

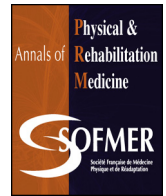


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Original article

Cognitive and vocational rehabilitation after mild-to-moderate traumatic brain injury: A randomised controlled trial



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ABSTRACT

Background: Returning to work is often a primary rehabilitation goal after traumatic brain injury (TBI). However, the evidence base for treatment options regarding return to work (RTW) and stable work maintenance remains scarce.

Objective: This study aimed to examine the effect of a combined cognitive and vocational intervention on work-related outcomes after mild-to-moderate TBI.

Methods: In this study, we compared 6 months of a combined compensatory cognitive training and supported employment (CCT-SE) intervention with 6 months of treatment as usual (TAU) in a randomised controlled trial to examine the effect on time to RTW, work percentage, hours worked per week and work stability. Eligible patients were those with mild-to-moderate TBI who were employed $\geq 50\%$ at the time of injury, 18 to 60 years old and sick-listed $\geq 50\%$ at 8 to 12 weeks after injury due to post-concussion symptoms, assessed by the Rivermead Post Concussion Symptoms Questionnaire. Both treatments were provided at the outpatient TBI department at Oslo University Hospital, and follow-ups were conducted at 3, 6 and 12 months after inclusion. **Results:** We included 116 individuals, 60 randomised to CCT-SE and 56 to TAU. The groups did not differ in characteristics at the 12-month follow-up. Overall, a high proportion had returned to work at 12 months (CCT-SE, 90%; TAU, 84%, $P = 0.40$), and all except 3 were stably employed after the RTW. However, a significantly higher proportion of participants in the CCT-SE than TAU group had returned to stable employment at 3 months (81% vs. 60%, $P = 0.02$).

Conclusion: These results suggest that the CCT-SE intervention might help patients with mild-to-moderate TBI who are still sick-listed 8 to 12 weeks after injury in an earlier return to stable employment. However, the results should be replicated and a cost-benefit analysis performed before concluding.

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1. Introduction

Approximately 50 million people globally sustain a traumatic brain injury (TBI) each year [1]. Of these, roughly 90% are classified as mild TBI (mTBI) [2], with about 15% to 20% experiencing symptoms for more than 3 months [3]. Physical, cognitive and emotional symptoms affect patients, their families and their ability to remain competitively employed [4,5].

An estimated 18% to 60% of patients had a return to work (RTW) [6] after TBI. The vast variability of RTW rates is due to the inclusion of different TBI severities, follow-up times, sample sizes and definitions of RTW. One study of patients with mTBI without structured rehabilitation reported an RTW rate of 62% at 1 year after injury [7]. Several factors complicate the process of RTW. Some of the factors most often assessed are post-concussion symptoms, demographic factors, pre-injury occupational status, previous psychiatric history and injury severity [4,5].

The same factors that complicate RTW after TBI may also affect the ability to retain a stable work attachment. Concerning work stability, studies including individuals with intracranial injuries of all severity levels have reported that 34% to 55% found stable work after TBI [8,9]. With few studies reporting work stability after TBI and an inconsistent method of defining work stability, there is a definite lack of data concerning work stability, particularly after mild-to-moderate TBI.

A systematic review from 2016 found strong evidence supporting work-directed interventions combined with education/coaching for improving RTW outcomes after acquired brain injury [10]. Other systematic reviews examined the effect of cognitive rehabilitation on RTW after TBI; one supported the treatment methods, with particular emphasis on compensatory strategies [4], but others found no evidence of effect [11,12].

The diverging results concerning the effect of cognitive rehabilitation on RTW has led to an increased focus on vocational rehabilitation interventions provided at the workplace. In 2015, a multicentre, randomised controlled trial (RCT) of 1193 participants found that work-focused cognitive behavioural therapy combined with individual job support improved RTW proportions to some extent in patients with common mental disorders [13]. Likewise, there is some preliminary evidence supporting the use of supported employment in vocational rehabilitation after TBI [14].

In 2015, Twamley et al. [15] published 1-year follow-up results from a pilot RCT combining compensatory cognitive rehabilitation and supported employment in veterans with a history of mTBI. They observed no group differences in the attainment of competitive work but some improvement regarding symptoms and quality of life. These results require replication in larger-scale studies using a civilian sample.

