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ORIGINAL RESEARCH

Insomnia is Associated with the Effect of Inpatient Multimodal Occupational Rehabilitation on Work Participation in Workers with Musculoskeletal or Mental Health Disorders: Secondary Analyses of a Randomized Clinical Trial

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Study Objectives: Insomnia is common among people with musculoskeletal and/or mental health disorders. This study aimed to assess whether insomnia is associated with the favorable effect from inpatient multimodal occupational rehabilitation on future work participation among individuals with these conditions.

Methods: Insomnia was measured at baseline through a randomized clinical trial that compared the effect of inpatient multimodal occupational rehabilitation with a less-comprehensive program of outpatient acceptance and commitment therapy on future work participation. The inpatient multimodal program lasted 3.5 weeks at the rehabilitation center, comprising psychoeducational sessions (including sleep education), fixed schedules, acceptance and commitment therapy, physical exercise and work-related problem-solving, whereas the outpatient program comprised mainly six weekly acceptance and commitment therapy sessions. Both programs were group-based. The study tracked cumulative sick leave during the 12 months of follow-up using national registry data.

Results: Among the 163 adults included in this subgroup analysis, 56% (n=91) reported insomnia. Overall, we found statistical evidence of interaction between the occupational program and insomnia concerning cumulative sick leave ($p=0.03$). Compared with people without insomnia in the comprehensive inpatient multimodal program, people with insomnia had 12 (95% CI: -48 to 24) fewer days with sick leave if they participated in the inpatient program and 46 (95% CI: 8 to 83) more days if they participated in the outpatient program.

Conclusion: These findings suggest that insomnia should be addressed specifically before individuals on sick leave are considered for participation in occupational rehabilitation and that individuals with insomnia may benefit in particular from inpatient rehabilitation.

Keywords: sleep problems, occupational therapy, work, chronic pain, mental health, sick leave

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Introduction

Musculoskeletal and common mental health disorders are the greatest contributors to work disability in the Western world.¹ To improve work functioning and reduce costs associated with work disability from these conditions, implementation of multimodal occupational programs for sick-listed workers is recommended.²

However, results on the effect of such programs are inconsistent,^{3–6} possibly because of the large heterogeneity among workers with musculoskeletal and mental health disorders.^{7,8} Considering the high costs of providing inpatient programs, it is essential to gain further insight about subgroups that would benefit the most.

Several studies suggest a strong link between insomnia and the risk of sick leave and work disability due to musculoskeletal and mental health disorders,^{9–11} and it has been implied that insomnia should be recognized and targeted in occupational rehabilitation and prevention programs.¹² Insomnia is common among people with musculoskeletal disorders¹³ or mental health disorders,¹⁴ and it plays an important role in the risk and progression of these conditions.^{15–20} Additionally, these conditions appear to be bidirectionally related, where musculoskeletal pain and mental health disorders also increase the risk of insomnia.^{21,22} Inpatient rehabilitation programs incorporate principles known to be helpful for good sleep quality,^{23,24} such as physical exercise,^{25,26} psychoeducational sessions, including sleep education, and fixed schedules.²⁷ However, few studies have examined whether insomnia is associated with the beneficial effect of such programs on future work participation. This knowledge may help determine who will benefit from such programs and provide valuable input on the development of effective interventions.

In a recent randomized clinical trial of sick-listed individuals with musculoskeletal or mental health disorders, we found that individuals participating in a 3.5-week-long inpatient multimodal occupational rehabilitation program had 32 fewer sickness absence days during 12 months of follow-up than a less-comprehensive outpatient program.²⁴ The inpatient program consisted of various treatment modalities, such as physical exercise, psychoeducation, acceptance and commitment therapy, work-related problem solving and the development of a written return to work plan, while the outpatient program consisted mainly of acceptance and commitment therapy.²⁴ The present study aimed to examine whether the favorable effect of the multimodal inpatient program on future work participation was associated with insomnia.

Materials and Methods

Study Design

The study used a subgroup analysis of a randomized, controlled trial with 12 months of follow-up that aimed to

evaluate the effect of inpatient, multimodal, occupational rehabilitation on future work participation. In the subgroup analyses, it was assessed whether the effect of the inpatient and outpatient programs on accumulated sick leave was different for participants with or without insomnia. More in-depth information about the trial can be found elsewhere.^{24,28} The primary outcome of this trial is available in another publication.²⁴

The Regional Committee for Medical and Health Research Ethics in Central Norway (No.: 2012/1241) approved the study.

