Behaviour Research and Therapy 153 (2022) 104083

Contents lists available at ScienceDirect

Behaviour Research and Therapy

journal homepage: www.elsevier.com/locate/brat

The effects of digital CBT-I on work productivity and activity levels and the mediational role of insomnia symptoms: Data from a randomized controlled trial with 6-month follow-up

Kaia Kjørstad [a,*], Børge Sivertsen [a,c,d], Øystein Vedaa [a,b,c], Knut Langsrud [a,b], Daniel Vethe [a,b], Patrick M. Faaland [a,b], Cecilie L. Vestergaard [a,b], Stian Lydersen [a], Otto R.F. Smith [c], Jan Scott [a,e], Håvard Kallestad [a,b]

[a] Department of Mental Health, Norwegian University of Science and Technology, Trondheim, Norway
[b] Department of Research and Development, St. Olavs University Hospital, Trondheim, Norway
[c] Department of Health Promotion, Norwegian Institute of Public Health, Bergen, Norway
[d] Department of Research and Innovation, Helse-Fonna HF, Haugesund, Norway
[e] Institute of Neuroscience, Newcastle University, Newcastle upon Tyne, UK

ARTICLE INFO

Keywords:
Insomnia
Cognitive behavior therapy
Mediation
Work
Activities of daily living

ABSTRACT

Study objectives: Cognitive behavioral therapy for insomnia (CBT-I) is a well-established treatment for insomnia, but few studies have explored its impact on work and activity impairment.
Methods: Data stem from 1721 participants enrolled in a randomized controlled trial comparing the efficacy of digital CBT-I compared with Patient Education. Baseline and 6-month follow-up assessments included self-reported ratings of presenteeism and general impairment (Work Productivity and Activity Impairment Questionnaire), and absenteeism (hours of missed work) and employment status. Insomnia was measured using the Insomnia Severity Index (ISI). Mediation analyses were conducted for each outcome with ISI scores at baseline and 9-week follow-up as the mediator. The analyses were adjusted for potential confounders (e.g., sex, age, comorbidities).
Results: dCBT-I was found to be associated with reduced activity impairment compared with PE (by 5.6%) but not presenteeism, absenteeism, or changes in employment status. Mediation analysis showed that changes in insomnia severity largely mediated improvements in presenteeism (by 5.4%) and activity impairment (by 5.5%). There were no significant mediational effects on absenteeism or employment status.
Conclusions: This study shows that dCBT-I is not only effective in improving insomnia. But also demonstrates positive effects on work and daily activities in general, supporting the need for increased access to dCBT-I.

1. Introduction

Insomnia has an estimated prevalence of 10–15% (Pallesen et al., 2001, 2014), and is characterized by difficulties with initiating or maintaining sleep, with associated daytime impairment (American Psychiatric Association, 2013). The disorder is associated with adverse health consequences (Sivertsen et al., 2012), reduced quality of life (Kyle et al., 2010) and may lead to reduced workplace productivity (presenteeism), short- and long-term absenteeism (missing scheduled work time), and permanent work disability (Léger & Bayon, 2010; Overland et al., 2008; Sivertsen et al., 2006, 2009, 2012).

The recommended first-line treatment for insomnia is Cognitive Behavioral Therapy for Insomnia (CBT-I) and both face-to-face and digital adaptations of CBT-I (dCBT-I) are shown to be effective in reducing insomnia severity (Morin et al., 2006; Riemann et al., 2017; van Straten et al., 2018; Wilson et al., 2019; Zachariae et al., 2016). In a recent publication using the same dataset as the current study, Vedaa et al. (2020) found a between-group Cohen's *d* effect size of 1.21 on the Insomnia Severity Index (ISI) when comparing dCBT-I with Patient Education about sleep. Furthermore, a systematic review of 86 studies

* Corresponding author. Department of Mental Health, Faculty of Medicine and Health Sciences, Norwegian University of Science and Technology, Østmarkveien 15, 7040, Trondheim, Norway.
E-mail address: kaia.kjorstad@ntnu.no (K. Kjørstad).

https://doi.org/10.1016/j.brat.2022.104083
Received 12 January 2022; Received in revised form 23 March 2022; Accepted 24 March 2022
Available online 31 March 2022

(n = 15578) found that CBT-I has a small-to-moderate effect on daytime functioning and that positive effects on nighttime symptoms are associated with improvement in daytime symptoms (Benz, 2020). However, it is not known if a reduction in insomnia severity mediates any improvement in functioning at work or in activities outside of work, as only a few studies have looked at the effects of CBT-I on work specific variables. For example, a randomized controlled trial (RCT) in a UK community sample showed that, unlike sleep hygiene education, dCBT-I is associated with reduced presenteeism (i.e., less impairment in productivity whilst at work) but not absenteeism (Espie et al., 2019). Interestingly, secondary analysis of the baseline (n = 906) and 48-week post-randomization data (n = 365) in the CBT-I group found reduced levels of presenteeism and absenteeism (Luik et al., 2020). However, these findings should be treated with caution given the high attrition within the CBT-I group and absence of any follow-up data on the control group. Finally, our research group recently reported findings from a small-scale study on work- and activity-related impairment of employed adults (n = 77) with insomnia disorder who received either face-to-face or digital CBT-I (Kjørstad et al., 2021). Using the Work Productivity and Activity Impairment Questionnaire (WPAI; Reilly et al., 1993), we demonstrated that post-intervention remission is associated with improvements in presenteeism and in activities outside of work (irrespective of modality of CBT-I) (Kjørstad et al., 2021).

Taken together, although there is robust evidence that dCBT-I significantly reduces insomnia, there is limited research on its impact on different elements of daytime impairment, such as work productivity or general daily activities (outside of work). Further, the existing studies are small scale and/or hampered by sample attrition. As such, there is a need for more research in this field.

