ADS-K) (Hautzinger and Bailer, 1993). To assess the quality of life participants were asked how good or bad their health is on a visual analog scale (QoL-VAS) from 0 (the worst health you can imagine) to 100 (the best health you can imagine) (EQ-5D-5L; Herdman et al., 2011). At post-treatment, we assessed an adapted version of a patient satisfaction questionnaire, the ZUF-8 (Schmidt et al., 1989). This brief and reliable instrument was originally developed as a translation of the Client Satisfaction Questionnaire (CSQ-8; Attkisson and Greenfield, 2004). As well, user satisfaction was measured via the System Usability Scale (SUS) (Brooke, 1996).

Sleep protocol. As described above, we assessed different variables with 1-item Likert-scale questions in both active conditions using daily morning and evening protocols by the German Association for Sleep Research and Sleep medicine (DGSM) within each of the internet-based programs. Sleep quality (1 "very good" – 5 "very bad"), recovery (1 "very recovered" – 5 "very unrecovered") and tiredness before going to bed (1 "not tired at all" – 5 "very tired") were assessed in the morning protocol. Daytime tiredness (1 "no daytime tiredness" – 8 "strong daytime tiredness"), concentration (1 "very unconcentrated" – 8 "very concentrated"), mood (1 "very bad mood" – 8 "very good mood"), and relaxation (1 "unrelaxed" – 8 "very relaxed") were assessed in the evening protocol.

Diagnostic measures. Assessors interviewed participants via telephone at baseline (M.I.N.I and ICSD-3). The German Version of the M.I.N.I. (Ackenheil et al., 1999) screened for possible psychiatric comorbidities. The ICSD-3 (American Academy of Sleep Medicine, 2014) provides specific coding information for an insomnia diagnosis (Mayer et al., 2015). Participants were interviewed at post-intervention to check whether they still fulfilled the criteria for insomnia. Eight advanced master students in clinical psychology and the second

author conducted the interviews. All of the assessors had been trained in using the interviews in a workshop including test interviews and feedback and were supervised by the second author.

2.5 Description of conditions

Multicomponent internet-based guided treatment (MCT). The self-help program consists of eight text-based sessions and tasks (see Table 1) and is based on interventions by Perlis et al. (Perlis et al., 2006). The psychoeducational component covers information about the processes of sleep, sleep hygiene and general information on stress management. The behavioral techniques include sleep restriction (i.e., reducing the sleep window to enhance sleep consolidation), stimulus control (e.g., getting out of bed after a certain time of wakefulness), and relaxation (e.g., progressive muscle relaxation). The cognitive techniques included belief restructuring (e.g., targeting unrealistic beliefs about sleep). Comparable MCTs have already been successfully evaluated in other studies (Holmqvist et al., 2014, Blom et al., 2015, van Straten et al., 2014). All participants received guidance during 8-weeks of treatment. Guidance consisted of weekly messages in an integrated secured environment of guides who monitored the participant's progress in the program and provided feedback and structure. The participants could also use the integrated message function to contact their guide whenever they felt the need to and were informed that the guide would answer within three working days. The main aim of the guides' messages was to reinforce the independent program use and maintain the participant's motivation. When a participant was inactive for a week, the guide offered support with the respective module.

Internet-based guided sleep restriction treatment (SRT). The 8-week treatment program mainly consists of sleep restriction instructions that are embedded in an introductory and psychoeducational module (see Table 1). Sleep restriction induces mild sleep deprivation to enhance the endogenous sleep drive. A sleep window was proposed depending on the time a participant wanted to get up. Every week, a new sleep window was calculated based on the participants' sleep diary data together with the participant to select the timing of the window (e.g., earlier versus later in the night). A more lenient sleep window was suggested for moderate-to-severe tiredness. The sleep window was regularly reviewed at each module after it had been introduced. If the sleep diary data indicate a sleep efficiency of 90% or higher, the participant was advised to add 30 min to the sleep window (Morin et al., 2006, Perlis et al., 2010, Riemann and Spiegelhalder, 2015). The minimum sleep window for this intervention

was set at six hours (Müller and Paterok, 2010). Guidance was the same as in the multicomponent internet-based treatment (see also below).

Care as usual (CAU). Participants in the control group received access to the MCT program after a waiting period of 8 weeks, at post-treatment of the active treatment conditions. Because participants were allowed to use other resources from the healthcare system during the study, we labeled this group as care-as-usual (CAU).

2.6 Guidance

The guides were one psychologist with a Master's degree in clinical psychology in his first year of a post-graduate CBT training program and eight Master students who were in their last term of a graduate program in clinical psychology. All guides had an introduction to both online interventions and training of the principals of iCBT. Furthermore, they were supervised by the second and the last author and received support regarding email correspondence when needed. For this, the guides contacted the second and the last author when needed. In the case of uncertainties, the co-authors from the Sleep-Wake-Epilepsy-Center were asked for additional advice. To ensure adherence, the second author regularly screened the content of all messages sent. Participants were consecutively allocated to guides without randomization to minimize waiting times. All guides provided guidance in both conditions.

