ORIGINAL PAPER

The effect of hypnotic suggestion on labor market attachment, functioning, and cognition after brain injury - a randomized controlled trial

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ABSTRACT

Introduction and aim. Cognitive impairments after acquired brain injury (ABI) or concussion significantly affect work capacity. While hypnotic suggestion has shown promise in improving working memory and work ability, studies on its long-term effects on labor market attachment and cognition are lacking. The aim of this study was to estimate the long-term effect of hypnotic suggestion on labor market attachment, cognition, and functioning following acquired brain injury or concussion.

Material and methods. A randomized controlled trial (RCT) was conducted at a municipal vocational rehabilitation center in Denmark, among 87 patients aged 18 to 62 years who experienced ABI or concussion at least 6 months prior to the first therapy session. The study group were randomized according to the applied intervention: usual care (n=28), hypnosis (n=30) or mindfulness (n=29). Participants underwent baseline and 6-month follow-up assessments involving The Danish Register for Evaluation of Marginalization (DREAM), The Wechsler Adult Intelligence Scale - Fourth Edition (WAIS-IV), Impact on Participation and Autonomy questionnaire (IPA), The Working Memory Questionnaire and Trial Making Test related to working memory and functioning, assessing three dimensions: short-term storage, attention, and executive control.

Results. The primary outcome was the average number of weeks employed during the 12-24-month period post-inclusion. The mean number of weeks employed was 32.71 (SD: 22.31) in the usual care group, 35.97 (SD: 21.58) in the hypnosis group, and 32.90 (SD: 22.44) in the mindfulness group. All intervention groups had exhibited a working memory score of around 90, which improved to a range of 91 to 95 at the 6-month follow-up. No significant differences were found between the groups. Conclusion. Brief hypnotic treatment at a municipal vocational rehabilitation center for people with ABI and concussion showed no significant advantage over mindfulness or usual care in labor market attachment, cognition, or family functioning. However, participants in the hypnosis group demonstrated improved social functioning at the 6-month follow-up compared

Keywords. cognition, functioning, hypnosis, mindfulness, work

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Introduction

People with vascular and traumatic brain injuries, such as acquired brain injury (ABI) or concussions, often face challenges in occupational competencies and cognitive abilities, including working memory.^{1,2} These difficulties persist upon returning to work post-injury, contributing to significant vocational skills challenges and global implications for personal and economic well-being.³ The incidence of chronic cognitive consequences after ABI in a Danish context ranges from 5,000 to 15,000 citizens annually, with at least one-quarter belonging to the working-age population.^{4,5}

A common cognitive consequence following a stroke is diminished working memory, affecting people's ability to navigate complex situations and sustain concentration.⁶ The compromised cognitive function poses a substantial obstacle to work, with return-to-work rates after a stroke ranging widely from 11 to 88%.^{4,7,8} Among Danes aged 20–57 who had experienced a stroke, 62% were employed two years post-stroke.⁹

The effectiveness and cost-effectiveness of current cognitive rehabilitation approaches, specifically targeting work-related abilities for people with ABI and concussion, remain inconclusive. 10,11 Hypnosis has emerged as a promising intervention, leveraging its core mechanism of shaping expectancies in both pre- and post-injury stages. 12-15 Additionally, hypnotic sessions have been shown to enhance neural plasticity and improve pain regulation, offering potential for addressing cognitive and functional impairments following ABI. 16 Nevertheless, evidence supporting the efficacy of hypnotic treatments remains inconsistent, primarily due to small sample sizes and variability in clinical trial methodologies. 16

A recent RCT demonstrated significant improvements in working memory following ABI through hypnotic suggestion.17 This eight-session intervention successfully restored working memory capacity to levels observed in the healthy population, indicating substantial functional improvement. This was achieved through techniques such as age regression and visualizations of brain plasticity.17 Other studies also showed clinically noteworthy effects in the cognitive domain with small-to-medium effect sizes following hypnotic suggestion.¹⁸ Mindfulness-hypnosis exhibited impacts on fatigue, and in some certain studies, on depression and anxiety.17,19,20 However, there is a research gap regarding the long-term effects (> 2 months) of hypnotic suggestion on labor market attachment and cognitive abilities.