2. Aims

This study uses data from a large-scale community-based RCT comparing the efficacy of dCBT-I with Patient Education about sleep in self-referred adults with insomnia and aims to (1) examine any between-group differences in improvements in work- and activity-related impairment and (2) test whether change in work- and activity related impairment between baseline and 6-month follow-up is mediated by pre-to-post-intervention changes in the severity of insomnia symptoms (i.e., baseline to 9-week follow-up).

3. Methods and materials

De-identified data were obtained on the 1721 participants in our recent RCT comparing the efficacy of a fully automated, self-guided dCBT-I with a control condition for the treatment of insomnia (Vedaa et al., 2020). The trial received ethical approval from the Regional Committees for Medical and Health Research Ethics in Southeast Norway (2015/134) and is registered on the ClinicalTrials.gov website (NCT02558647). Full details of the protocol are available elsewhere (https://ntnuopen.ntnu.no/ntnu-xmlui/handle/11250/2611758) (Kallestad et al., 2018). A flow diagram of the study is shown in the supplementary materials (Supplementary Figure A1). Below, we summarize key information about the RCT and then detail the measures and analyses employed in this study.

3.1. Participants and eligibility

Between February 2016 and July 2018, 5349 individuals commenced the screening process for the RCT. Forty percent of these individuals (n = 2132) discontinued the screening process and a further 28% (n = 1479) declined to participate or were ineligible. The eligibility criteria were as follows: (1) age ≥18 years, (2) scored ≥12 on the Insomnia Severity Index (ISI) (Morin et al., 2011), which is the most sensitive score indicator of insomnia disorder in Norway (Filosa et al., 2020), and (3) willing to sign an online consent form. Individuals were excluded if they met one or more of the following criteria: (1) score >10 on the Epworth Sleepiness Scale (ESS) or reported regular snoring, breathing difficulties and difficulties staying awake during the day, which is indicative of an organic sleep disorder (e.g. sleep apnea or hypersomnia), (2) self-reported a medical condition for which self-guided dCBT-I may be contra-indicated (i.e., epilepsy, bipolar disorder, schizophrenia or psychotic disorders, and recent cardiac surgery), and/or (3) were currently engaged in night shift work and unable to discontinue this work pattern during the trial.

3.2. Interventions

Digital Cognitive Behavioral Therapy for Insomnia (dCBT-I). A Norwegian translation of Sleep Healthy Using the Internet (SHUTi) was used. The SHUTi-program is a fully automated adaptation of traditional face-to-face CBT-I with components such as sleep restriction, stimulus control, cognitive restructuring, sleep hygiene, and relapse prevention (Hagatun et al., 2019; Ritterband et al., 2009, 2017).

Patient Education about sleep. Digital PE is provided via a fixed website and is widely used as a control intervention in RCTs of insomnia treatments (Hagatun et al., 2019; Ritterband et al., 2017). The PE site describes the prevalence, causes, and impact of insomnia, giving advice about when to seek input from a health care professional and includes information about basic lifestyle, environmental, and behavioral strategies that may improve sleep-wake patterns (Ritterband et al., 2017).

3.3. Assessments

For this study, we extracted data on the following- *Demographic and clinical measures.* Participants self-reported demographics and information about any ongoing medical (e.g., cardiac, endocrine, renal, respiratory, skin, joint, and other problems) or mental health (e.g., anxiety, depression, post-traumatic stress disorder (PTSD), alcohol and/or substance use disorder (SUD), eating disorders, attention deficit hyperactivity disorder (ADHD), psychosis, and personality disorders) conditions were noted. The information about the presence or absence of comorbidities was categorized as no comorbidity, medical comorbidity, psychiatric comorbidity, or both.

Insomnia Severity Index (ISI). The ISI was administered at baseline and at 9-week follow-up. The ISI is a validated 7-item, self-report questionnaire that assesses the nature, severity, and impact of insomnia symptoms over the past two weeks and is recommended for use in insomnia research (Bastien, 2001; Buysse et al., 2006; Morin et al., 2011). The total score ranges from 0 to 28, with a higher score indicating greater severity of insomnia symptoms.

Work Productivity and Activity Impairment. Data on the work- and activity-related outcomes due to health problems were collected at baseline and 6-month follow-up. Presenteeism (productivity loss while at work due to health problems) and activity impairment (impairment in daily activities outside of work due to health problems) were assessed using single items from the general health version of the Work Productivity and Activity Impairment Questionnaire (WPAI; Reilly et al., 1993). The WPAI items were scored on a scale from 1 to 10, with a higher score indicating higher impairment. The reported data on presenteeism and activity impairment were then transformed to express levels of impairment in scale percentages. The WPAI has good psychometric properties and has been more frequently used than any other metric of productivity across various occupations and disease areas (Bolge et al., 2009). Two additional items were used to measure absenteeism (hours absent from work) and employment status (binary categorical measure).

3.4. Statistical analysis

Mediation analyses were undertaken by an independent researcher using Mplus version 8.2 (Muthén & Muthén, 1998–2010). For each

outcome, we estimated the direct and indirect effects of the exposure (treatment) on the outcome variable for the mediator (ISI) while adjusting for potential confounders (sex, age, educational attainment, relationship status, and comorbidities). Continuous baseline covariates were grand mean centered. As recommended, we included the exposure-mediator interaction in the model (VanderWeele, 2015). Sensitivity analyses were carried out to examine whether significant (in) direct effect estimates were robust to violations of no unmeasured mediator-outcome confounding (Muthén, 2011) and missing data assumptions (Enders, 2010). The former (no unmeasured mediator-outcome confounding) was tested by developing correlated residual plots in which the size of the residual correlation between outcome and mediator was plotted against the size of the (in)direct effect. For the latter (missing data assumptions), selection models were estimated in which binary missing data indicators were regressed on the dependent variables in the model to mimic a missing-not-at-random scenario. As noted, 9-week ISI scores were available for 1118 (64.9%) of the sample. Data on presenteeism, activity impairment, absenteeism, and employment status were available for 707 (41.1%), 765 (44.5%), 689 (40.0%), and 839 (48.8%) participants, respectively.