Participants

Eligibility criteria for the trial were as follows: a) ages 18–60; b) on sick leave for 2–12 months (with a current sick leave status of at least 50%); and c) diagnosed within the musculoskeletal (L), psychological (P) or general and unspecified (A) chapters of the International Classification of Primary Care (second edition, ICPC-2). The exclusion criteria were as follows: a) alcohol or drug abuse; b) having a serious somatic (eg, cancer and unstable heart disease), psychiatric (eg, high suicidal risk, psychosis and ongoing manic episodes) or neurological (eg, multiple sclerosis, chronic fatigue syndrome/myalgic encephalomyelitis) disorder; c) having a specific disorder that requires specialized treatment; d) pregnancy; e) currently participating in another treatment or rehabilitation program; f) insufficient oral or written Norwegian language skills needed to participate in group sessions and fill out questionnaires; g) scheduled for surgery within the next six months; and h) serious problems with social functioning in a group setting.

Interventions

The inpatient multimodal occupational rehabilitation program was both individual and group-based (maximum of eight participants in each group) and lasted three-and-a-half weeks, for six to seven hours each day except on weekends. The program took place at the Hysnes Rehabilitation Centre, which was established as part of St. Olavs Hospital in central Norway, with two to three designated coordinators (eg, physical therapy, psychology, exercise physiology, nursing) per group involved in coordinating and executing the interventions. The coordinators were trained in return-to-work problem-solving. The program comprised three main areas of rehabilitation: “mental training”; “physical training”; and “work-related problem solving”.²⁸ The mental training comprised acceptance and

commitment therapy,²⁹ a form of cognitive-behavioral therapy, along with mindfulness and psychoeducation (sleep hygiene, stress, nutrition and pain). The physical training comprised group and individual-based exercises that aimed to increase physical strength and endurance capacity. The work-related problem-solving aimed to motivate the participant, clarify the value of work, highlight challenges and resources, and create a realistic return-to-work plan.

The comparative program comprised mainly of outpatient, group-based acceptance and commitment therapy. The participants were offered two-and-a-half-hour-long group sessions (with a maximum of nine participants in each group) once a week for six weeks. In addition to the acceptance and commitment therapy group sessions, the participants participated in one-group session with psychoeducation on physical activity, two individual sessions with a social worker and a short individual closing session with a group therapist (psychologist or physician) specifically trained in acceptance and commitment therapy. The sessions were held at the Department of Physical Medicine and Rehabilitation, St. Olavs Hospital. The participants were encouraged not to start any new treatment during the intervention; however, they could continue any treatment agreed upon by their general practitioner. Among the group sessions, participants were also encouraged to practice at home, including 15 minutes of daily mindfulness. A more detailed description of the programs has been published elsewhere.²⁸

Insomnia

Insomnia was measured at baseline (before randomization) using the Insomnia Severity Index (ISI),³⁰ which is viewed as a reliable and valid instrument for detecting insomnia cases within a population.³¹ The ISI comprises a seven-item self-report questionnaire that assesses insomnia's nature, severity, and impact over the previous two weeks. The first three items assess the perceived severity of difficulties in initiating and maintaining sleep. The next four items assess satisfaction with current sleep patterns, interference with daily functioning, impairment due to sleep problems and distress/concerns regarding sleep problems. A 5-point Likert scale was used to rate each item (0 = no problems; 4 = severe problems), providing for a maximum score of 28, with high scores indicating greater insomnia severity. Considering that a cutoff score of ≥ 15 may be too stringent for diagnosing patients and produce too many false negatives,³¹ the participants were dichotomized into "no

insomnia" (< 11) and "insomnia" (≥ 11). A cutoff ≥ 11 was viewed as indicating high accuracy for diagnosing insomnia in a clinical sample.³¹

Other Variables

Information on demographic factors, such as gender, age (continuous variable) and education (categorized as high [college/university] or low), was obtained through questionnaires upon inclusion. Anxiety and depression symptoms were measured using the Hospital Anxiety and Depression scale (HADS),³² comprising 14 items in which seven measure anxiety symptoms and seven measure depression symptoms, all scored on a 4-point Likert scale according to intensity of symptoms last week, with a maximum score of 21 on each subscale. Average pain was measured using a numerical pain rating scale last week, ranging from 0 (no pain) to 10 (worst pain).³³

Sick Leave Register Data

Sick leave was measured using data from the Norwegian Labor and Welfare Service, in which all individuals receiving any form of sick leave or disability benefits in Norway are registered. The data comprised all registered medical benefits individually traceable to each participant through social security numbers. Combining data on different types of medical benefits, we calculated the number of sick leave days during 12 months of follow-up after the interventions ended.