This study aims to investigate whether the positive outcomes observed in Lindeløv et al.'s intervention can be sustained over an extended period.¹⁷

Aim

Therefore, the aim of this study was to estimate the longterm effect of hypnotic suggestion on labor market attachment, cognition, and functioning.

We hypothesized that hypnotic suggestion would have positive long-term effects in each of these domains compared to both mindfulness (active control group) and usual care.

Material and methods

Study design

A three-arm RCT with 6- and 24-month follow-up was undertaken, comparing the effects of hypnotic suggestions, mindfulness, and usual care. The trial is registered at ClinicalTrials.gov under the identifier NCT05142007.

Study setting and population

Recruitment, testing, and treatment took place from May 2017 to February 2021 at an outpatient municipal vocational rehabilitation center in Silkeborg, Denmark. People referred to the center were considered eligible for the study if they met the following inclusion criteria: 1) aged 18 to 62 years, 2) experienced ABI or concussion at least 6 months prior to the first therapy session as verified in the participant's medical journal, and 3) demonstrated a substantial risk of reduced labor market attachment, as assessed by the vocational rehabilitation center staff (social workers and physiotherapists) based on sequelae and previous employment status.

Participants were excluded based on criteria that could significantly diminish treatment effects for reasons unrelated to the effectiveness of the intervention. Exclusion criteria included: 1) progressive injuries, including dementias, 2) unemployed for more than 6 consecutive months immediately preceding the injury, 3) employment less than 50% of the time after finishing the latest education, 4) pensioned or recommended for pension due to old age, disability pension or both, and 5) ongoing mental disorders that require psychiatric treatment, with the exception of psychopharmaca for depression and anxiety (any subscale exceeding the per-instruction manual cutoffs on the Patient Health Questionnaire (PHQ).²¹

While hypnosis is generally considered a safe procedure across patient groups, one precaution was taken to screen out participants with a history of psychosis (PSQ), or substance abuse (PHQ) to avoid eliciting those behaviors.^{21,22}

Sample size

The effect sizes reported by Lindeløv et al. were so substantial that even the weakest model, with half the effect size of the weakest contrasts, achieved >90% power with only eight participants per group. However, such a small sample size is insufficient for a clinical study. Therefore,

we aimed for 30 participants per group (90 in total), as this was feasible within the available budget.

Randomization and blinding

A study coordinator utilized a computerized random sequence generator to allocated participants to the three intervention groups. We employed blocked randomization, with the constraint that multiples of five participants were to the hypnosis and mindfulness groups for logistical reasons. Stratification was implemented to ensure an equal number of participants in each arm and an equal ratio of participants with ABI to concussion in all three arms.

The coordinator communicated participants' allocations and scheduled appointments with a hypnotist. Participants were informed only about the two possible outcomes of the allocation: hypnosis or usual care, remaining unaware of the existence of two hypnosis groups (hypnosis and mindfulness). This strategy aimed to standardize treatment expectations across intervention groups, mitigating the potential confounding effect. The blinding was lifted after 6-month follow-up test for the last participant. The authors of this paper remained blinded until an agreed-upon analysis plan was established.

Interventions

Usual care

All participants were provided with usual care at the outpatient municipal vocational rehabilitation center in Silkeborg. This encompassed assistance to enhance labor market attachment for people with diminished work capacity due to ABI or concussion. Activities under usual care involved consultations with a social worker or neuropsychologist, participants in support patient groups, and engagement in mindfulness. The nature and frequency of these activities were tailored to individual needs, usually amounting to two activities per week.

Hypnosis

The hypnotic intervention comprised a series of four weekly one-hour treatment sessions aimed at enhancing working functions. These sessions involved the use of hypnotic suggestions to instantiate preinjury memory abilities in the present. Techniques included age regression, visualizations of neuroplasticity, and posthypnotic suggestions for continued improvement. The central theme of these suggestions was to make thinking effortless and reliable for the participant, ultimately leading to reduced fatigue, improved memory, and the avoidance of information overload.