All mediators and outcomes were treated as continuous variables, except for employment status. A Bayesian estimator with 95% credibility interval (CI) was used for all models. For employment status, the Bayesian estimator used the probit link function. The Bayesian estimator uses all available data and is valid under the assumption of data missing-at-random (MAR), similar to maximum likelihood estimation.

All indirect/direct effects were derived using the potential outcomes and counterfactual framework. As such, we distinguish between the direct effect (more precisely the pure natural direct effect (PNDE)), the indirect effect (more precisely the total natural indirect effect (TNIE)), and the total effect. Formally, the direct effect represents the effect that would have been realized if the exposure was administered while keeping the mediator at the level it would have taken in the absence of the exposure. In other words, it reflects differences in the outcome measures at 6-month follow-up depending on treatment allocation at baseline controlled for age, sex, education attainment, relationship status, and comorbidities as well as baseline levels of each outcome variable and the baseline level of the mediator (ISI score). The indirect effect represents the difference between the mean in the treatment group with the mediator varying as it would have under the treatment condition and the mean in the treatment group with the mediator varying as it would have under the control condition (i.e., the counterfactual). In other words, the indirect effect represents the effects on the outcome measures related to the changes in the mediator (insomnia symptom severity) from baseline to 9-week follow-up. The total effect is the sum of the direct and the indirect effect. If there are significant total effects, but no direct effects, the total effect will be driven by the indirect effect and vice versa. The analysis model is illustrated by the directed acyclic graph (DAG) in Fig. 1. An example of Mplus input commands is shown in the supplementary material (Appendix A).

4. Results

4.1. Descriptive statistics

Table 1 describes key demographic and clinical characteristics of the RCT participants included in this study. The sample had a mean age of 44.4 years (SD = 13.9 years), was predominantly female (73.3%), mostly married or cohabitating (63.3%), and college educated or higher (73.8%). The mean duration of self-reported insomnia was 13.7 years (SD = 10.8 years), and more than half (58.1%) self-reported at least one comorbid disorder.

Table 2 shows ISI scores at baseline and 9-week follow-up and work and activity-related outcomes (presenteeism, activity impairment, absenteeism, and employment status) at baseline and 6-month follow-up for the overall sample, and for dCBT-I and PE, respectively. Participants randomized to dCBT-I experienced a mean reduction in ISI score from 19.2 (SD = 3.9) to 10.4 (SD = 6.2), and participants in the control condition experienced a mean reduction from 19.6 (SD = 4.0) to 15.2 (SD = 5.3). For the overall sample, levels of presenteeism and activity impairment were reduced by 9.4% and 12.4%, respectively. Absenteeism in the study sample was reduced by 4.0 h and employment status for the overall sample remained virtually unchanged (69.2% vs 70.6%); see Table 2 for further details. Between-group Cohen's *d* effect sizes on the mediator and the work- and activity-related outcomes are reported in the supplementary material (Appendix A).

Table 1
Demographic and clinical information of the study sample.

	Digital CBT-I (n = 868)	Patient Education (n = 853)	All (n = 1721)
Age, mean (SD), years	44.2 (14.1)	44.7 (13.8)	44.4 (13.9)
Female, %	75.3	71.3	73.3
Relationship status, n (%)			
Married/cohabiting with partner	551 (63.5)	543 (63.6)	1094 (63.6)
Divorced, separated, or never married	316 (36.5)	310 (36.4)	626 (36.4)
Education attainment, n (%)			
High school or less	230 (26.5)	219 (25.7)	449 (26.1)
College or bachelor's degree	391 (45.1)	418 (48.9)	809 (47.0)
Higher degree	246 (28.4)	216 (25.3)	462 (26.8)
Insomnia duration, mean (SD), years	13.9 (10.8)	13.5 (10.9)	13.7 (10.8)
Comorbidity, n (%)			
No comorbidity	380 (43.9)	339 (39.8)	719 (41.9)
Medical comorbidity	102 (11.8)	109 (12.8)	211 (12.3)
Mental health comorbidity	303 (35.0)	286 (33.6)	589 (34.2)
Medical and mental health comorbidity	81 (9.4)	118 (13.8)	199 (11.6)

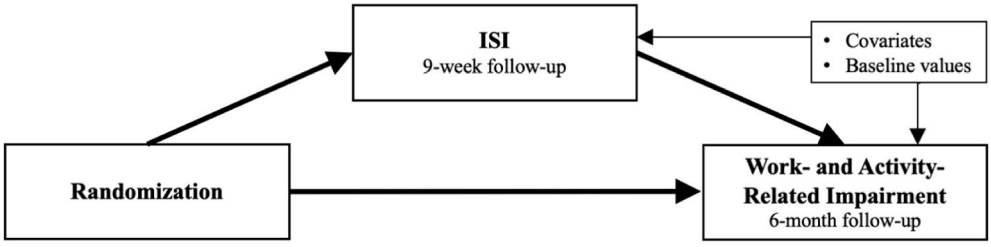

Fig. 1. A directed acyclic graph showing the analysis model. In addition, an interaction between treatment and ISI 9-week post-randomization was included in the model.