Randomization and Blinding

Potential participants were identified in the National Social Security System and invited through a letter. Invited participants completed a short eligibility questionnaire. Those who qualified were invited to an outpatient screening assessment. If they cleared this process, subjects were randomized to either the inpatient or outpatient program. A flexibly weighted randomization procedure was provided by the Unit of Applied Clinical Research (third-party) at the Norwegian University of Science and Technology (NTNU) to ensure that the rehabilitation center had enough participants to operate monthly groups during periods of low recruitment.

It was not possible to blind either the participants or the caregivers for treatment. Employees at the Norwegian Welfare and Labor Service, who were unaware of group allocation, provided sick leave data. The researchers were not blinded either.

Statistical Analysis

A linear regression model was used to estimate the programs' effect on people with and without insomnia through the mean number of sick leave days during the 12-month follow-up period. The precision of the estimates was assessed using 95% confidence intervals. To test for interaction on an additive scale, we entered a product term (occupational program x insomnia) into the linear regression model. The analyses were adjusted for age, gender and education. We also conducted three sensitivity analyses to test the results' robustness. First, we repeated the main analyses, adjusting for diagnosis of sick leave and length of sick leave upon inclusion. Second, since an ISI score ≥ 15 is often interpreted as moderate-to-severe insomnia,³¹ we repeated the main analysis using an ISI cutoff of 15, rather than 11, to dichotomize the participants into "no insomnia" and "clinically significant insomnia". The ISI cutoff of 15 was not chosen as our main analysis since this may produce several false positives.³¹ Third, we used a logistic regression model to estimate the probability of sustainable return to work (sustainable return to work was defined as one month without receiving medical benefits during follow-up). Fourth, since there is a considerable overlap, but unclear temporal effects,

between insomnia and mental health conditions,²² we repeated the main analysis adjusting for depression.

All the analyses were performed using STATA 16 (StataCorp. 2019. Stata Statistical Software: Release 16. College Station, TX: StataCorp LP).

Results

Table 1 presents the baseline characteristics of the 163 participants stratified by occupational programs and insomnia. The proportion of participants who fulfilled the criteria for chronic insomnia at baseline was 56% (n = 91). Overall, the mean total days with sick leave during the 12-month follow-up were 114 (SD 86), and 49% achieved sustainable return to work. **Figure 1** shows the participant flow in the study.

Table 2 presents the mean differences in accumulated sick leave during 12 months of follow-up for each stratum of occupational program and insomnia, with a single reference category comprising people in a comprehensive inpatient program without insomnia. Compared with this reference category, people with insomnia had 12 (95% CI -48 to 24) fewer days with sick leave if they participated in the inpatient program and 46 (95% CI 8–83) more days if they participated in the outpatient program. People

Table 1 Characteristics of the Study Population Stratified by Occupational Program and Insomnia

	Occupational Rehabilitation Program			
	Inpatient (n=86)		Outpatient (n=77)	
	Insomnia ^a	No Insomnia	Insomnia ^a	No Insomnia
Participants, % (n)	56 (48)	44 (38)	56 (43)	44 (34)
Age, mean (SD)	46.2 (9.1)	46.3 (8.3)	46.9 (10.2)	43.0 (10.3)
Women % (n)	85 (41)	76 (24)	63 (27)	91 (31)
Higher education % (n) ^b	33 (16)	42 (16)	40 (17)	50 (17)
Main diagnoses for sick-leave (ICPC-2) % (n) ^c				
L- musculoskeletal	58 (28)	68 (26)	49 (21)	53 (18)
P- psychological ^d	42 (20)	32 (12)	51 (22)	47 (16)
Number of days with sick leave at inclusion, median days (IQR) ^e	200 (165–263)	211 (161–273)	202 (172–287)	219 (190–244)
Average pain (0–10), mean (SD) ^f	5.5 (2.0)	4.2 (1.8)	4.9 (2.4)	4.7 (1.9)
HADS, mean (SD)				
Anxiety (0–21)	8.8 (4.0)	5.6 (2.9)	10.0 (3.8)	6.7 (3.6)
Depression (0–21)	6.6 (4.6)	4.6 (3.3)	7.9 (3.7)	4.5 (3.6)
Insomnia severity index (0–28), mean (SD)	16.6 (4.1)	5.2 (3.5)	16.8 (3.3)	5.7 (3.0)