Each session followed a manualized hypnosis script, dictated by three experienced hypnotists with several years of hypnotherapy practice, including working with brain injuries and concussions.¹⁷ The only variation among hypnotists were in intonation and speed.

The treatment sessions adhered to a consistent strategy, encompassing four main steps: 1) re-instantiating pre-morbid brain functioning in the present, 2) reprogramming the unconscious mind for effectiveness, 3) regaining control and inducing relaxation, and 4) fostering a healthy self-image.²³

Furthermore, hypnotic suggestions encouraged participants to adopt alternative emotional or cognitive appraisals of problems, disrupting habitual thought patterns.

Mindfulness

This group also involved four weekly one-hour treatments. Each treatment session utilized the same induction and termination procedures as the hypnosis group and was matched in duration. However, the suggestions within the sessions were derived from the Mindfulness-Based Stress Reduction method (MBSR), with no explicit mention of brain injury or working memory-related abilities. Therefore, the "mindfulness" intervention was formally a hypnosis with mindfulness suggestions, and this group served to isolate the specificity of the hypnotic suggestion, while also controlling for other influences such as placebo effects and retest effects.

Mindfulness sessions incorporated techniques such as body scanning to cultivate focused attention and open monitoring of thoughts in a non-judgmental manner. Specifically, these sessions aimed to train participants in letting worrying thoughts pass without fixation and promoting general relaxation and well-being, focusing solely on the hypnosis session. Importantly, there were no suggestions regarding the transfer of these abilities to other contexts.

Data sources

Participants underwent baseline and 6-month follow-up assessments involving questionnaires and tests related to working memory and functioning. Information on injury type, time since injury, gender and age was collected from questionnaires and cross-verified with patient records.

Employment status was obtained from The Danish Register for Evaluation of Marginalization (DREAM) (24). DREAM supplied weekly data on public transfer payments, including compensation benefits for sick leave, unemployment benefits, and disability pension. The specific type of social benefits in DREAM is recorded for each week if the person has received the benefit for at least 1 day. Termination of registration occurs following the first full week without receiving any social benefits and is interpreted as working. Previous validation studies demonstrated the reliability of DREAM data, comparing it against workplace-registered data on sick leave and self-reported information on income type.^{24,25} Both studies concluded that DREAM provides accurate and valid data.

Outcomes

Primary outcome

The primary outcome measure was the number of weeks employed during the 12–24-month period following inclusion, as derived from DREAM data. Working was defined as not receiving any social benefits, excluding unemployment benefits (indicating fitness for duty without current employment), and flexible job arrangements (for people with a significantly and permanently reduced working capacity due to illness). Thus, the outcome was calculated as the total number of weeks during the 12–24-month period without receiving any benefits, even for a single day.

Secondary outcomes

The assessment focused on the number of weeks participants were employed during the initial 0–6 months after study inclusion. Participants' work status (yes/no) was determined 6 month (26 weeks) and 24 months (104 weeks) after inclusion. To ensure a sustained connection to the labor market, the criterion for working also required participants to have worked in the last 4 weeks leading up to each time points.

Cognitive tests and questionnaires were administered three times: at baseline (21–3 days before the first possible treatment date), at post-test (3–11 days after the last possible treatment date, and at the 6-month follow-up (6 months after the last possible treatment day \pm 14 days).