Table 2
Descriptive statistics of the mediator (ISI score) at baseline and 9-week follow-up, and the outcome variables at baseline and 6-month follow-up.

	n	dCBT-I	n	Patient Education	n	Total
ISI score, mean (SD)						
Baseline	868	19.2 (3.9)	853	19.6 (4.0)	1721	19.4 (3.9)
9-week follow-up	584	10.4 (6.2)	534	15.2 (5.3)	1118	12.7 (6.3)
Presenteeism[a b], % mean (SD)						
Baseline	785	28.1 (25.4)	773	30.5 (27.0)	1558	29.3 (26.2)
6-month follow-up	370	17.5 (24.0)	337	22.5 (25.1)	707	19.9 (26.6)
Activity impairment[a c], % mean (SD)						
Baseline	867	41.6 (29.6)	853	43.9 (28.8)	1720	42.7 (29.2)
6-month follow-up	400	27.9 (28.8)	365	33.0 (29.5)	765	30.3 (29.2)
Absenteeism, mean (SD), hours						
Baseline	805	10.5 (26.5)	792	10.3 (23.5)	1597	10.4 (25.1)
6-month follow-up	359	6.6 (19.8)	330	6.2 (17.0)	689	6.4 (18.5)
Employed, n (%)						
Baseline	867	590 (68.1)	853	601 (70.5)	1720	1191 (69.2)
6-month follow-up	433	296 (68.4)	406	296 (72.9)	839	592 (70.6)

[a] From the "Work Productivity and Activity Impairment Questionnaire: General Health (WPAI).
[b] Average reduced productivity while working.
[c] Average reduced productivity in daily activities outside of work.

4.2. Effect of dCBT-I on work-related outcomes and the mediational role of insomnia symptoms

Treatment effect. As shown in Table 3, the analysis demonstrated a significant total effect of dCBT-I compared with PE on activity impairment outside of work (estimated effect −5.6% in favor of dCBT-I). There were no significant total effects on presenteeism, absenteeism, or employment status.

Mediation effects. In the mediation analysis, we found a significant indirect effect of the mediator on presenteeism (estimated effect −5.4%) and activity impairment (estimated effect −5.5%) at 6-month follow-up. There were no significant indirect effects on absenteeism or employment status.

Results from the sensitivity analyses of unmeasured confounders and the MNAR selection models can be found in the supplementary material (Appendix A).

Table 3
The direct effect, indirect effect, and total effect of treatment on the outcome variables at 6-month follow-up for the mediator (insomnia symptom severity; ISI) at 9-week follow-up. The analyses are adjusted for sex, age, educational level, relationship status, and comorbidities, as well as for the baseline value of the ISI and the outcome variable. 95% confidence intervals are shown in parentheses. The analyses assume a data missing-at-random scenario.

	Presenteeism, %	Activity impairment, %	Absenteeism, hours	Employment, probit link scale
ISI				
Direct effect	1.4 (−3.5 to 6.3)	−0.2 (−5.4 to 5.3)	2.18 (−1.31 to 5.82)	-.021 (−.11 to .065)
Indirect effect	**−5.4* (-7.8 to -3.1)**	**−5.5* (-8.1 to -3.0)**	-.90 (−2.68 to .77)	.008 (−.031 to .045)
Total effect	−4.0 (−8.1 to 0.1)	**−5.6* (-9.9 to -1.0)**	1.29−1.71 to 4.19)	-.012 (−.090 to .057)

*$p < .05$.

5. Discussion

The purpose of the present study was two-fold. First, we investigated if dCBT-I was associated with better work and activity-related outcomes at 6-month follow-up compared with PE. We found that participants randomized to dCBT-I demonstrated significantly less activity impairment, but there were no statistically significant changes in presenteeism, absenteeism, or employment status depending on treatment allocation. Second, we explored whether changes in work- and activity-related outcomes were mediated by change in severity of insomnia symptoms between baseline and 9-week follow-up. This analysis showed that changes in presenteeism and activity impairment, but not absenteeism or employment status, were largely mediated by change in insomnia severity.

Baseline assessment demonstrated that some form of work or social impairment occurs in at least 40% of individuals recruited to an RCT of interventions for insomnia. This degree of impairment is similar to that of other studies. For example, an RCT about the effect of insomnia treatment (sleep restriction therapy or CBT-I) on daytime functioning and work performance in postmenopausal women reported similar levels of impairment in activities outside of work (~40% impairment) and at work (~30% productivity loss) prior to treatment (Kalmbach et al., 2019). Kalmbach et al. (2019) reported that trial participants reported moderate improvements in both activity impairment (~20% improvement; Cohen's $d = 0.63$) and presenteeism (~15% improvement; Cohen's $d = 0.50$) at 6-month follow-up. On average, our study sample reported 12.4% less impairment in daytime activities outside of work and a 9.4% productivity gain at work (i.e., reduced presenteeism attributed to health problems). The differences in the observed effects on activity impairment (~20% vs. 12.4%) and presenteeism (~15% vs. 9.4%) between these two studies might partly be explained by slight differences in how the outcomes were measured (impairment due to work-specific issues vs. impairment due to health problems).

Further, Kalmbach and colleagues did not control for the effects of covariates nor explore the mediational role of insomnia symptoms on daytime impairment. In our study, we found that the changes in both presenteeism and activities outside of work were largely mediated by change in insomnia symptom severity. As such, participants randomized to dCBT-I appear to experience 5.6% less activity impairment compared with participants in the control condition, not only as an effect of treatment allocation but likely also because participants randomized to dCBT-I showed more improvement in insomnia symptoms. Although this issue is under-explored, some support for this idea comes from an RCT that showed that change in insomnia symptom severity mediates a moderate reduction in presenteeism after approximately 2 months (8 weeks; Cohen's $d = -0.41$) and 6 months (24 weeks; Cohen's $d = -0.42$) (Espie et al., 2019).

The major difference between the two conditions is that the dCBT-I intervention presents information over a 6-week course and introduces the participants to a significantly larger volume of comprehensive therapeutic material, in addition to conducting a partially individually tailored follow-up of the participants. In particular, the tailoring of the sleep restriction regime and participant adherence to a strict rise time would allow participants more time to pursue daily activities by spending more time out of bed. It could also be that they feel less tired and have more energy to pursue daily activities (i.e., their productivity improves in parallel with reductions in a range of insomnia symptoms).