The current study incorporated this knowledge in an RCT using a combined cognitive and vocational intervention to assess the effect on RTW and work stability in patients after mild-to-moderate TBI. The 3- and 6-month interim results of this study have been published [16]. We hypothesized that the intervention would result in a higher proportion of patients returning to stable competitive employment by the 12-month follow-up in addition to having a higher work percentage and more work hours per week as compared with the control group.

2. Methods

2.1. Study design

The study is a prospective RCT. Eligible patients were recruited from a specialised TBI-rehabilitation outpatient clinic at Oslo University Hospital and were randomised to the combined

compensatory cognitive training and supported employment (CCT-SE) intervention or treatment as usual (TAU). The results of a feasibility study have been published previously [17]. Physiatrists at the Department of Physical Medicine and Rehabilitation of the hospital informed eligible patients about the study, and all participants provided written consent. Baseline assessments were performed 8 to 12 weeks after injury, with follow-up assessments at 3, 6 and 12 months after inclusion. The Regional Committee for Medical and Health Ethics in South-East Norway approved the trial (2016/2038), and the protocol was registered at ClinicalTrials.gov (NCT03092713) [18]. This study follows the CONSORT statement [19] and the ethical principles of the Helsinki declaration.

2.2. Participants

Eligible participants had sustained a mild-to-moderate TBI 8 to 12 weeks previously, lived in Oslo or Akershus county (approximately 1.3 million inhabitants; one-fourth of the Norwegian population), were of working age (18–60 years), were employed $\geq 50\%$ at the time of injury and were sick-listed $\geq 50\%$ at inclusion due to post-concussion symptoms assessed with the Rivermead Post Concussion Symptoms Questionnaire (RPQ) [20]. They were deemed as having post-concussion symptoms if at least one symptom was rated as ≥ 2 . Mean total RPQ score at baseline was 28 (range 5–54). Classification of mTBI involved using the American Congress of Rehabilitation Medicine criteria [21]. Mild-to-moderate TBI was defined as Glasgow Coma Scale ([22]) 10–15, loss of consciousness < 24 hr and post-traumatic amnesia < 7 days. Exclusion criteria included progressive neurological disease, ongoing substance abuse and/or inability to speak or write Norwegian.

2.3. Interventions

2.3.1. CCT-SE

Participants in the intervention group received a combination of compensatory cognitive training (CCT [23]) and supported employment (SE [24]). CCT is a 10-week, group-based, manualized intervention with weekly sessions of 2 hr provided by a clinical psychologist and a physician. CCT aimed at teaching the participants compensatory strategies to help manage post-concussion symptoms, specifically focusing on strategies to alleviate cognitive symptoms. Topics in the sessions included headache, fatigue, difficulties with sleep, concentration, memory and executive function.

The vocational part of the intervention was based on SE in which a “place-and-train” method is adapted [25]: participants were supported by an employment specialist in returning to their current jobs by working at their actual, competitive, workplace. This part of the intervention was delivered individually, for a maximum of 6 months per participant, and administered by the Department of Vocational Rehabilitation, Norwegian Labour and Welfare Administration. The employment specialists attended all sessions of one CCT group to improve the integration of concepts from the CCT into the RTW process.

Monthly meetings were held during the intervention period and were attended by the CCT interventionists, employment specialists and at least one senior researcher to ensure optimal trans-sectoral collaboration and a shared understanding of the individual participants.

2.3.2. TAU

The control group received TAU for a maximum of 6 months after inclusion. At Oslo University Hospital, TAU entails treatment and follow-up from a specialised multidisciplinary TBI team at the TBI outpatient department. The participants received a