2.7 Statistical analyses

All statistical analyses were performed with SPSS or R (R Core Team, 2018) and the packages *nlme* (Pinheiro et al., 2018). ANOVAs and ??^{2}-tests were used to detect differences in baseline data. To compare the two active treatments with the waiting list, we analyzed all primary and secondary outcome measures with mixed-effect models using unstructured covariance matrices and restricted maximum likelihood estimation (REML) with time-points nested within subjects. This approach uses all available data of each subject without substituting missing values and allows the inclusion of all participants in the analyses, following the intention-to-treat (ITT) principle. The models were further examined using contrast analyses. Within- and between-group effect sizes (Cohen's *d*) were calculated based on estimated means and the pooled standard deviation from the observed means. We compared the two active treatments on the basis of daily diary entries (max. 56) in the program during the eight weeks (scaled from 0 to 1). Within-group effect sizes (Cohen's *d*) were calculated based on the estimated means at the beginning and after eight weeks and the

pooled SD throughout the 56 days. Within-group changes in outcome scores from post-treatment to follow-up were analyzed with mixed-effect models and REML for the active conditions only, as the CAU group was offered the online intervention after eight weeks. Participants were considered responders if their ISI change score compared with baseline was greater than seven at post, and treatment remitters if their absolute ISI score at post was less than eight, following previous recommendations (Morin et al., 2009). Applying a conservative approach, we defined all missing data for response, remission and diagnostic status as unchanged from baseline, i.e., first observation carried forward.

3. RESULTS

3.1 Baseline differences

Participants did not differ in primary and secondary outcomes or any demographic or diagnostic variables (see Table 2) between the three conditions.

3.2 Study dropout analysis

In total, 16 of 104 participants (15.4%) did not complete the post-assessment questionnaires, although they had been invited three times at weekly intervals via email. Non-completion rates did not differ with respect to experimental group, $??^2(2, n=104) = 2.34$, $p = .31$, $V = 0.15$, nor demographic data, nor baseline symptomatology (all p's > .40).

3.3 Overall effects and pairwise comparisons at post-treatment

Observed and estimated means for all self-report measures assessed at baseline and post are presented in Table 3. Linear mixed models with group as a fixed factor and time as a repeated factor (pre--post) were fitted separately for each of the dependent measures. Significant *group x time* interaction effects were found for all primary and secondary outcomes, except for quality of life assessed with the QoL-VAS. Bonferroni-corrected consecutive contrast analyses for models with a significant interaction effect, showed that both active treatments were significantly superior to CAU on all involved measures except depressive symptoms and quality of life. Regarding depressive symptoms assessed with the ADS-K, only the MCT condition proved to be significantly superior to CAU ($p = .012$) while the SRT was not significantly different from CAU ($p = .168$). Regarding quality of life, the MCT group significantly differed from CAU ($p = .020$) while the SRT group did not differ from CAU ($p = .207$). Furthermore, there was no significant difference between the active conditions on

primary and secondary outcomes, except for dysfunctional beliefs about sleep assessed with the DBAS-16. Here, the MCT group showed significantly lower scores indicating less dysfunctional beliefs compared to the SRT group (p = .045).

3.4 Effect sizes at post-treatment

Effect sizes (Cohen's d) are presented in Table 3. For the ISI, the between-group effect sizes at post-treatment were d = -0.46 for MCT vs. SRT (in favor of MCT), d = 1.15 for MCT vs. CAU (in favor of MCT), and d = -.68 for SRT vs. CAU (in favor of SRT). For the ISI, within-group comparisons revealed large effect sizes in MCT (d = 1.62) and SRT (d = 1.41), and a medium effect size for CAU (d = 0.64).

3.5 Response, remission, and deterioration

Regarding response (change in ISI > 7), 9.5% of the participants in the CAU (n = 2), 31.7% in the SRT (n = 13), and 40.5% (n = 17) in the MCT condition were considered responders at post-treatment. Significantly more cases in the MCT showed response compared to CAU, $??^2(1, n=63) = 6.37$, p = .012, V = 0.32. This was not the case for the SRT group compared to CAU, $??^2(1, n=62) = 3.73$, p = .054, V = 0.25. However, the two active conditions did not significantly differ between each other $??^2(1, n=83) = 0.69$, p = .41, V = 0.09.

Regarding remission (ISI post score < 8), 4.8% of the participants in the CAU (n = 1), 24.4% in the SRT (n = 10), and 38.1% (n = 16) in the MCT condition were considered remitted at post-treatment. Significantly more cases in the MCT remitted compared to the CAU, $??^2(1, n=63) = 7.90$, p = .005, V = 0.35. This was not the case for the SRT group compared to the CAU, $??^2(1, n=62) = 3.67$, p = .056, V = 0.24. Again, the two active groups did not differ from each other $??^2(1, n=83) = 1.81$, p = .178, V = 0.15.