Overall, the participants in our study (independent of treatment allocation) reported a 9.4% productivity gain at work (i.e., reduced presenteeism attributed to health problems). Approximately half of the gain (5.4% divided by 9.4% = 57%) was mediated by lessening of insomnia symptoms. As there was no direct effect of treatment allocation on presenteeism (i.e., no total effect), the estimated, but nonsignificant, 4.0% difference between conditions in favor of dCBT-I (as shown in Table 3) is likely explained by the fact that participants who received dCBT-I experienced more improvement in insomnia symptoms

than participants in the control condition (i.e., the mediational effect).

Focusing on work functioning, the overall reduction in the levels of presenteeism in our sample (~10%) may sound modest but equates to approximately 4 more hours of effective work time during a 37.5 h working week. Assuming a work year of 48 weeks, we can extrapolate that offering interventions for insomnia could lead to an overall productivity gain equivalent to 4.4 weeks per year per individual compared with not getting access to such an intervention (Bolge et al., 2009). However, the overall estimate of improvement in presenteeism is based on descriptive data, and it cannot be ascertained whether the observed ~10% improvement is attributable to the dCBT-I, improvements in insomnia symptoms, or other non-specific factors, but the mediation analyses demonstrate that approximately half of the 4.4 weeks of productivity gain (i.e., 57% or 2.5 weeks per year per individual) is directly attributable to the improvements regarding insomnia symptoms during treatment. Kessler et al. (2011) similarly estimated the lost work productivity associated specifically with insomnia to be 2.3 weeks (11.3 days) per year per individual (adjusted for age, sex, and education attainment) and that complete eradication of insomnia would lead to proportional reductions of between 5.4% and 7.8% of all population-level lost work performance due to presenteeism. Likewise, Darden et al. (2020), employing more conservative assumptions, estimated that untreated insomnia was associated with a productivity loss of 1.9 weeks per individual per year, and that insomnia was associated with 1 extra week of absence from work compared with individuals without insomnia (extrapolated by dividing estimates of annual costs by median hourly salary). Their estimates did not consider the effect of comorbidity, whereas our sample included insomnia alone (42%) or in combination with comorbid conditions (58%), which may partly explain the slightly higher estimate of presenteeism in our study. However, this should be considered a strength rather than a weakness of our project, as insomnia in the community frequently co-occurs with physical and mental disorders.

Taken together, the findings on activity impairment and presenteeism support the established connection of insomnia with reduced work productivity and activity impairment, and they suggest that treatment of insomnia and reduction of insomnia symptoms, to some degree, reverse daytime impairment. Nonetheless, we need to consider why we find that insomnia symptoms only play a limited role in mediating activity impairment and presenteeism. As argued in the systematic review performed by Benz and colleagues (2020), we speculate that the findings reflect that while there are effects on daytime symptoms (such as reduced daytime sleepiness, stress, improved daytime and social functioning, etc.), they will predominantly be small to moderate compared to the far stronger effects on the core symptoms of insomnia unless therapeutic techniques that directly address daytime symptoms are added.

We found no effects of dCBT-I or changes in insomnia severity on absenteeism. Similarly, the RCT on postmenopausal women showed no effect on absenteeism 6 months after treatment (Kalmbach et al., 2019). In another recent study, we were also unable to demonstrate an effect of CBT-I (face-to-face or online) on absenteeism in patients referred to treatment with CBT-I at an outpatient public sleep clinic (Kjørstad et al., 2021). One possible explanation for this could be that insomnia is more closely related to presenteeism than absenteeism (Johns, 2009), and that absenteeism may be a reflection of many factors other than sleep. It may further be difficult to differentiate the effects of poor sleep by itself from those of e.g., chronic diseases or work conditions that may simultaneously have an impact on sleep (Leger, 2014). Therefore, we speculate that in considering absenteeism, a very high threshold is set for testing the direct or indirect impact of any therapy on work and social functioning (Johns, 2009). However, Espie et al. (2019) found a significant but small effect in terms of reduced absenteeism attributed specifically to poor sleep after approximately 6 months (Cohen's $d = 0.013$) but not at earlier time-points (mid-treatment and post-treatment). This implies that reversal of absence from work caused by insomnia takes time to manifest, although we cannot ascertain whether the participants of their study had indeed increased work attendance, or, rather, had started attributing their absence to causes other than poor sleep.

Lastly, we found no effects of dCBT-I or changes in insomnia severity on employment status. Gaining employment after unemployment (or becoming unemployed and receive social benefits) is usually a process that takes time, and 6 months might not be sufficient to capture the subtle effects of dCBT-I or a reduction in insomnia symptom severity on an individual's employment status. Individual needs when applying for, changing, or quitting jobs may vary depending on profession (e.g., physically demanding work versus a desk job), personal economic drivers (e.g., national policies on social security), workload (e.g., the possibility of a gradual return to the work force), or e.g., the presence or nature of comorbid health problems. Thus, employment status assessed as a binary measure is not sensitive to subtle changes in an individual's affiliation with working life. Future research should consider more sensitive measures of affiliation with working life (e.g., number of job adverts read, applications sent, or interviews attended) and make use of employer and/or national registry data.

5.1. Strengths and limitations

There are some strengths of the present study. One strength was the RCT design with a sufficient sample size to detect small effects and to investigate whether the effects on work- and activity at 6 months are mediated by change in insomnia severity during the intervention. This reduces the risk of false negatives (type I errors). Further, the statistical analyses were performed as recommended in the literature (Vander-Weele, 2015).