The Wechsler Adult Intelligence Scale – Fourth Edition (WAIS-IV) (26) was utilized to measure Working Memory, employing subtest such as digit span, arithmetic and letter-number sequencing. Tests were scored, aggregated, and transformed into index scores ranging from 50 (worst) to 150 (best), as outlined in the WAIS-IV manual (26). The index exhibits favorable psychometric properties.²⁷

The executive component of working memory was evaluated through the Trial Making Test (28), consisting of two parts (A and B) that assess visual attention and task switching. Total time in seconds for completing both parts A and B was recorded. Direct scores were obtained, and a log-ratio score (log(B/A)) was calculated to better capture the exponential increase in reaction times with decreasing ability, aiding in generalizing results across healthy and clinical groups.²⁸

The Working Memory Questionnaire is a self-administered scale addressing three dimensions: short-term storage, attention, and executive control. Each dimension comprises 10 items, rated on a five-point Likert-type scale (0 to 4), with higher total scores (maximal score 120) indicating more difficulties or complaints. The questionnaire demonstrates good validity among people with brain injury.²⁹

Functioning was evaluated using the Impact on Participation and Autonomy questionnaire, with two sub-

scales: Family and Social, each containing 7 items.³⁰ Items were rated on a 5-point scale (0 to 4), and subscale scores were calculated using the median, following conventional scoring criteria (score range 0–4). Higher scores indicate more perceived restrictions on everyday functioning.

Ethics

Participants were required to disclose any adverse effects after each hypnosis session. Specifically, they were explicitly asked if they wished to withdraw from the study in the event of such effects. In cases of serious side effects, the blinding could be temporarily lifted for an individual participant. If a side effect was deemed severe enough to warrant halting the entire study, all blinding measures would be lifted to identify at-risk participants. Fortunately, no serious side effects were reported by the participants, and consequently, the procedure was never implemented. Approval was granted by the regional ethics committee (North Denmark Region) (May 15., 2017, no. N-20170022) and by the Danish Data Protection Agency (Sept. 18., 2015 and no. 2015-57-0001).

Statistics

Initially, baseline characteristics of participants across the three intervention groups were presented.

Differences in mean number of weeks employed during the 0–6- and 12–24-month periods after inclusion among intervention groups were analyzed using linear regression, with the group receiving usual care as reference for comparison to the two active groups. Analyses were conducted in both crude form and adjusted for months since injury (log-transformed), injury type, age, gender and baseline employment status. The log transformation of months since injury accounted for its asymptotic nature in spontaneous recovery, as expected a priori to be related to the treatment effect.³¹

Differences in work status between the intervention groups at 6- and 24-months' follow-up were analyzed through logistic regression models, again using the group receiving usual care as the reference. These analyses were conducted in both crude and adjusted models, accounting for baseline employment status and injury type.

For mean scores on questionnaires and tests at baseline and 6 months' follow-up, as well as the differences between these time points, linear regression was employed to analyze treatment effects at 6 months. The 6-month score served as the dependent, with the baseline score as a covariate and the group as a categorical predictor (usual care as the reference group). An adjusted model additionally included covariates for log-transformed months since injury, injury type, age, and gender.

Analyses regarding labor market attachment were conducted as intention-to-treat, while other outcomes were only collected and analyzed if participants adhered to the protocol. All point estimates are presented

with 95% confidence intervals (CI). Statistical significance was determined by a two-sided probability of p<0.05. Stata version 17 served as the statistical software (StataCorp LLC, Lakeway Dr, TX, USA).³²

Results

A total of 95 individuals were eligible for participation, and 87 agreed to participate and were randomized to usual care (n=28), hypnosis (n=30) or mindfulness (n=29) (Fig. 1).

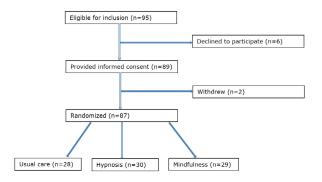


Fig. 1. Flow chart of the selection of participants in the study

Participants in the hypnosis group received an average 3.9 sessions, while those in the mindfulness group received 3.8 sessions.

The mean age of the participants ranged from 47.8 years in the usual care group to 50.7 years in the mindfulness group (Table 1). Two-thirds of the participants in the hypnosis and mindfulness groups were women, while women comprised three-quarters of the usual care group. Across all intervention groups, approximately 40% reported suffering from concussion, and the mean time since injury ranging from 22 to 25.6 months. At baseline, around 29% of participants were working at baseline in the usual care group, compared to 40% in the hypnosis groups.