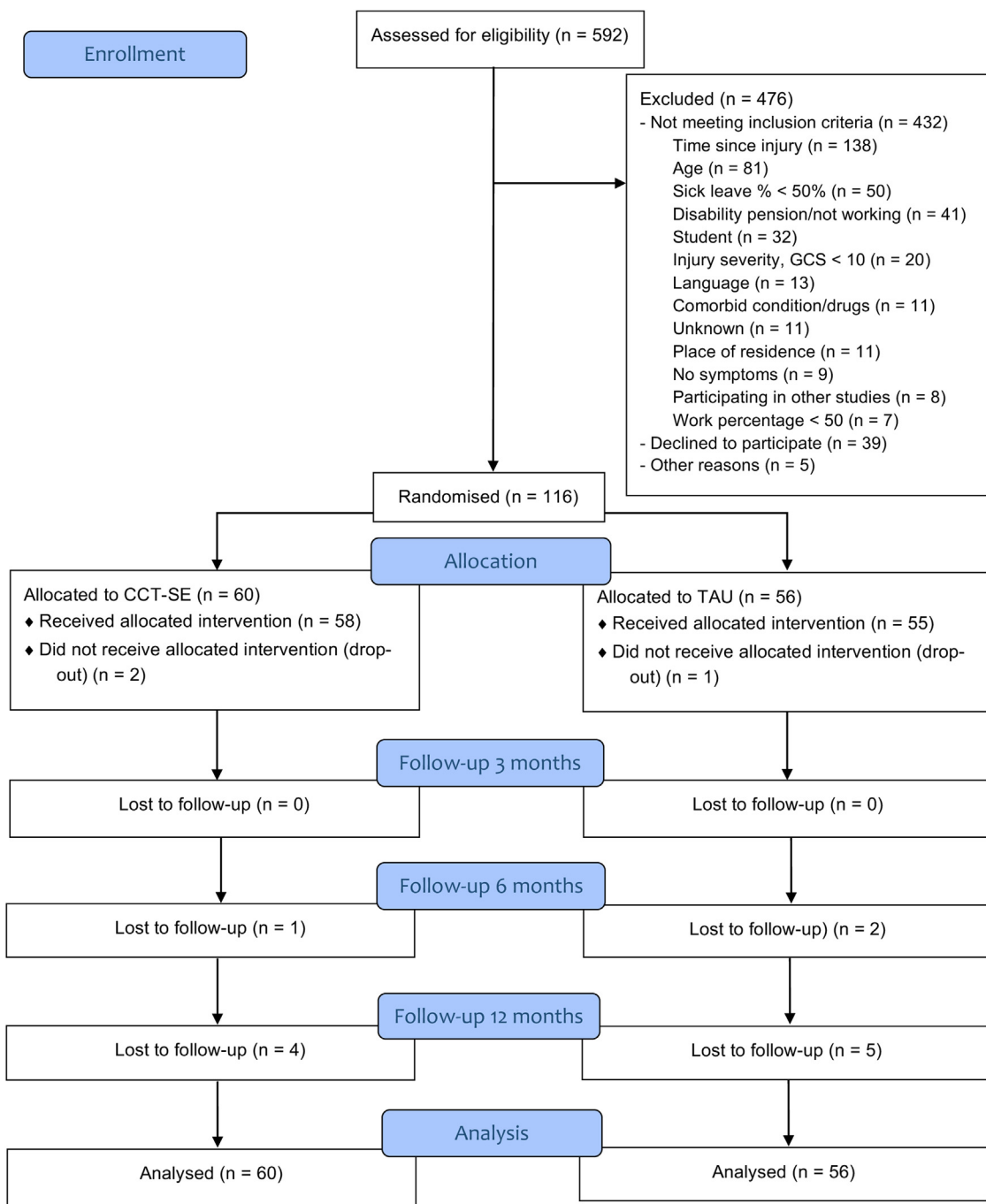


Fig. 1. Flow chart of inclusion and follow-up. CCT-SE, compensatory cognitive training and supported employment; GCS, Glasgow Coma Scale; TAU, treatment as usual.

consultation with a physiatrist and were referred to a physiatrist, physical therapist, occupational therapist, neuropsychologist or a social worker as required. Some participants were also offered participation in an educational group that focused on common problems after TBI and lasted for 2 hr per week for 4 weeks.

A detailed description of interventions in both treatment groups is in the study protocol [18].

2.4. Study outcomes

The primary outcome was self-reported work participation at the 12-month follow-up measured by the proportion of patients who had returned to work (0–100%). Furthermore, working hours

per week (0–37.5 hr), work percentage (0–100%), work stability and self-reported time from injury to return to pre-injury work levels (in days) were secondary outcomes. Data were collected during appointments at the TBI outpatient clinic at inclusion and follow-up at 3, 6 and 12 months after inclusion. Working hours per week were calculated from work percentage [(work percentage * 37.5)/100]. To operationalise work stability, each participant was assigned a work category at each follow-up depending on their current work percentage (0%, ≤ 50%, 50–79% or 80–100%). Patients who moved to a lower work category from any follow-up to the next were classified as “unstably employed”. Patients who maintained or improved their level of work participation were classified as “stably employed”.