Notes: ^aInsomnia defined as an Insomnia Severity Index score ≥ 11 . ^bCollege or university. ^cBased on data in the medical certificate from the National Social Security System Registry. ^dThese include 13 participants with fatigue and one with perinatal distress. ^eNumber of days on sick leave during the last 12 months prior to inclusion. Measured as calendar days, not adjusted for graded sick-leave or part time job. ^fAverage pain last week.

Abbreviation: HADS, Hospital Anxiety and Depression scale.

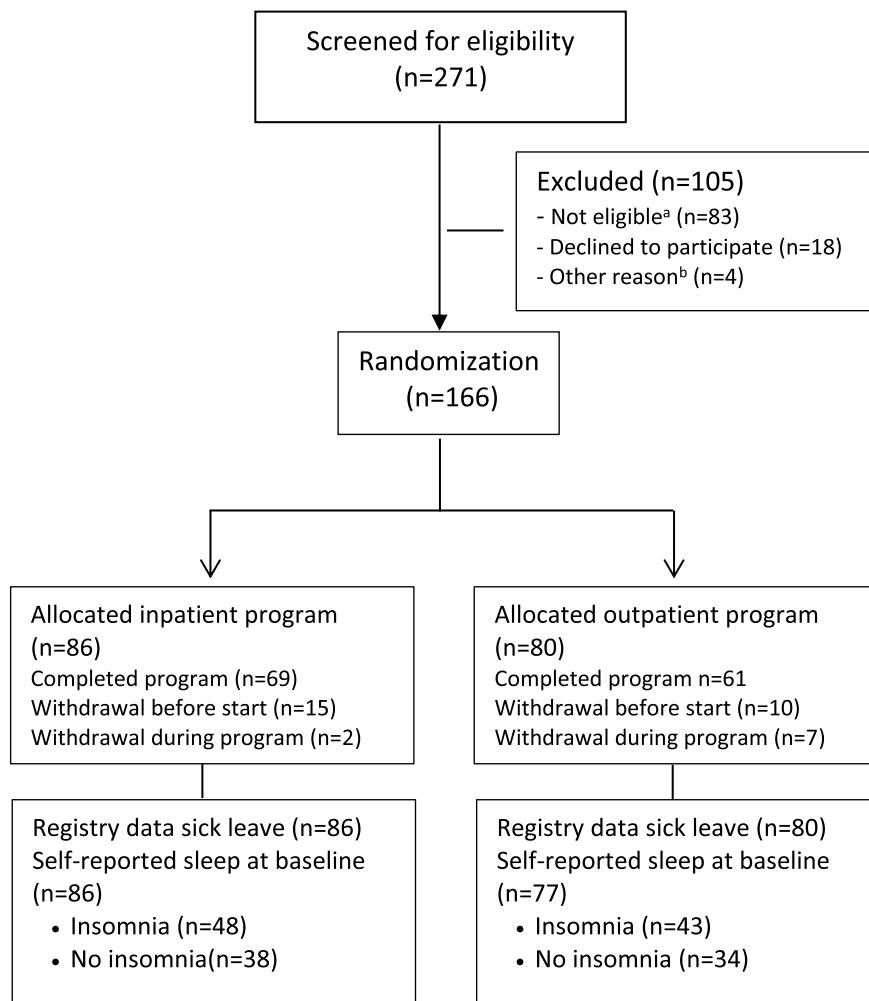


Figure 1 Flowchart of the participants in the study. ^aNot eligible: Participating in another treatment program (n=22), serious somatic/psychiatric illness (n=11), specialized treatment needs (n=4), problems with functioning in groups (n=3), surgery scheduled next 6 months (n=2), insufficient language skills (n=2), alcohol/drug abuse (n=1), no longer on sick-leave (n=10), medical assessment not completed (n=15), not motivated (n=6), inability to participate in an inpatient intervention (n=7), ^bOther reason: unknown (n=4).

without insomnia in the outpatient program had the same number of days with sick leave (mean difference: -3, 95% CI -43 to 37) as the reference category. We found statistical evidence of an interaction between intervention and insomnia ($p = 0.03$). Figure 2 presents days of medical benefits throughout the 12 months of follow-up (cumulative mean) for individuals in each stratum of occupational program and insomnia.