No participant in any condition showed a reliable deterioration on the ISI (difference of 8 or more) at post compared to the baseline score.

3.6 Diagnostic status at post-treatment

In total, 86 participants could be reached for a second clinical interview after the treatment (MCT: n = 35 [83.3%]; SRT: n = 31 [75.6%]; and CAU: n = 20 [95.2%]). Results in the intention-to-treat sample indicated that 81% (n = 17) in CAU, 52.4% (n = 22) in MCT, and 48.8% (n = 20) in SRT still fulfilled the criteria for an insomnia according to the ICSD-3 criteria at post-assessment. The groups differed significantly regarding the diagnostic status at

post, $??^2(2, N=104) = 6.40$, $p = .04$, $V = 0.25$. Both active groups showed fewer people still suffering from insomnia than in the control condition, p's < .028. The two treatments did not significantly differ from each other at post-assessment, $??^2(1, n=83) = 0.11$, $p = .74$, $V = -0.04$.

3.7 Comparing the two active treatments based on daily protocols

Participants in both active conditions were instructed to complete a daily protocol. Based on these daily assessments we ran separate mixed models analyses with group and days (0-55), recoded as Time from 0 to 1, and its interaction from baseline to post-assessment (eight weeks) assuming a linear change for all protocol items. Results are presented in Table 4. All interactions regarding the primary (*sleep efficacy*) and most secondary outcomes (*sleep quality*, *feeling unrecovered*, *daytime tiredness*, *concentration*, *mood*, and *relaxation*) were non-significant (all p's > .10). An exception was *tiredness when going to bed* ($p = .003$), which remained stable in MCT but increased significantly in SRT. Within- and between-group effect sizes were mostly in the small to medium range and can be seen in Table 4.

3.8 Maintenance of treatment effects at 6-month follow-up

All analyses in this section only include the two active conditions, as the CAU group had already received access to the treatment after eight weeks. Mixed models analyses including pre, post and follow-up scores (see Table 3) showed significant time effects for all scales assessed at follow-up (ISI, PSQI, ADS-K, EQ_VAS), all ps < .027. Contrast analyses indicate that follow-up scores improved from baseline, and post hoc tests using Bonferroni-correction indicate stability from post-treatment to follow-up, as no significant differences were detected. All *Time X Group* interactions were non-significant, $F(2, 54.56\text{-}68.00) = 0.15\text{-}1.00$, all ps ≥ .35, therefore through all time points, neither of the conditions proved to be significantly superior.

3.9 Diagnostic status at follow-up

Regarding insomnia diagnostic status at follow-up, 30 of 42 (71.4%) in the MCT and 24 of 41(58.5%) in the SRT condition could be reached for a diagnostic interview. Again using a conservative approach defining missings as unchanged from baseline, 20 participants of 42 (47.6%) in the MCT condition and 25 of 41 participants (61.0%) in the SRT condition fulfilled the criteria for insomnia at follow-up. This difference, however, was not statistically significant, $??^2(1, n=83) = 1.49$, $p = .22$, $V = 0.13$.

3.10 Patient Satisfaction

Regarding the ZUF-8 assessed after eight weeks, participants in the MCT (M = 3.42, SD = 0.55) condition showed significantly higher levels of satisfaction than participants in the SRT (M = 2.99, SD = 0.57), $t(65.92)=3.23$, p = .002. Regarding usability assessed with the SUS, the two interventions were rated equally, MCT: M = 4.39, SD = 0.60; SRT: M = 4.18, SD = 0.64; $t(66)=1.43$, p = .16.

3.11 Program usage

The average of completed modules in MCT was 6.66 (SD = 2.12) out of eight, mean completed modules in SRT was 4.61 (SD = 0.80) out of five, over the eight weeks. For time spent in the program, the median was 7.57 h in MCT, and 5.32 h in SRT. Using a non-parametric U-test, this difference was statistically significant p = .008.

Regarding the usage of the sleep restriction module, the median for time spent in this module was 14.7 min in MCT and 13.0 min in SRT for all participants. Using a U-Test, this difference was not significant, p = .45. Relatedly, for the number of adjustments of the sleep window, the median was three in the MCT and two in the SRT. This difference was also not significant, p = .57.

3.12 Guidance

On average, therapists wrote 9.66 messages (SD = 3.19, Md = 10) in MCT and 10.05 messages (SD = 3.38, Md = 10) in SRT. This difference was not significant, U = 757.5, p = .44. Participants wrote on average 5.44 messages (SD = 4.10, Md = 5) in MCT and 6.12 in SRT (SD = 5.81, Md = 5). This difference was not statistically significant, U = 836.0, p = .97. The two groups furthermore did not differ regarding the number of words written by participants (MCT: Md = 508; SRT: Md = 427; U = 755.0, p = .43) nor by therapists (MCT: Md = 1484; SRT: Md = 1494; U = 820.0, p = .85).