Table 1
Baseline characteristics of individuals with mild-to-moderate traumatic brain injury at 8 to 12 weeks post-injury by study group and for the total sample.

	<i>n</i>	CCT-SE (<i>n</i> = 60)	TAU (<i>n</i> = 56)	Total sample (<i>n</i> = 116)
Sociodemographic factors				
Age, years, median (range)	60/56	42 (24-60)	44 (27-60)	43 (24-60)
Sex, female	60/56	33 (55)	36 (64)	69 (59)
Education, years, mean (SD)	60/56	16 (2)	16 (3)	16 (3)
Married/cohabitating	60/56	43 (72)	34 (61)	77 (66)
Injury-related factors				
Cause of injury				
Falls	60/56	19 (31)	30 (54)	49 (42)
Traffic accidents		12 (20)	11 (20)	23 (20)
Sports		10 (17)	4 (7)	14 (12)
Violence		3 (5)	3 (5)	6 (5)
Exposure to inanimate objects		15 (25)	8 (14)	23 (20)
Unknown		1 (2)	0 (0)	1 (1)
CT/MRI findings, traumatic intracranial	60/56	11 (18)	16 (29)	27 (23)
Injury severity by ACRM criteria				
Mild	60/56	58 (97)	51 (91)	109 (94)
Moderate		2 (3)	5 (9)	7 (6)
Loss of consciousness (LOC)				
< 30 min	60/56	21 (35)	16 (29)	37 (32)
30 min–24 hr		1 (1)	2 (4)	3 (3)
No LOC		31 (52)	30 (53)	61 (52)
Not registered		7 (12)	8 (14)	15 (13)
Post-traumatic amnesia (PTA)				
< 1 hr	60/56	18 (30)	17 (31)	35 (30)
1–24 hr		7 (12)	9 (16)	16 (14)
25 hours–7 days		0 (0)	2 (4)	2 (2)
No PTA		25 (42)	26 (47)	51 (44)
Not registered		10 (16)	2 (2)	12 (10)
Work-related factors				
Occupation, white collar	60/56	53 (88)	50 (89)	103 (89)
Permanent position	60/56	56 (93)	49 (88)	105 (91)
Full-time position	60/56	55 (92)	48 (86)	103 (89)
Private sector	60/56	36 (60)	28 (50)	64 (55)
Duration of employment, months, median (range)	59/55	54 (0-408)	42 (0-480)	51 (0-480)

Data are *n* (%) unless otherwise indicated. CCT-SE: compensatory cognitive training and supported employment; TAU: treatment as usual.

2.5. Sample size

The sample size was calculated based on the proportions of RTW, aiming for a 33% absolute difference in RTW status between the 2 treatment groups at the 12-month follow-up [18]. From studies of occupational health care on RTW, we assumed that an odds ratio of 2.0 was the smallest clinical and societal relevant ratio [26]. This indicates that participants in the intervention group returned to work twice as quickly as participants in the control group. Assuming that two-thirds of the participants would achieve RTW during the follow-up, the sample size calculated with

G*Power resulted in 110 patients, with 55 patients in each treatment group ($\alpha = 0.05$, power level 80%). With an expected loss to follow-up of 15%, 125 participants were required.

2.6. Randomisation and blinding

All included patients were randomised in a 1:1 ratio to one of the 2 treatment groups after baseline assessment. An independent statistician produced a computer-generated permuted block sequence with randomised block sizes (2, 4, 6 or 8) before starting inclusion. The researcher who was responsible for the allocation of patients to the treatment groups was not involved in patient recruitment or assessment. Outcome assessors were blinded to patient allocation. Blinding of rehabilitation specialists and patients was not possible.