The present work has some limitations that should be addressed. For instance, there is significant participant attrition at the 6-month follow-up (~60%). This is a major challenge in research involving repeated measures, and the observed effects may be explained by the differences between individuals who leave a study and those who do not (Nunan et al., 2018). To address this possibility, preventive steps were taken when designing the present study (e.g., recruitment of a sufficiently large sample and randomized allocation to either the intervention or the control condition) and sensitivity analyses of the data were performed to investigate whether there were systematic differences in symptom severity, age, sex, relationship status, educational attainment, or comorbidities prior to the intervention between those who completed the 6-month follow-up assessment and those who did not (see Supplementary Table A2). We did not find evidence that the attrition was associated with systematic differences in any of the abovementioned variables or that the attrition biased the results of the mediation analysis. However, results from the mediation analyses should be interpreted with caution, as sensitivity analyses indicated that the possibility for the impact of significant mediator-outcome confounding on the estimated indirect effects could not be excluded. Furthermore, the present study was a secondary analysis of data from an RCT, and its main aim was to investigate the effects of digital CBT-I on insomnia disorder symptom severity compared with a control condition (Patient Education). As such, some of the participants were unemployed at baseline. Further, the included measure of absenteeism in the present study is a proxy measure with participants only reporting the number of hours absent from work, and, therefore, we were unable to calculate, e.g., percentage of work hours absent. The RCT was, however, designed with a large enough sample size to have sufficient statistical power (80%) to also detect significant differences ($p < 0.05$) in rates of sick leave (Kallestad et al., 2018), so although the measure included here is not perfect, we are confident that any effects of insomnia severity on sick leave would have detected them with our proxy measure. Another limitation of this work is that we have not obtained objective data on sleep or daytime impairment. The usefulness of objective sleep data for insomnia is in itself questionable, as it does not predict the outcome of treatment with CBT-I (Galbiati et al., 2021), but the lack of objective data on

absenteeism and employment status over longer time periods implies that our results regarding these outcomes should be interpreted with some caution. Finally, self-report questionnaires on symptoms and degree of impairment are vulnerable to biases (e.g., recall bias or social desirability as discussed above) (Demetriou et al., 2015). Therefore, another important consideration is that individuals interested in digital mental health interventions are likely older, females, separated/divorced, and highly educated compared to those who chose not to participate, for which the ease and convenience of use versus finding time to participate is a major barrier to their participation (Crisp & Griffiths, 2014). Thus, a possible self-selection bias in the sample might indicate that digital versions of mental health interventions, while being effective, might not be suitable for or preferred by all individuals who need treatment for a mental health condition such as insomnia. Therefore, future studies should investigate whether a brief version of dCBT-I, which requires a lower time commitment, could benefit individuals who are hesitant to participate due to busy schedules.

6. Conclusions

The results of this trial suggest that dCBT-I is not only effective in improving insomnia symptoms but also demonstrates positive effects on work and daily activities in general. In addition, improvements related to the severity of insomnia symptoms serve as a mediator of these benefits. These results demonstrate that interventions targeted at insomnia can have positive benefits on the around-the-clock symptoms associated with this problem. Given that CBT-I is one of the most effective interventions available, this study offers evidence of potential clinical, social, and economic benefits that further support calls for increased access to this therapy. We acknowledge that these findings need confirmation and that future studies designed to specifically examine work and social impairment are also needed. These might include studies that explore whether face to face CBT-I demonstrates a bigger effect size for changes in work and social impairment than dCBT-I. This is relevant as access to face-to-face therapy is more restricted than access to digital therapies. Moreover, given that even subtle changes in an individual's work productivity can have personal and societal impacts, additional, more detailed health economic analyses are required that include examination of employer record data on work participation and function as well as objective data from national work and disability registries.

Declaration of competing interest

The authors declare that they have no competing interests.

Relationships

There are no additional relationships to disclose.

Patents and intellectual property

There are no patents to disclose.

Other activities

There are no additional activities to disclose.

Funding

This study was funded by the Research Council of Norway (grant number 239985), the Liaison Committee for education, research, and innovation in Central Norway (grant number 90061500), and the Dam Foundation for Health and Rehabilitation (project number 2018/FO198760).

CRediT authorship contribution statement

Kaia Kjørstad: Conceptualization, Formal analysis, Data curation, Writing – original draft. **Børge Sivertsen:** Conceptualization, Writing – review & editing, Supervision, Project administration, Funding acquisition. **Øystein Vedaa:** Investigation, Data curation, Writing – review & editing, Project administration. **Knut Langsrud:** Conceptualization, Writing – review & editing. **Daniel Vethe:** Data curation, Writing – review & editing. **Patrick M. Faaland:** Writing – review & editing. **Cecilie L. Vestergaard:** Writing – review & editing. **Stian Lydersen:** Formal analysis. **Otto R.F. Smith:** Methodology, Formal analysis. **Jan Scott:** Writing – review & editing, Supervision. **Håvard Kallestad:** Conceptualization, Investigation, Supervision, Funding acquisition.

Acknowledgements

The authors would like to thank the patient user group, Regionalt brukerutvalg Helse Midt-Norge, for their contributions when designing the trial.

Appendix A. Supplementary data

Supplementary data to this article can be found online at https://doi.org/10.1016/j.brat.2022.104083.

References

American Psychiatric Association. (2013). *Diagnostic and statistical manual of mental disorders* (5th ed.). American Psychiatric Association. https://doi.org/10.1176/appi.books.9780890425596

Bastien, C. (2001). Validation of the Insomnia Severity Index as an outcome measure for insomnia research. *Sleep Medicine, 2*(4), 297–307. https://doi.org/10.1016/S1389-9457(00)00065-4

Benz, F. (2020). The efficacy of cognitive and behavior therapies for insomnia on daytime symptoms_ A systematic review and network meta-analysis. *Clinical Psychology Review, 24*.

Bolge, S. C., Doan, J. F., Kannan, H., & Baran, R. W. (2009). Association of insomnia with quality of life, work productivity, and activity impairment. *Quality of Life Research, 18*(4), 415–422. https://doi.org/10.1007/s11136-009-9462-6

Buysse, D. J., Ancoli-Israel, S., Edinger, J. D., Lichstein, K. L., & Morin, C. M. (2006). Recommendations for a standard research assessment of insomnia. *Sleep, 29*(9), 1155–1173. https://doi.org/10.1093/sleep/29.9.1155

Crisp, D. A., & Griffiths, K. M. (2014). Participating in online mental health interventions: Who is most likely to sign up and why? *Depression Research and Treatment*, 1–11. https://doi.org/10.1155/2014/790457, 2014.