Table 1. Baseline characteristics of the study population

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Usual care n=28 (32.2%)	Hypnosis n=30 (34.5%)	Mindfulness n=29 (33.3%)		
47.8 (9.5)	48.1 (8.3)	50.7 (8.2)		
22 (78.6)	20 (66.7)	19 (65.5)		
6 (21.4)	10 (33.3)	10 (34.5)		
22.0 (19.4)	25.6 (26)	23.8 (24.5)		
11 (40.7)	12 (40.0)	12 (41.4)		
16 (59.3)	18 (60.0)	17 (58.6)		
8 (28.6)	12 (40.0)	10 (34.5)		
	n=28 (32.2%) 47.8 (9.5) 22 (78.6) 6 (21.4) 22.0 (19.4) 11 (40.7) 16 (59.3)	n=28 (32.2%) n=30 (34.5%) 47.8 (9.5) 48.1 (8.3) 22 (78.6) 20 (66.7) 6 (21.4) 10 (33.3) 22.0 (19.4) 25.6 (26) 11 (40.7) 12 (40.0) 16 (59.3) 18 (60.0)		

The mean number of weeks participants worked during the first 6 months after inclusion ranged from

10.36 in the usual care group to 12.77 in the hypnosis group (Table 2). Similarly, during the 12 to 24 months' follow-up period, the correspond varied from 32.71 in the usual care group to 35.97 in the hypnosis group. No statistically significant differences in treatment effects were observed in either the crude or adjusted analyses for either time intervals.

Table 2. Mean number of weeks working up to the 24-month follow-up in the three intervention groups*

	Usual care (n=28)	Hypnosis (n=30)	Mindfulness (n=29)	р
Weeks working during				
0–6 months, mean (SD)	10.36 (11.52)	12.77 (12.03)	10.45 (12.24)	
Diff from control, crude (CI)	0 (ref)	2.41 (-3.83;8.65)	0.09 (-6.20;6.38)	0.68
Diff from control, adj.a (CI)	0 (ref)	-0.32 (-4.28;3.65)	-1.67 (-5.67;2.33)	0.67
12–24 months, mean (SD)	32.71 (22.31)	35.97 (21.58)	32.90 (22.44)	
Diff from control, crude (CI)	0 (ref)	3.25 (-8.30;14.80)	0.18 (-11.46;11.83)	0.82
Diff from control, adj.a (CI)	0 (ref)	-0.73 (-12.32;10.86)	-2.34 (-14.03;9.34)	0.92

*a – adjusted for months since injury (log), injury type, age and gender, baseline employment status

At 6-month of follow-up, 35% of participants in the usual care group were working, compared to approximately 40% in both the hypnosis and mindfulness groups (Table 3). By the 24-month follow-up, these figures had risen to around 55% in the usual care group and mindfulness groups, while 63% were working in the hypnosis group. No statistically significant differences in treatment effects were observed in the crude or the adjusted OR for working.

Table 3. Odds ratio (OR) for working at 6 and 24-month follow-up*

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	Usual care (n=28)	Hypnosis (n=30)	Mindfulness (n=29)	р
Working at				
6 months, n (%)	10 (35.7)	13 (43.3)	12 (41.4)	
Compared to usual care, crude OR (CI)	1 (ref)	1.38 (0.48;3.96)	1.27 (0.44;3.70)	0.83
Compared to usual care, adj. ORa (CI)	1 (ref)	0.84 (0.22;3.25)	0.93 (0.24;3.57)	0.97
24 months, n (%)	16 (57.1)	19 (63.3)	16 (55.2)	
Compared to usual care, crude OR (CI)	1 (ref)	1.30 (0.45;3.72)	0.92 (0.32;2.63)	0.80
Compared to usual care, adj. ORa (CI)	1 (ref)	1.21 (0.40;3.66)	0.89 (0.30;2.69)	0.86

^{*}a – adjusted for baseline employment status and injury type

At baseline, all intervention groups had exhibited a working memory score of around 90, which improved to a range of 91 to 95 at the 6-month follow-up (Table 4). The log ratio for the executive working memory (where lower scores are better) was approximately 0.80 for participants in the hypnosis and mindfulness groups and 0.68 for those in the usual care group. At the 6-month follow-up, the scores were approximately 0.75 in both the usual care group and hypnosis groups, and 0.86 in the mindfulness group.