2.7. Statistical analysis

Data analyses were performed with Stata 16. Descriptive methods were used to describe baseline and injury-related characteristics. A mixed-effects logistic regression was applied to evaluate the proportion of participants who had returned to work. Linear mixed-effects models were fitted to analyse working hours per week and work percentage between groups and within groups. Time and time-by-treatment interaction were fixed effects in all models, allowing a random intercept and random effect of time. The main effect of treatment was removed from the models to adjust for potential baseline differences. Differences between the groups in days to returning to pre-injury work levels were analysed by Kaplan–Meier curves and a log-rank test. The Kaplan–Meier curves were adjusted for the possible confounding effect of the presence of traumatic intracranial injury on CT/MRI or

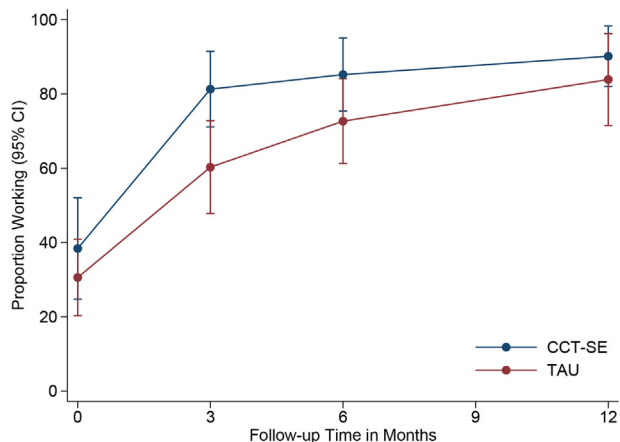


Fig. 2. Proportion of patients who returned to work after mild-to-moderate TBI. CCT-SE, compensatory cognitive training and supported employment; TAU, treatment as usual.

whether the participants were working at baseline. Analyses were carried out on an intention-to-treat basis by an independent statistician who was blinded to group allocation. The level of significance was set at $P < 0.05$.

3. Results

Because of lower-than-expected loss to follow-up (6%) and the time limit of the study, the study inclusion, which began in July 2017, was terminated in April 2019 after inclusion of 121 patients (Fig. 1). Treatment in both groups was performed from August 2017 to November 2019. Five patients who initially consented to participate withdrew their consent before randomisation. Consequently, 116 participants were included in the analyses, 60 randomised to the CCT-SE group and 56 to TAU. Participants in the CCT-SE group were included at a mean (SD) of 77 (3) days after injury, and those in the TAU group at 68 (3) days after injury. Adherence to the CCT intervention was high. Three patients were absent from a total of 6 sessions, which resulted in a 99% attendance rate for the group [16].

Many included patients were female (59%), most were highly educated, and most had an mTBI (94%) (Table 1). The groups did not differ in baseline characteristics. A more comprehensive description of baseline characteristics is reported elsewhere, and a detailed description of the treatment received in both groups is reported in other publications from the project [16–18].

3.1. Proportion of patients returning to work

The proportion of patients returning to work at 3 months was higher in the CCT-SE than TAU group (mean 81% vs. 60%, mean between-group difference from baseline to 3 months 14%, 95% confidence interval [CI] 5; 32, $P = 0.02$) (Fig. 2). The control group had caught up with the treatment group by the 6- and 12-month follow-ups, and the mean between-group differences were no longer significant (–9% and –6%). In line with the finding that the RTW process mainly occurred within the first 3 months in the CCT-SE group, the within-group difference was significant only from baseline to 3 months for this group but was significant between all time points for the TAU group (see Table 2 for between- and within-group differences).

3.2. Working hours per week and work percentage

Linear mixed-effects models showed that the number of working hours per week and work percentage increased over time but did not significantly differ between groups.

3.3. Days until pre-injury work levels

Overall, 39 (65%) participants in the CCT-SE group and 30 (54%) in the TAU group returned to pre-injury work levels during the study period. Half of the patients were back to pre-injury levels within 365 days after injury in the CCT-SE group and by 415 days in the TAU group. The 50-day difference was not significant. The presence of traumatic intracranial abnormalities confounded the association between treatment groups and days before reaching pre-injury work levels and was adjusted for (Fig. 3). Adjustment for whether the patients were working at baseline did not affect this association (data not shown).

3.4. Work stability

Only 3 participants showed decreased work percentage category from 6 to 12 months, so most patients had stably

Table 2 Proportion working, work percentages and hours worked per week. Results from mixed-model analyses.