Darden, M., Espie, C. A., Carl, J. R., Henry, A. L., Kanady, J. C., Krystal, D., & Miller, C. B. (2020). *Cost-effectiveness of digital CBT (Sleepio) for insomnia: A Markov simulation model in the United States* (Vol. 37).

Demetriou, C., Ozer, B. U., & Essau, C. A. (2015). Self-report questionnaires. In R. L. Cautin, & S. O. Lilienfeld (Eds.), *The encyclopedia of clinical psychology* (pp. 1–6). John Wiley & Sons, Inc. https://doi.org/10.1002/9781118625392.wbecp507.

Enders, C. K. (2010). *Applied missing data analysis*. Guilford Press.

Espie, C. A., Emsley, R., Kyle, S. D., Gordon, C., Drake, C. L., Siriwardena, A. N., Cape, J., Ong, J. C., Sheaves, B., Foster, R., Freeman, D., Costa-Font, J., Marsden, A., & Luik, A. I. (2019). 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, 76*(1), 21. https://doi.org/10.1001/jamapsychiatry.2018.2745

Filosa, J., Omland, P. M., Langsrud, K., Hagen, K., Engstrøm, M., Drange, O. K., Knutsen, A. J., Brenner, E., Kallestad, H., & Sand, T. (2020). Validation of insomnia questionnaires in the general population: The Nord-Trøndelag health study (HUNT). *Journal of Sleep Research*. https://doi.org/10.1111/jsr.13222

Galbiati, A., Sforza, M., Leitner, C., Castelnovo, A., D'Este, G., Ferini-Strambi, L., Manconi, M., & Castronovo, V. (2021). The reliability of objective total sleep time in predicting the effectiveness of cognitive-behavioral therapy for insomnia. *Sleep Medicine, 82*, 43–46. https://doi.org/10.1016/j.sleep.2021.03.021

Hagatun, S., Vedaa, Ø., Nordgreen, T., Smith, O. R. F., Pallesen, S., Havik, O. E., Bjorvatn, B., Thorndike, F. P., Ritterband, L. M., & Sivertsen, B. (2019). The short-term efficacy of an unguided internet-based cognitive-behavioral therapy for insomnia: A randomized controlled trial with a six-month nonrandomized follow-up. *Behavioral Sleep Medicine, 17*(2), 137–155. https://doi.org/10.1080/15402002.2017.1301941

Johns, G. (2009). Presenteeism in the workplace: A review and research agenda. *Journal of Organizational Behavior, 31*(4), 519–542. https://doi.org/10.1002/job.630

Kallestad, H., Vedaa, Ø., Scott, J., Morken, G., Pallesen, S., Harvey, A. G., Gehrman, P., Thorndike, F., Ritterband, L., Stiles, T. C., & Sivertsen, B. (2018). Overcoming insomnia: Protocol for a large-scale randomised controlled trial of online cognitive