Table 4. Differences in working memory and functioning between intervention groups at baseline and 6-month follow-up*

	Usual care n=28	n	Hypnosis n=30	n	Mindfulness n=29	n	p
	Mean (SD)		Mean (SD)		Mean (SD)		
Working memory							
Baseline	90.88 (11.98)	24	89.17 (12.90)	29	88.11 (7.74)	27	
6 months	95.60 (11.20)	15	92.62 (11.74)	21	91.81 (8.58)	21	
Diff (baseline-6 months)	0.87 (7.01)	15	1.62 (6.12)	21	3.38 (5.63)	21	
Diff from control at	0 (****)		0.36		1.30		0.7
6-month, crude (CI) ^a	0 (ref)		(-3.99;4.07)		(-2.80;5.41)		0.74
Diff from control at	0 (ref)		-0.17		0.66		0.9
6-month, adj. (CI) ^b	o (ici)		(-4.68;4.34)		(-4.06;5.38)		0.7
Executive working							
memory							
Baseline							
Trail A	41.79 (17.98)	24	40.72 (14.58)	29	40.37 (14.94)	27	
Trail B	83.21 (38.91)	24	93.34 (39.24)	29	93.11 (33.63)	27	
Log(B/A)	0.68 (0.24)	24	0.80 (0.24)	29	0.84 (0.33)	27	
6 months							
Trail A	36.47 (16.60)	15	34.62 (13.06)	21	31.05 (7.72)	21	
Trail B	76.60 (38.03)	15	75.67 (28.53)	21	74.05 (22.95)	21	
Log(B/A)	0.75 (0.20)	15	0.76 (0.34)	21	0.86 (0.32)	21	
Diff (baseline-6 months),	0.13 (0.10)	15	0.01 (0.21)	21	0.05 (0.30)	21	
Log(B/A)	0.12 (0.18)	15	-0.01 (0.31)	21	0.05 (0.28)	21	
Diff from control at			-0.07		-0.00		
6-month, crude Log(B/A)	0 (ref)		(-0.25;0.10)		(-0.18;0.17)		0.5
(CI) ^a			(0.23/0.10/		(0.10,0.17)		
Diff from control at	2/ 0		-0.08		-0.00		
6-month, adj. Log(B/A) (CI) ^b	0 (ref)		(-0.26;0.11)		(-0.19;0.19)		0.5
Storage, attention, and executive control							
Baseline	48.08 (22.70)	25	48.71 (22.34)	24	55.41 (20.39)	27	
6 months	47.67 (20.99)	18	34.36 (25.05)	22	47.74 (22.89)	19	
Diff (baseline-6 months)	-6.88 (14.83)	17	-13.39 (18.05)	18		19	
Diff from control at	0.00 (14.03)	-17	-8.53	10	-13.26 (13.41) 19 -5.46		
6-month, crude (CI) ^a	0 (ref)		(-19.19;2.14)		(-15.76;4.85)		0.2
Diff from control at			-9.56		-7.17		
6-month, adj. (CI) ^b	0 (ref)		(-20.12;1.00)		(-17.65;3.32)		0.1
Functioning, Family							
Baseline	1.12 (1.01)	25	1.13 (1.12)	24	1.48 (1.12)	27	
6 months	1.39 (1.24)	18	1.00 (1.11)	22	1.47 (0.90)	19	
Diff (baseline-6 months)	0.18 (0.81)	17	-0.06 (0.54)	18	-0.21 (0.71)	19	
Diff from control at			-0.25		-0.30		
6-month, crude (CI) ^a	0 (ref)		(-0.71;0.21)		(-0.76;0.16)		0.3
Diff from control at	2/ 0		-0.42		-0.43		
6-month, adj. (CI)b	0 (ref)		(-0.89;0.04)		(-0.90;0.03)		0.1
Functioning, Social							
Baseline	0.76 (0.79)	25	0.75 (0.69)	24	1.09 (0.88)	27	
6 months	0.86 (0.80)	18	0.41 (0.53)	22	1.13 (0.60)	19	
Diff (baseline-6 months)	-0.06 (1.01)	17	-0.31 (0.64)	18	-0.11 (0.92)	19	
Diff from control at	0 (ref) -0.44			0.20			
6-month, crude (CI) ^a			(-0.22;0.63)	0.01			
Diff from control at			-0.49		0.26		
6-month, adj. (CI) ^b	0 (ref)		(-0.92;-0.06)		(-0.18;0.70)		0.00