	Baseline	3 months	6 months	12 months	Within-group difference 0–3 months	Between-group difference 0–3 months	Within-group difference 3–6 months	Between-group difference 3–6 months	Within-group difference 6–12 months	Between-group difference 6–12 months	
Proportion working											
	CCT-SE	38 (25; 52)	81 (71; 92)	85 (75; 95)	90 (82; 98)	43 (29; 57) $P < 0.001$	14 (-5; 32) $P = 0.022$	4 (-6; 14) $P = 0.434$	-9 (-24; 7) $P = 0.164$	5 (-3; 13) $P = 0.236$	-6 (-20; 7) $P = 0.397$
	TAU	31 (20; 41)	60 (48; 73)	73 (61; 84)	84 (72; 96)	29 (18; 42) $P < 0.001$	13 (1; 24) $P < 0.001$	17 (10; 24) $P < 0.001$	0 (-11; 11) $P = 0.518$	11 (0; 22) $P < 0.001$	6 (-5; 18) $P = 0.194$
Work percentage											
	CCT-SE	12 (6; 18)	34 (27; 40)	51 (43; 59)	77 (67; 88)	22 (14; 29) $P < 0.001$	2 (-9; 12) $P = 0.474$	17 (9; 24) $P < 0.001$	26 (19; 35) $P < 0.001$	20 (12; 29) $P < 0.001$	6 (-5; 18) $P = 0.194$
	TAU	10 (4; 16)	30 (23; 37)	47 (39; 55)	67 (56; 78)	20 (13; 28) $P < 0.001$	0.5 (-3.4; 4.5) $P = 0.474$	6.4 (3.6; 9.1) $P < 0.001$	0.1 (-3.9; 4.1) $P = 0.518$	10.0 (7.0; 12.9) $P < 0.001$	2.3 (-2.0; 6.6) $P = 0.194$
Hours worked per week											
	CCT-SE	4.5 (2.3; 6.8)	12.6 (10.0; 15.2)	18.9 (15.9; 21.9)	28.9 (25.0; 32.8)	8.0 (5.3; 10.8) $P < 0.001$	0.5 (-3.4; 4.5) $P = 0.474$	6.4 (3.6; 9.1) $P < 0.001$	0.1 (-3.9; 4.1) $P = 0.518$	10.0 (7.0; 12.9) $P < 0.001$	2.3 (-2.0; 6.6) $P = 0.194$
	TAU	3.7 (1.3; 6.0)	11.2 (8.6; 13.9)	17.5 (14.4; 20.6)	25.1 (21.1; 29.2)	7.5 (4.7; 10.4) $P < 0.001$	0.5 (-3.4; 4.5) $P = 0.474$	6.3 (3.4; 9.2) $P < 0.001$	7.6 (4.5; 10.7) $P < 0.001$	10.0 (7.0; 12.9) $P < 0.001$	2.3 (-2.0; 6.6) $P = 0.194$

Data are mean (95% confidence interval). CCT-SE: compensatory cognitive training and supported employment; TAU: treatment as usual.