behaviour therapy for insomnia compared with online patient education about sleep. *BMJ Open, 8*(8), Article e025152. https://doi.org/10.1136/bmjopen-2018-025152
Kalmbach, D. A., Cheng, P., Arnedt, J. T., Cuamatzi-Castelan, A., Atkinson, R. L., Fellman-Couture, C., Roehrs, T., & Drake, C. L. (2019). Improving daytime functioning, work performance, and quality of life in postmenopausal women with insomnia: Comparing cognitive behavioral therapy for insomnia, sleep restriction therapy, and sleep hygiene education. *Journal of Clinical Sleep Medicine, 15*, 999–1010. https://doi.org/10.5664/jcsm.7882, 07.
Kessler, R. C., Berglund, P. A., Coulouvrat, C., Hajak, G., Roth, T., Shahly, V., Shillington, A. C., Stephenson, J. J., & Walsh, J. K. (2011). Insomnia and the performance of US workers: Results from the America insomnia survey. *Sleep, 34*(9), 1161–1171. https://doi.org/10.5665/SLEEP.1230
Kjørstad, K., Sivertsen, B., Vedaa, Ø., Langsrud, K., Faaland, P. M., Vethe, D., Vestergaard, C. L., Scott, J., & Kallestad, H. (2021). The effect of reducing insomnia severity on work- and activity-related impairment. *Behavioral Sleep Medicine, 19*(4), 505–515. https://doi.org/10.1080/15402002.2020.1799792
Kyle, S. D., Morgan, K., & Espie, C. A. (2010). Insomnia and health-related quality of life. *Sleep Medicine Reviews, 14*(1), 69–82. https://doi.org/10.1016/j.smrv.2009.07.004
Leger, D. (2014). *Working with poor sleep*. SLEEP. https://doi.org/10.5665/sleep.3978
Léger, D., & Bayon, V. (2010). Societal costs of insomnia. *Sleep Medicine Reviews, 14*(6), 379–389. https://doi.org/10.1016/j.smrv.2010.01.003
Luik, A. I., Marsden, A., Emsley, R., Henry, A. L., Stott, R., Miller, C. B., & Espie, C. A. (2020). Long-term benefits of digital cognitive behavioural therapy for insomnia: Follow-up report from a randomized clinical trial. *Journal of Sleep Research, 29*(4). https://doi.org/10.1111/jsr.13018
Morin, C. M., Belleville, G., Bélanger, L., & Ivers, H. (2011). The insomnia severity Index: Psychometric indicators to detect insomnia cases and evaluate treatment response. *Sleep, 34*(5), 601–608. https://doi.org/10.1093/sleep/34.5.601
Morin, C. M., Bootzin, R. R., Buysse, D. J., Edinger, J. D., Espie, C. A., & Lichstein, K. L. (2006). Psychological and behavioral treatment of insomnia: Update of the recent evidence (1998–2004). *Sleep, 29*(11), 1398–1414. https://doi.org/10.1093/sleep/29.11.1398
Muthén, B. O. (2011). *Applications of causally defined direct and indirect effects in mediation analysis using SEM in Mplus*. Unpublished Manuscript.
Muthén, L. K., & Muthén, B. O. (1998). *Mplus user's guide* (6th ed.). Los Angeles, CA: Muthén & Muthén.
Nunan, D., Aronson, J., & Bankhead, C. (2018). Catalogue of bias: Attrition bias. *BMJ Evidence-Based Medicine, 23*(1), 21–22. https://doi.org/10.1136/ebmed-2017-110883
Overland, S., Glozier, N., Sivertsen, B., Stewart, R., Neckelmann, D., Krokstad, S., & Mykletun, A. (2008). *A Comparison of Insomnia and Depression as Predictors of Disability Pension: The HUNT Study. 31* p. 6), 6.
Pallesen, S., Nordhus, I. H., Nielsen, G. H., Havik, O. E., Kvale, G., Johnsen, B. H., & Skjøtskift, S. (2001). Prevalence of insomnia in the adult Norwegian Population.pdf. *Sleep, 24*(7), 771–779. https://doi.org/10.1093/sleep/24.7.771
Pallesen, S., Sivertsen, B., Nordhus, I. H., & Bjorvatn, B. (2014). A 10-year trend of insomnia prevalence in the adult Norwegian population. *Sleep Medicine, 15*(2), 173–179. https://doi.org/10.1016/j.sleep.2013.10.009
Reilly, M. C., Zbrozek, A. S., & Dukes, E. M. (1993). The validity and reproducibility of a work productivity and activity impairment instrument. *PharmacoEconomics, 4*(5), 353–365. https://doi.org/10.2165/00019053-199304050-00006
Riemann, D., Baglioni, C., Bassetti, C., Bjorvatn, B., Dolenc Groselj, L., Ellis, J. G., Espie, C. A., Garcia-Borreguero, D., Gjerstad, M., Gonçalves, M., Hertenstein, E., Jansson-Fröjmark, M., Jennum, P. J., Leger, D., Nissen, C., Parrino, L., Paunio, T., Pevernagie, D., Verbraecken, J., & Spiegelhalder, K. (2017). European guideline for the diagnosis and treatment of insomnia. *Journal of Sleep Research, 26*(6), 675–700. https://doi.org/10.1111/jsr.12594
Ritterband, L. M., Thorndike, F. P., Gonder-Frederick, L. A., Magee, J. C., Bailey, E. T., Saylor, D. K., & Morin, C. M. (2009). Efficacy of an internet-based behavioral intervention for adults with insomnia. *Archives of General Psychiatry, 66*(7), 8.
Ritterband, L. M., Thorndike, F. P., Ingersoll, K. S., Lord, H. R., Gonder-Frederick, L., Frederick, C., Quigg, M. S., Cohn, W. F., & Morin, C. M. (2017). Effect of a web-based cognitive behavior therapy for insomnia intervention with 1-year follow-up: A randomized clinical trial. *JAMA Psychiatry, 74*(1), 68. https://doi.org/10.1001/jamapsychiatry.2016.3249
Sivertsen, B., Overland, S., Neckelmann, D., Glozier, N., Krokstad, S., Pallesen, S., Nordhus, I. H., Bjorvatn, B., & Mykletun, A. (2006). The long-term effect of insomnia on work disability. *American Journal of Epidemiology, 163*(11), 1018–1024. https://doi.org/10.1093/aje/kwj145
Sivertsen, B., Øverland, S., Pallesen, S., Bjorvatn, B., Nordhus, I. H., Maeland, J. G., & Mykletun, A. (2009). Insomnia and long sleep duration are risk factors for later work disability. The Hordaland Health Study. *Journal of Sleep Research, 18*(1), 122–128. https://doi.org/10.1111/j.1365-2869.2008.00697.x
Sivertsen, B., Salo, P., Mykletun, A., Hysing, M., Pallesen, S., Krokstad, S., Nordhus, I. H., & Øverland, S. (2012). The bidirectional association between depression and insomnia: The HUNT study. *Psychosomatic Medicine, 74*(7), 758–765. https://doi.org/10.1097/PSY.0b013e3182648619
van Straten, A., van der Zweerde, T., Kleiboer, A., Cuijpers, P., Morin, C. M., & Lancee, J. (2018). Cognitive and behavioral therapies in the treatment of insomnia: A meta-analysis. *Sleep Medicine Reviews, 38*, 3–16. https://doi.org/10.1016/j.smrv.2017.02.001
VanderWeele, T. J. (2015). *Explanation in causal inference: Methods for mediation and interaction*. Oxford University Press.
Vedaa, Ø., Kallestad, H., Scott, J., Smith, O. R. F., Pallesen, S., Morken, G., Langsrud, K., Gehrman, P., Thorndike, F. P., Ritterband, L. M., Harvey, A. G., Stiles, T., & Sivertsen, B. (2020). Effects of digital cognitive behavioural therapy for insomnia on insomnia severity: A large-scale randomised controlled trial. *The Lancet Digital Health, 2*(8), e397–e406. https://doi.org/10.1016/S2589-7500(20)30135-7
Wilson, S., Anderson, K., Baldwin, D., Dijk, D.-J., Espie, A., Espie, C., Gringras, P., Krystal, A., Nutt, D., Selsick, H., & Sharpley, A. (2019). British Association for Psychopharmacology consensus statement on evidence-based treatment of insomnia, parasomnias and circadian rhythm disorders: An update. *Journal of Psychopharmacology, 33*(8), 923–947. https://doi.org/10.1177/0269881119855343
Zachariae, R., Lyby, M. S., Ritterband, L. M., & O'Toole, M. S. (2016). Efficacy of internet-delivered cognitive-behavioral therapy for insomnia – a systematic review and meta-analysis of randomized controlled trials. *Sleep Medicine Reviews, 30*, 1–10. https://doi.org/10.1016/j.smrv.2015.10.004