^{*}a – controlled for baseline score, b – adjusted for baseline score, months since injury (log), injury type, age and gender

The baseline score on the Working Memory Questionnaire total score (covering storage, attention and executive control) was 48 for participants in the usual care and hypnosis groups, while it was 55 for participants in the mindfulness group. By 6-month follow-up, the scores had improved by 13 points in the two active intervention groups, whereas the score in the usual care group had deteriorated with 6.8 points.

Regarding the Impact on Participation and Autonomy questionnaire (IPA), the baseline score for family functioning was approximately 1.1 in both the usual care and hypnosis groups, slightly higher at 1.48 in the mindfulness group. At the 6-month follow-up, participants in the active intervention groups reported fewer problems, while the usual care group reported more problems. The IPA score for social context functioning was about 0.75 in both the usual care group and hypnosis group and 1.09 in the mindfulness group. While all groups experienced a decrease in social problems, the hypnosis group showed the most significant improvement at 6 months, with a statistically significant treatment effect in both crude and adjusted analyses. No significantly differences were found between groups for the other outcomes.

Discussion

In this RCT, we compared the effects of hypnotic suggestion after 6- and 24- months' follow-up with mindfulness and usual care. There were no statistically significant differences in the mean number of weeks employed or work status at either 6 or 24 months of follow-up among the three intervention groups. However, participants assigned to hypnosis demonstrated a statistically significant improvement in social functioning at the 6-month follow-up compared to the usual care group. No differences were found between the groups regarding working memory or family functioning.

Interestingly, our study revealed that between 55% and 63% of participants were working at the 24-month follow-up. These percentages align closely with the 62% found in a Danish population of 20-57-year-old patients two years after stroke. Contrary to our hypothesis, we did not observe a higher attachment to the labor market for participants in the hypnosis group compared to the other two groups. The sample size and the characteristics of participants included in the study may have influenced the results, as the average time since injury was approximately two years, suggesting that some participants might have been dealing with chronic conditions.

The relatively late onset of the intervention and its single-element nature might explain the lack of significant difference. Early rehabilitation has been recommended for improving functional outcomes and increasing the likelihood of returning to work.¹ The absence of workplace involvement in the intervention,

a factor identified in other studies, could also contribute to the lack of observed differences.³³

Our study did not replicate the large effect sizes on working memory reported by Lindeløv et al. and contradicts earlier findings on the WAIS working memory index, the Trial Making Test or subjective assessments on the Working Memory Questionnaire. ^{17,34} Similarly, the mindfulness group did show improvement in fatigue, contrary to previous studies. ^{19,20} This raises questions about the comparability of the present study with earlier ones and whether they differ on critical variables.

The setting of our intervention at a municipal vocational rehabilitation center contrasts with previous studies on hypnosis that took place in research medical institutions. ^{17,18} The impact of different settings on perceived authority and treatment effectiveness should be considered, as expectancy plays a crucial role in the outcomes of hypnosis and placebos and for the success of brain injury rehabilitation in general. ^{14,15,23,35,36} Thus, the present null result may indicate that hypnotic suggestion for this patient group may require certain settings to be effective.