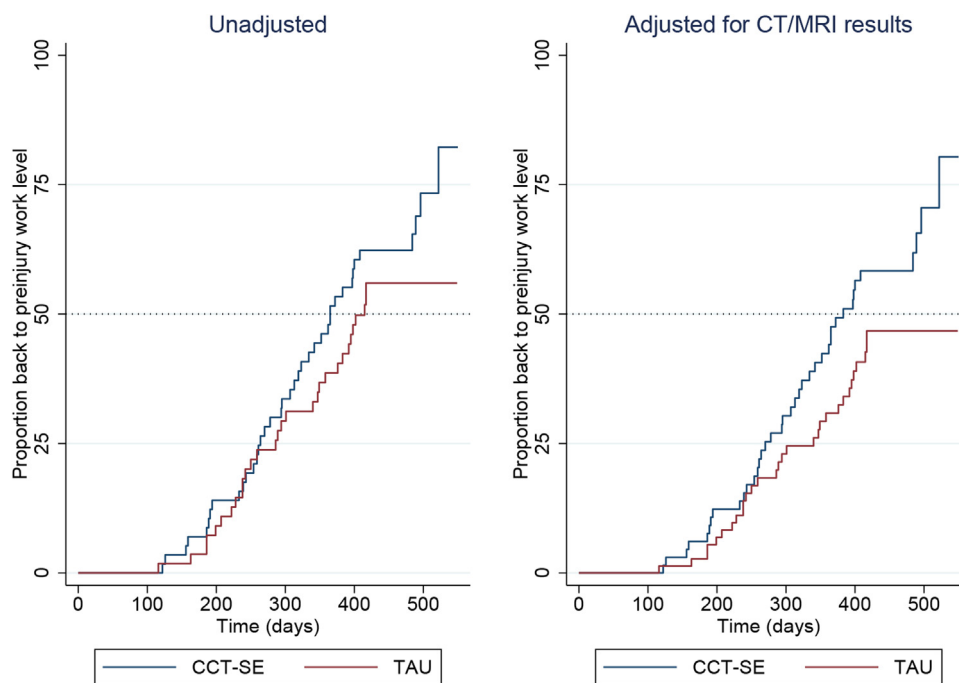


Fig. 3. Days to reach pre-injury work level by treatment group: unadjusted and adjusted for the presence of traumatic intracranial injury on CT/MRI. CCT-SE, compensatory cognitive training and supported employment; TAU, treatment as usual.

returned to work, regardless of group. From baseline to 3-month follow-up, 4 patients (CCT-SE: $n = 2$, TAU: $n = 2$) were unstably employed, and from 3 to 6-month follow-up, 6 (CCT-SE: $n = 2$, TAU: $n = 4$) were unstably employed. The group difference was not significant.

4. Discussion

This study examined the effectiveness of a pragmatic, cross-sectoral and innovative complex intervention (CCT-SE) on RTW in patients with mild-to-moderate TBI who were still symptomatic and on sick leave 8 to 12 weeks after injury. In contrast to our hypotheses, we found no differences in work outcomes between the CCT-SE and TAU groups at the 12-month follow-up. However, a significantly higher proportion of the CCT-SE group had returned to work after 3 months as compared with the TAU group, which suggests an early effect of the CCT-SE intervention on return to competitive work after mild-to-moderate TBI. We found no significant group differences in the other work-related outcomes. However, the median difference in time from injury to return to pre-injury work levels was 50 days, which supports accelerated RTW in the CCT-SE group. Overall, the within-group differences showed an improvement in all outcomes over time, and most patients in both groups were stably employed after an initial RTW.

Returning to work is a primary rehabilitation goal after TBI. Vocational rehabilitation may be challenging because of the heterogeneity of health-related TBI consequences and pre-morbid and contextual factors (i.e., personal and environmental factors). The literature has suggested focusing on both health and work factors, the involvement of the patient and employer, a combination of work-directed interventions [10], and the integration of these factors into early rehabilitation after TBI [27].

At the study planning time, evidence was lacking to support the effectiveness of vocational rehabilitation for people with mild-to-moderate TBI [5,28]. A novel approach to vocational rehabilitation, the “place-and-train” principles, involving SE, gained empirical

support in the Norwegian context, with positive results for both work- and non-work-related outcomes for people with mental illness [25]. The present study was further inspired by Twamley et al. [15], who conducted a pilot study using the original CogSMART intervention combined with SE in veterans with mild-to-moderate TBI. The authors found improvement in affective post-concussion symptoms and quality of life but no significant improvement in RTW. The present study and Twamley et al. [15] used different inclusion criteria, such as time since injury (8–12 weeks vs. > 4 years), tools used to determine impairment (the RPQ in the current sample vs. neuropsychological performance in the pilot study) and duration of SE support (6 vs. 12 months). Furthermore, our sample used the criterion of employment at the time of injury, whereas participants in the pilot study were unemployed but were motivated to return to work. Additionally, the sample in the current study was civilian; our study was conducted within a different governmental welfare system and included more than twice as many participants.

Of note, TAU in this study was relatively comprehensive. Vikane et al. [29] assessed the effect of the program constituting TAU in the current study compared to follow-up by a general practitioner for patients at risk or sick-listed with post-concussion symptoms at 2 months after mTBI. The group receiving follow-up care by a general practitioner also had a multidisciplinary examination with subsequent advice. The authors found that participants in the TAU program showed decreased symptom burden on the RPQ after 1 year, but the groups did not differ in days to sustainable RTW, so TAU was not effective for RTW.