Sensitivity Analyses

When adjusting for diagnosis of sick leave and length of sick leave at inclusion, the results remained largely unchanged. Similar associations were found when we used an ISI cutoff of ≥ 15 or repeated the analyses, estimating the probability for sustainable return to work. Finally, adjusting for depression had only a negligible influence on

our estimates (Supplementary material: Figure S1 and Tables S1–S3).

Discussion

In this subgroup analysis of a clinical trial on sick-listed individuals randomized to multimodal inpatient rehabilitation or a less-comprehensive outpatient program, the difference in cumulative sick leave during 12 months of follow-up was particularly evident among participants with insomnia. Individuals with insomnia in the multimodal inpatient rehabilitation program had substantially fewer days with sick leave than the outpatient group, but no difference between the programs was found in those without insomnia.

This is the first study to evaluate whether insomnia is associated with occupational rehabilitation's effectiveness

Table 2 Associations of Occupational Program and Insomnia with Accumulated Sick Leave During 12 Months Follow-Up. Insomnia Measured by Insomnia Severity Index (ISI)

	No. of Persons	Days with Sick Leave		
		Age Adjusted Mean	Age-Adjusted Mean Difference (95% CI) ^a	Multi-Adjusted Mean Difference (95% CI) ^{ab}
No insomnia ^c				
Inpatient program	38	105	Reference	Reference
Outpatient program	34	105	0 (-40 to 39)	-3 (-43 to 37)
Insomnia ^d				
Inpatient program	48	97	-8 (-44 to 28)	-12 (-48 to 24)
Outpatient program	43	148	43 (5 to 80)	46 (8 to 83)

Notes: ^aMean difference: difference in number of sick leave days relative to the reference group of people in the inpatient program without insomnia. ^bAdjusted for age, sex and education. ^cISI-score <11. ^dISI-score ≥11.

Abbreviations: CI, confidence interval; ISI, Insomnia Severity Index.

in future work participation in individuals with musculoskeletal and common mental health disorders. The results from our study complement evidence from observational and clinical studies indicating that insomnia is associated with sick leave and work disability.^{9–11} That our findings found a greater difference between the two programs in those with insomnia may be related to the multimodal inpatient rehabilitation program's comprehensive design. The inpatient rehabilitation incorporated principles that are known to be helpful for good sleep quality, such as physical exercise,^{25,26} psychoeducational sessions, including sleep guidance and fixed schedules.²⁷ A consistent wakeup time is a recommended component in the treatment of insomnia,²⁷ and regular physical activity has been suggested as an alternative treatment option for people with insomnia.³⁴ In addition, the psychoeducational sessions

included sleep, management of stress and work life, and problem-solving techniques and coping strategies, which may exert positive effects on sleep quality.^{35,36} Furthermore, participants in the inpatient program broke away from regular life and had time to focus solely on their own situations. In contrast, participants in the outpatient program lived their regular lives at home. However, the outpatient program comprised regular acceptance and commitment therapy sessions that are also likely to improve sleep quality,³⁷ but did not include sleep guidance or fixed schedules. Thus, the estimates in this study might be conservative.

The positive effect of the comprehensive inpatient program on future work participation among those with insomnia was considerable, compared with those with insomnia in the outpatient program. However, insomnia may be a proxy for health status, ie, people with comorbid chronic pain and insomnia have greater symptom severity, longer duration of symptoms, more disability and comorbidities,³⁸ and the effect from inpatient rehabilitation may be related to a more complex mechanism than improvement of insomnia alone. For instance, although the data in the current study show that insomnia is prevalent among sick-listed workers with musculoskeletal pain or mental health conditions, it is well established that insomnia is bi-directionally related with pain and mental health conditions.^{16,21,22} Supplementary analyses with additional adjustment for depression had negligible influence on our estimates. However, the study design in the current study cannot verify the causal pathways between these conditions throughout the follow-up, that is, which factors that are likely to influence each other. In addition to improved