Moreover, participants in previous mindfulness studies were self-selected via newspapers, whereas our study included everyone meeting the inclusion criteria at the vocational rehabilitation center.^{17,19,20} This may indicate that participants in the former RCTs were more motivated to improve their functioning, suggesting a potential limitation in the effectiveness of hypnotic suggestion for a group facing vocational challenges.

The lack of efficacy in the present study may, in part, also be attributable to the short treatment duration of only 4 sessions (4 hours total) compared to 8 sessions in Lindeløv et al. (8 hours total) and 9 sessions in Johansson et al. (27 hours total plus home training).

While our RCT found no differences between the groups, the results underscored a higher attachment to the labor market at 24 months' follow-up compared to 6 months', indicating the duration of symptoms after ABI and the gradual but continual progress experienced by the persons. The reversible nature of the disease is suggested by most secondary outcomes, even though no significant difference was found between the groups.

Study limitations and strengths

The study had several strengths, including the blinding of both participants and researchers. The utilization of the DREAM register helped mitigate the risk of bias by ensuring full follow-up and minimizing misclassification. Additionally, employing a broader and validated set of questionnaires and cognitive tests expanded the scope of outcomes assessed compared to previous studies.

However, the study had its limitations, notably the small sample size, resulting in low statistical power to detect differences between groups. The impact of COVID-19 prevented the inclusion of more participants or complete follow-up on all enrolled participants. Furthermore, a lower-than-expected signup ratio necessitated an extension of the inclusion period. At 6-month follow-up, the dropout rate for secondary outcomes ranged between 37% and 46 % across the three groups, leading to reduced power for detecting difference between intervention groups.

In terms of the intervention, mindfulness was integrated into the usual care program, with approximately a quarter of participants engaging in at least one session. Unfortunately, records of specific participants were unavailable, precluding per-protocol analyses and potentially obscuring differences between the groups.

The cause, location, and severity of the participants' injuries were characterized by scanning their medical records. However, the data quality and completeness were insufficient for detailed analysis, and as a result, some injury characteristics remain unknown. This limits the ability to explore how specific injury profiles may have influenced treatment outcomes and may affect the generalizability of the findings to other populations with varying injury characteristics. Additionally, the timing of cognitive tests was not standardized across groups, which may have introduced bias in cognitive assessments. The study also lacked control for the amount of time participants spent in standard care, which could have confounded the comparison between groups. Furthermore, we did not measure hypnotic susceptibility, which may have influenced the outcomes. Lastly, the specific reasons for participant exclusion were not fully documented, limiting transparency regarding the selection process.

Conclusion

Brief hypnotic treatment at a municipal vocational rehabilitation center for people with ABI and concussion showed no significant advantage over mindfulness or usual care in labor market attachment, cognition, or family functioning. However, participants in the hypnosis group demonstrated significantly improved social functioning at the 6-month follow-up compared to usual care.

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Declarations

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Author contributions

Conceptualization, P.P., C.L., C.M.S., C.V.N. and J.K.L.; Methodology, P.P., C.L., C.M.S., C.V.N. and J.K.L.; Formal Analysis, P.P.; Investigation, J.K.L.; Resources, J.K.L. and C.V.N.; Data Curation, J.K.L.; Writing – Original Draft Preparation, P.P., C.L. and J.K.L.; Writing – Review & Editing, P.P., C.L., C.M.S., C.V.N. and J.K.L.; Visualization, P.P. and J.K.L.; Supervision, C.V.N.; Project Administration, P.P., C.L. and C.V.N.; Funding Acquisition, J.K.L. and C.V.N.

Conflicts of interest

The authors declare that they have no conflict of interest.

Data availability

Data supporting the findings of this study are available from the last author upon reasonable request, subject to institutional and ethical approval.

Ethics approval

This study was performed in line with the principles of the Declaration of Helsinki. Approval was granted by the regional ethics committee (North Denmark Region) (May 15., 2017, no. N-20170022) and by the Danish Data Protection Agency (Sept. 18., 2015 and no. 2015-57-0001).

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