4. DISCUSSION

The current study set out to compare two guided internet-based interventions to a waiting-list control group for people suffering from insomnia. Both active groups showed significant differences compared to the control group regarding the primary outcome. As such, the present study adds to the growing literature of the efficacy of internet-based interventions for insomnia also in people not suffering from other psychiatric conditions. Quality of life did not

increase compared to the waiting-list control condition in both active conditions. One reason could be that potential participants with comorbid psychological disorders were excluded. However, this finding has been reported in a previous study on iCBT-I with or without phone support in which comorbid psychological disorders were not excluded and not assessed (Ho et al., 2014).

Concerning the comparison of the two active conditions, the results of the present study provide preliminary evidence that a multicomponent treatment (MCT condition) is not superior with regard to insomnia severity to an intervention that focuses on sleep restriction and omits working on dysfunctional cognitions (SRT condition). This was the case for comparisons of insomnia severity at post as well as at follow-up assessment. However, results indicate that the MCT group benefited significantly more regarding dysfunctional sleep-related beliefs. The additional module on cognitive restructuring could have caused this difference. Additionally, on a descriptive level but not at a statistical level more people in MCT compared to the SRT condition no longer fulfilled the criteria for insomnia at six months. This is in line with results found in traditional CBT-I (Epstein et al., 2012, Harvey et al., 2014).

Regarding depressive symptoms, only MCT proved to be superior to the control condition; this was not the case for SRT. This might also be due to the extra module on cognitive restructuring. However, the results of the present study on comorbid depressive symptoms may be underestimated, if comorbid major depression had been permitted in the present study. Nevertheless, the result that MCT may have a stronger effect on depressive symptoms seems important because a recent RCT in people suffering from symptoms of depression and insomnia revealed that ICBT-I is effective in the reduction of depressive symptoms (van der Zweerde et al., 2018). This result is also consistent with another study showing that patients who suffer from insomnia and depression profit highly from insomnia treatment (Blom et al., 2017). The result of the present study suggests that cognitive restructuring may play an important role.

A sleep restriction module was part of both active interventions. A review of treatment studies for insomnia showed that the absolute minimal sleep window – also called “minimal time in bed” – can vary considerably (Kyle et al., 2015). This is important since sleep restriction treatment can be associated with reduced objective total sleep time, increased daytime tiredness, and objective performance impairment (Kyle et al., 2014). In the present study, we set the minimum sleep window at six hours. It cannot be ruled out that a shorter sleep window

– although bearing more "pain" - would have led to more "gain" regarding treatment response (Kyle et al., 2011). However, to minimize the risk of negative effects, we decided to use a comparably long minimal time in bed. Future studies should systematically test the association of different minimal time windows and treatment response.

All comparisons of different variables of sleep diary data, such as sleep efficacy, revealed no significant differences between the two active conditions (all *p*-values > .10). However, it is striking that - on a descriptive level - daytime tiredness decreased in MCT while it increased in SRT throughout the interventions. Therefore, it can be assumed that more statistical power would have led to a statistically significant difference between the two conditions regarding daytime tiredness. More daytime tiredness should be considered a negative side effect of the SRT condition. Of note, although participants had the same module on sleep restriction with the same instructions and although usage of the sleep restriction module in both conditions was similar, in MCT daytime tiredness decreased. One explanation for this finding could be that if participants in a sleep intervention can choose from different interventions, they apply the ones that work best for them or have fewer side effects. More research on which specific interventions of internet-based treatments participants do apply and maintain in daily life is needed.

Note that from a user perspective, participants in MCT were significantly more satisfied with the intervention than participants in SRT. Also, more participants reported that they have a specific preference for MCT (32.7%) than for SRT (5.8%) before the intervention started. Considering that the amount of guidance and therefore the use of resources did not differ between the two conditions, in sum, results from a patient perspective are in favor of MCT. However, treatment preferences that may be associated with treatment outcome expectancies could have influenced the results of the present study (Constantino et al., 2007).

There are some important limitations of the present study that have to be considered. First, due to clinical considerations, we excluded participants if they met the criteria for a psychiatric disorder. On the one hand, this limits the generalizability of our results, on the other hand, the results of the present study have a higher internal validity for people suffering from insomnia. Second, apart from a diagnostic interview, all measures were based on mere self-report. Third, the power of the present study was not sufficient to yield significant small to medium effects between the two active conditions. A future study to find significant differences between these active conditions should be powered adequately. We assume that small significant effects could be expected in a replication of the present study with more

power. The recruitment for the present study had to be discontinued since recruitment was slower than expected. A reason for this slow recruitment could be that most people only seek support to cope with insomnia when additional problems such as depression or anxiety arise. Since we advertised that people with comorbid psychological disorders could not be included in the present study, these people did not contact us. Fourth, we did not systematically assess the negative effects associated with the two interventions apart from reliable deterioration.