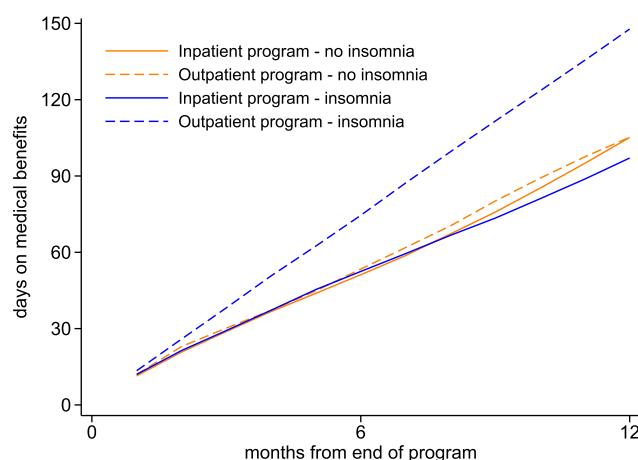


Figure 2 Sick leave days (cumulative mean) during 12 months of follow-up for participants in each stratum of occupational programme and insomnia.

sleep quality, therapies that target insomnia may improve pain,^{39,40} psychological well-being^{41,42} and fatigue.⁴³ To understand this complexity, future studies should be designed to assess the effect of targeting insomnia in return to work interventions, and if and how specific principles from cognitive-behavioral therapy for insomnia should be combined with other dimensions of the multimodal inpatient program. Furthermore, more research is needed on which interventions are most effective for certain individuals. It has been suggested that subgroups should be identified based on prognostic return-to-work factors;⁷ therefore, our findings are important, as they suggest that insomnia should be addressed before sick-listed individuals take part in occupational rehabilitation programs, and that insomnia may assist in early identification of individuals at high risk for long-term sick leave.

This trial's strengths include the use of high-quality sick-leave registry data that provided complete and detailed data on sick leave and return to work throughout the long follow-up (12 months). Another strength is the detailed sleep questionnaire administered at the start of the intervention. Although primary researchers were not blinded in preparing for the data set, one of the authors was blinded to initiate and perform a separate analysis when conducting the primary outcome in the original study.²⁴ Moreover, employees at the Norwegian Labor and Welfare Service who registered sick-leave data were unaware of the group allocation in this study. Another strength is that the Norwegian Labor and Welfare Service invited participants from among those who fit the eligibility criteria in the registry. However, only 38% (of 3808 invited) responded, and only 271 underwent a full clinical multidisciplinary eligibility assessment. Some limitations should be mentioned when interpreting the findings. First, we had no usual care control group and, therefore, no information on how these interventions compare with usual care. Although the inpatient program included a consistent wakeup time, information about sleep habits, and recommendations to improve sleep, the program did not include specific treatment components from the cognitive-behavioral therapy for insomnia. Unfortunately, we had no information about the use of sleep medication or if the participants had other sleep disorders (eg, obstructive sleep apnea, restless legs syndrome). It should also be noted that legislation, social security systems and occupational rehabilitation services differ between countries. Thus, generalizing our findings to other countries or settings with different services may not be straightforward.

Subgroup analysis itself presents some challenges as well. For instance, considering that our subgroup analysis was not part of the original study protocol,²⁸ the participants were not randomized within subgroups by stratification. Although this might have created imbalances in possible confounders between the programs, it should be noted that insomnia at baseline was not influenced by the intervention itself or by prognostic characteristics that emerged after randomization. Finally, the study may have been underpowered to detect statistically significant interaction between insomnia and occupational programs on future work participation.

In conclusion, we found that the favorable effect of a multimodal inpatient program on future work participation was associated with insomnia. No difference between the programs was found in those without insomnia. These findings suggest that insomnia should be addressed specifically before individuals on sick leave are considered for participation in occupational rehabilitation, and that individuals with insomnia may benefit in particular from inpatient multimodal occupational rehabilitation.

Data Sharing Statement

The data are not available, as the participants have not consented to this.

Ethical Approval

The study was approved by the Regional Committee for Ethics in Medical Research (project no. 2012/1241 REK Mid-Norway). The study was conducted in accordance with the ethical standards of the 1964 Helsinki declaration and its later amendments. Informed consent was obtained from all individual participants included in the study.

Clinical Trial Registration Number

NCT01926574.

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Author Contributions

All authors made a significant contribution to the work reported, whether that is in the conception, study design, execution, acquisition of data, analysis and interpretation, or in all these areas; took part in drafting, revising or critically reviewing the article; gave final approval of the version to be published; have agreed on the journal to which the article has been submitted; and agree to be accountable for all aspects of the work.

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Disclosure

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