However, the results of the 2 studies are not directly comparable. In the current study, TAU constituted the control group. Furthermore, the differences in inclusion criteria between the studies hamper comparisons, such as different severity levels (mild-to-moderate TBI vs. mTBI), time of inclusion (8–12 vs. 6–8 weeks after injury), age of sample (18–60 vs. 18–55 years) and whether the patients had been hospitalised (not necessarily vs. ≥ 5 hr). Additionally, Vikane et al. used a different definition of stable RTW than the current study and collected sick leave data

from a national registry [29]. Considering these differences, the high level of care received in TAU, with high attendance rate and low loss to follow-up, might still have affected the results and reduced the difference between the 2 treatment groups. Using a control group receiving a less-comprehensive follow-up might have resulted in a larger primary-outcome difference between the groups. A qualitative process evaluation that explores patients' experience with the RTW process will be published, in addition to the evaluation of clinical outcomes.

Overall rates of return to competitive employment (part or full time) at 12 months were high in both CCT-SE and TAU groups (90% and 84%). This finding may be explained in part by the context of the study, in addition to expected spontaneous recovery. The Norwegian welfare system includes measures to ensure a low unemployment rate, in addition to universally accessible, affordable and high-quality health care services. Furthermore, all patients in this study were employed $\geq 50\%$ at the time of injury, which increases their likelihood of regaining employment after injury as compared with unemployed patients [5]. Conversely, only 65% of patients in the CCT-SE group and 54% in the TAU group had returned to their pre-injury work level at 12 months' follow-up. The Norwegian welfare system also includes a generous workers' compensation program that covers 100% of lost income for the first year of sick-listing and approximately 66% beyond the first year. The Organization for Economic Cooperation and Development has previously revealed that, of its member countries, Norway has the highest level of sick-listings and costs related to lost labour [13]. Reimbursement for the loss of income when sick-listed (i.e., up to 12 months) might have affected the patients' motivation to return quickly to full-time labour [5] and may, in general, hamper the efficacy of work-related interventions.

4.1. Strengths and limitations

The current study is a well-designed, innovative and cross-sectoral RCT examining RTW in a specific subsample of TBI patients with persistent symptoms. The risk of bias was minimised by the low loss to follow-up [30]. Because of the civilian sample, the results are more generalisable than those obtained from a sample of military veterans. The study was conducted in the context of generous income compensation during sick leave, thus potentially decreasing its generalisability to countries with other welfare systems because this may influence motivation for RTW and consequently RTW rates [5,31]. The generalisability should also be considered in light of the comprehensive multidisciplinary care received in TAU, which is not representative of the standard of care received at most other national or international facilities.

Atypically for the general TBI population, the sample was predominantly women, in white collar occupations, and full-time employees. However, this sample represents the patients after mild-to-moderate TBI with prolonged symptoms who are seeking treatment and reside in an urban area. Data from the Quality Registry at the TBI outpatient clinic show that 10% more female than male patients are referred for multidisciplinary follow-up (personal communication with Quality Registry staff).

The main outcomes were based on self-reported data, which could be considered a limitation if respondents report false values or do not remember correctly. However, the study participants had sustained mild-to-moderate TBI, and their knowledge of personal work-related data was not suspected to be notably affected.

The original sample size calculation was designed to detect a 33% absolute difference between the treatment groups in the proportion that returned to work at the 12-month follow-up. In previous work-related intervention studies on occupational back pain and mental disorder, both 30% and 20% differences between groups in RTW were used [26,32]. In our study, we found only a 6%

difference between groups at the 12-month follow-up. This finding could be related to the pragmatic context of the study (inclusion of the multidisciplinary follow-up as the TAU group) and the natural recovery process of mild-to-moderate TBI. However, the 50-day median difference in time from injury to return to pre-injury work levels might indicate an important effect of the CCT-SE intervention. This finding will be explored further in a study on the cost-effectiveness of this intervention.

5. Conclusions

The study results suggest that the combined cognitive and vocational intervention improved the early return to stable employment in patients with mild-to-moderate TBI. Expediting a stable RTW may substantially reduce costs related to lost labour after mild-to-moderate TBI, in addition to helping patients return to their pre-injury levels of functioning. The results of this study require replication, and a cost-benefit analysis should be performed before drawing a firm conclusion.

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Disclosure of interest

The authors declare that they have no competing interest.

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