Taken together, both active conditions, MCT and SRT, proved to be efficacious compared to CAU alone. Also, there is preliminary evidence that MCT might be more efficient regarding dysfunctional beliefs about sleep, probably due to the additional cognitive module included in MCT. Furthermore, participants in MCT were more satisfied with the treatment compared to participants in SRT. Considering the equally-used resources (e.g., messages sent, number of words used in the messages) in both conditions, one could argue that MCT should be the internet-based treatment of choice for people suffering from insomnia.

Highlighting the high potential health-economic benefit of providing low-threshold internet-based interventions for insomnia, two recent RCTs showed that improvements in insomnia symptoms mediate improvements in functional health, psychological well-being, and sleep-related quality of life (Espie et al., 2018) and psychotic experiences and other psychological symptoms (Freeman et al., 2017). Despite these encouraging results of internet-based interventions for insomnia one has to bear in mind that not all people suffering from insomnia can profit from internet-based interventions. In the current study, in the MCT condition, around 60% did not fulfill the self-report-based criterion for remission regarding insomnia severity and around 50 % still fulfilled the criteria for insomnia in a diagnostic interview at post-treatment. As a consequence, research that improves existing interventions seems necessary, or people who do not profit from internet-based interventions should be offered complementary or other interventions in different settings. Related to the latter point, more research on stepped care approaches in insomnia seems necessary. Likewise, generally more research is needed in routine practice settings, such as in primary care or sleep clinics, to generalize the encouraging results of internet-based treatments for insomnia.

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CONFLICT OF INTEREST

None.

ETHICAL STANDARDS

The authors assert that all procedures contributing to this work comply with the ethical standards of the relevant national and institutional committees on human experimentation and with the Helsinki Declaration of 1975, as revised in 2008.

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Table 1

Content of the two online interventions

	MCT	SRT
Session 1:	Introduction	Introduction
Session 2:	Psychoeducation	Psychoeducation
Session 3:	Sleep restriction	Sleep restriction
Session 4:	Progressive Muscle Relaxation (PMR)	Continuation instruction for sleep restriction
Session 5:	Cognitive restructuring	-
Session 6:	Sleep hygiene	-
Session 7:	Relapse prevention	-
Session 8:	Repetition and Termination	Repetition and Termination

Note. MCT = Multicomponent treatment; SRT = Sleep restriction treatment

Table 2

Baseline demographics and sample characteristics for both intervention groups and the control group.

	MCT (n = 42)	SRT (n = 41)	CAU (n = 21)	Statistic
Mean age, years (standard deviation)	42.17 (12.40)	46.59 (17.52)	45.24 (12.40)	$F(2,101) = 0.98$; $p = .38$
Gender, *n* (%)				
Male	16 (38.1%)	13 (31.7%)	4 (19.0%)	$??^2(2) = 2.35$; $p = .31$
Female	26 (61.9%)	28 (68.3%)	17 (81.0 %)	
Marital status, *n* (%)				$??^2(6) = 7.02$; $p = .32$
Single/living alone	11 (26.2%)	9 (22.0%)	4 (19.0%)	
Living together	9 (21.4%)	13 (31.7%)	2 (9.5%)	
Married	20 (47.6%)	14 (34.1%)	12 (57.1%)	
Divorced	2 (4.8%)	5 (12.2%)	3 (14.3%)	
Widowed	0 (0.0%)	0 (0.0%)	0 (0.0%)	
Highest education, *n* (%)				$??^2(6) = 4.20$; $p = .68$
Compulsory school	0 (0.0%)	2 (4.9%)	0 (0.0%)	
Apprenticeship	11 (26.2%)	12 (29.3%)	6 (28.6%)	
College	4 (9.5%)	3 (7.3%)	3 (14.3%)	
University	27 (64.3%)	24 (58.5%)	12 (57.1%)	
Employment, *n* (%)				$??^2(8) = 5.13$; $p = .74$
Full-time paid work	24 (57.1%)	17 (41.5%)	12 (57.1%)	
Part-time paid work	12 (28.6%)	13 (31.7%)	6 (28.6%)	
Student	5 (11.9%)	6 (14.6%)	2 (9.5%)	
unemployed	0 (0.0%)	0 (0.0%)	0 (0.0%)	
At-home parent	0 (0.0%)	0 (0.0%)	0 (0.0%)	
Retired	1 (2.4%)	4 (9.8%)	1 (4.8%)	
Body Mass Index (standard deviation)	23.60 (3.64)	24.23 (5.20)	23.62 (3.79)	$F(2,101) = 0.26$; $p = .78$
Sleep medication within the last three months				$??^2(2) = 0.44$; $p = .80$
Yes	16 (38.1%)	13 (31.7%)	8 (38.1%)	
No	26 (61.9%)	28 (68.3%)	13 (31.7%)	
Current treatment for sleep problems (multiple answers possible)				
General practitioner	7 (16.7%)	7 (17.1%)	1 (4.8%)	$??^2(2) = 1.99$; $p = .37$
Psychotherapy	2 (4.8%)	0 (0.0%)	0 (0.0%)	$??^2(2) = 3.01$; $p = .22$

Specialist	2 (4.8%)	3 (7.3%)	0 (0.0%)	??^{2}(2) = 1.63; p = .44
Medication	8 (19.0%)	4 (9.8%)	2 (9.5%)	??^{2}(2) = 1.89; p = .39
Other	16 (38.1%)	14 (34.1%)	6 (28.6%)	??^{2}(2) = 0.57; p = .75
None	32 (76.2%)	36 (87.8%)	15 (71.4%)	??^{2}(2) = 2.88; p = .24
Chronicity of insomnia				
3-12 months	5 (11.9%)	10 (24.4%)	1 (4.8%)	??^{2}(2) = 4.77; p = .09
More than 12 months	37 (88.1%)	31 (75.6%)	20 (95.2%)	
Preference				??^{2}(4) = 4.66; p = .32
MCT	20 (47.6%)	18 (43.9%)	6 (28.6%)	
SRT	4 (9.5%)	1 (2.4%)	1 (4.8%)	
no preference	18 (42.9%)	22 (53.7%)	14 (66.7%)	

Note. MCT = Multicomponent treatment; SRT = Sleep restriction treatment; CAU = Care as usual.

Table 3

Observed and estimated means for primary and secondary outcome measures, overall effects, within-group effects, and post-treatment between-group comparisons.

	Baseline		Post (observed)		Post (estimated[a])		FU (observed)		FU (estimated[b])		Pre-post within-group effect sizes (estimated means)		Overall effects at post-treatment (group x time interaction)[c]	Pairwise comparisons at post-treatment (Bonferroni-corrected)	Between-group effect sizes at post-treatment (estimated means)
Measure	*M* (*SD*)	*n*	*M* (*SD*)	*n*	*M (SE)*	*n*	*M* (*SD*)	*n*	*M (SE)*	*n*	Cohen's *d*	95% CI	*F* and *df*		Cohen's *d* [95% CI]
ISI															
MCT	16.20 (3.75)	41	8.88 (4.94)	34	9.08 (0.82)	41	7.50 (3.82)	32	8.11 (0.72)	41	1.62	[1.11; 2.11]			MCT vs. SRT: -0.46 [-0.89; -0.01]
SRT	17.37 (3.44)	41	11.29 (4.99)	34	11.34 (0.82)	41	9.46 (4.37)	26	10.20 (0.77)	41	1.41	[0.91; 1.88]		MCT vs. SRT: p = .159	MCT vs. CAU: -1.15 [-1.70; -0.57]
CAU	17.43 (3.83)	21	14.75 (4.73)	20	14.67 (1.08)	21					0.64	[0.01; 1.25]	$F_{(2, 86.735)}$ = 6.56 p = .002	MCT vs. CAU: p < .001 SRT vs. CAU: p = .049	SRT vs. CAU: -0.68 [-1.21; -0.13]
PSQI															
MCT	10.12 (3.13)	42	6.41 (3.41)	34	6.43 (0.56)	42	5.44 (2.26)	32	5.52 (0.46)	42	1.13	[0.66; 1.58]	$F_{(2, 91.012)}$ = 6.63	MCT vs. SRT:	MCT vs. SRT:
SRT	11.05	41	7.38	34	7.32	41	7.04	26	7.18	41	1.18	[0.71;	p = .002	p = .793	-0.27

CAU	(3.14)		(3.13)		(0.56)		(3.22)		(0.49)			1.65]		MCT vs. CAU: $p < .001$ SRT vs. CAU: $p = .007$	[-0.70; 0.16] MCT vs. CAU: -1.09 [-1.63; -0.52] SRT vs. CAU: -0.88 [-1.41; -0.32]
	10.95 (2.52)	21	10.20 (3.67)	20	10.23 (0.74)	21					0.23	[-0.38; 0.83]			
ADS-K															
MCT	12.83 (6.33)	41	7.29 (5.26)	34	7.17 (1.02)	41	7.16 (4.68)	31	6.73 (0.88)	41	0.97	[0.51; 1.42]			MCT vs. SRT: -0.33 [-0.76; 0.11] MCT vs. CAU: -0.80 [-1.33; -0.25] SRT vs. CAU: -0.51 [-1.04; 0.03]
SRT	13.05 (5.42)	41	8.79 (5.49)	34	8.92 (1.02)	41	6.96 (5.26)	26	7.48 (0.94)	41	0.75	[0.30; 1.20]			
CAU													$F_{(2, 87.488)} = 3.32$ $p = .041$	MCT vs. SRT: $p = .690$ MCT vs. CAU: $p = .012$ SRT vs. CAU: $p = .168$	
	13.67 (6.69)	21	11.90 (8.00)	20	12.21 (1.36)	21					0.20	[-0.41; 0.80]			
DBAS															
MCT	70.63 (21.83)	41	41.65 (24.04)	34	43.03 (4.19)	41	-[d]	-	-	-	1.20	[0.72; 1.66]	$F_{(2, 87.896)} = 15.19$	MCT vs. SRT:	MCT vs. SRT:

SRT CAU	80.63 (21.40)	41	57.97 (23.94)	34	57.71 (4.19)	41	-	-	-	-	1.01	[0.54; 1.46]	$p < .001$	$p = .045$ MCT vs. CAU: $p < .001$ SRT vs. CAU: $p < .001$	-0.61 [-1.05; -0.16] MCT vs. CAU: -1.73 [-2.31; -1.10] SRT vs. CAU: -1.17 [-1.72; -0.59]
	84.05 (30.48)	21	87.00 (29.70)	20	88.06 (5.60)	21					-0.13	[-0.74; 0.47]			
QoL VAS															
MCT	74.27 (17.62)	41	82.82 (12.12)	34	82.49 (2.24)	41	79.74 (15.90)	31	79.85 (2.70)	41	-0.54	[-0.98; -0.10]			MCT vs. SRT: 0.26 [-0.18; 0.69] MCT vs. CAU: 0.85 [0.29; 1.38] SRT vs. CAU: 0.49 [-0.05; 1.02]
SRT CAU	73.00 (15.25)	41	78.91 (14.55)	34	79.04 (2.24)	41	77.69 (13.56)	26	76.38 (2.90)	41	-0.41	[-0.84; 0.04]	$F_{(2, 90.306)} = 2.10$ $p = .128$	MCT vs. SRT: $p = .836$ MCT vs. CAU: $p = .020$ SRT vs. CAU: $p = .207$	
	73.62 (14.38)	21	72.30 (12.03)	20	72.25 (2.93)	21					0.10	[-0.50; 0.71]			

Note. MCT = Multicomponent treatment; SRT = Sleep restriction treatment; CAU = Care as usual; ISI = Insomnia severity index; PSQI = Pittsburgh Sleep Quality Index; DBAS = Dysfunctional Beliefs and Attitudes about Sleep Scale; ADS-K = Center for Epidemiological Studies-Depression – German short version; QoL VAS = Quality of Life - visual analogue scale. [a] Based on models including all conditions and pre and

post-assessments; [b] based on models including the two active conditions and baseline, post and FU-assessments. [c] Intention-to-treat (ITT) analyses; [d] DBAS was not assessed at follow-up.

Table 4

Estimated means and overall effects for continuous sleep diary data during the intervention period.

	n^a	Start of the intervention (estimated) *M (SE)*	After eight weeks (estimated) *M (SE)*	Overall effect (group x time interaction)[c] *F* and *df*	*Pooled standard deviation over 56 days* SD_{pooled}	Pre-post within-group effect sizes (estimated means; pooled SD) Cohen's *d*	Between-group effect sizes (within-group ES_{MCT} − within-group ES_{SR}) Cohen's *d*
Morning protocol							
Sleep efficacy (%)							
MCT	40	79.43 (1.89)	84.91 (2.18)	$F(1,2823) = 0.71$	13.96	-0.42	0.04
SRT	39	74.09 (1.90)	81.81 (2.26)	$p = .40$	16.76	-0.46	
Tiredness when going to bed							
MCT	40	4.03 (0.08)	4.02 (0.09)	$F(1,2830) = 9.08$	0.84	0.01	0.51
SRT	39	3.82 (0.08)	4.24 (0.09)	$p = .003$	0.86	-0.50	
Sleep quality							
MCT	40	2.80 (0.07)	2.43 (0.10)	$F(1,2834) = 0.03$	1.04	0.36	0.00
SRT	39	2.83 (0.07)	2.48 (0.10)	$p = .86$	0.96	0.36	
Feeling unrecovered							
MCT	40	3.02 (0.08)	2.63 (0.10)	$F(1,2834) = 0.20$	0.96	0.41	0.07
SRT	39	3.04 (0.08)	2.72 (0.10)	$p = .65$	0.94	0.34	
Evening protocol							
Daytime tiredness							
MCT	39	3.99 (0.18)	3.48 (0.24)	$F(1,2537) = 2.61$	1.85	0.28	0.35
SRT	39	4.01 (0.18)	4.15 (0.24)	$p = .11$	1.87	-0.07	
Concentration							
MCT	39	4.59 (0.16)	5.48 (0.21)	$F(1,2537) = 0.91$	1.72	-0.52	0.18
SRT	39	4.56 (0.15)	5.11 (0.21)	$p = .34$	1.61	-0.34	

Mood							
MCT	39	5.31 (0.16)	5.73 (0.23)	$F(1,2537) = 1.05$	1.53	-0.27	0.21
SRT	39	5.24 (0.16)	5.34 (0.23)	$p = .30$	1.54	-0.06	
Relaxation							
MCT	39	3.39 (0.15)	3.05 (0.18)	$F(1,2537) < 0.01$	1.56	0.22	-0.03
SRT	39	3.44 (0.15)	3.09 (0.18)	$p = .98$	1.40	0.25	

Note. MCT = Multicomponent treatment; SRT = Sleep restriction treatment; [a] Number of participants with a least one value. Time was coded over the 56 days with values from 0-1.

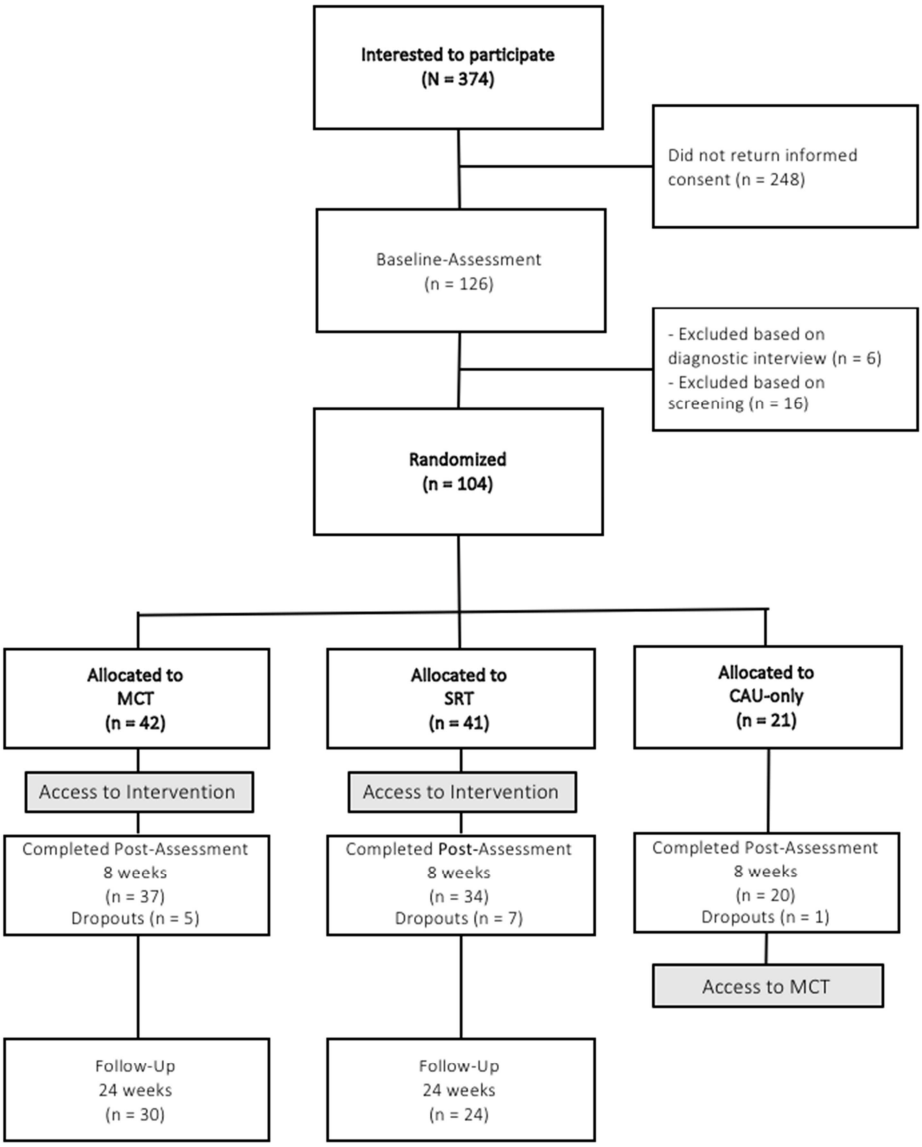

Figure 1. Flow chart (MCT = Multicomponent treatment; SRT = Sleep restriction treatment; CAU = Care as usual)

Highlights

- Internet-based cognitive behavioral treatment (iCBT-I) is effective in insomnia
- An abridged iCBT-I focusing on sleep restriction is effective in insomnia
- The treatment gains remained stable up to 6-month follow-up
- The effects of the two versions of iCBT-I did not differ from each other
- Patients were more satisfied with the full version of iCBT-I