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Letter to the editor

Cognitive remediation combined with brain stimulation after acquired brain injury: A single-case experimental design with 15 individuals

Dear Editor,

Executive function (EF) disorders can occur after traumatic or vascular brain injury. Impairment of these cognitive processes can lead to deficits in working memory, divided attention or mental flexibility, which can cause difficulties in initiating, planning or organizing actions [1]. These deficits have a direct impact on individual's lives. Several cognitive remediation approaches have been developed to improve the performance of activities of daily living in people with acquired brain injury (ABI) and EF disorders [2]. However, available cognitive remediations, such as analytical approaches, are mostly of low ecological validity and involve the performance of laboratory tasks in rehabilitation centers (eg, paper-and-pencil tasks). These approaches focus on the impairment and capacity of specific EFs, which does not sufficiently reflect the person's activity limitations in daily life [3]. Furthermore, the effectiveness of more ecological rehabilitation to improve EFs has been demonstrated [4].

To improve the transfer of learning to everyday life, we propose a "pseudo-ecological" training program (Covirtua Cognition®)¹ that has several real-life functional simulations, such as shopping or driving a car in a virtual environment. We consider this program to be "pseudo-ecological" since the functional activities proposed are on a 2D screen, and not in the real environment. We chose pseudo-ecological over ecological activities for 3 main reasons: ecological activities are difficult, if not impossible, to implement in a rehabilitation center; the pseudo-ecological environment allows functional exercises (eg, driving a car) to be performed in a controlled, safe environment; and Covirtua offers an individualized approach, which means that the difficulty of each activity can be modulated according to the individual's abilities and adjusted as they progress.

In parallel, transcranial electrical stimulation (tES) has emerged as a tool to modulate the excitability of neurons. tES can be applied to improve symptoms associated with brain disorders. Of the different techniques available, transcranial Random Noise Stimulation (tRNS) has been shown to modulate brain plasticity by increasing cortical excitability [5] and theoretically potentiates the effects of cognitive training [6]. Cognitive training, coupled with tRNS, has been shown to improve working memory performance in healthy participants [7].

We hypothesized that the concomitant application of these 2 approaches could offer promising prospects to improve EFs. A

combined approach could also be "more ecological" in that skills that were not necessarily acquired in the program could be maximally transferred to activities of daily living.

To assess the effect of such an intervention, we used a single-case experimental design (SCED) with replications of multiple baselines across participants. With this design, the effect of the intervention can be evaluated on a small number of people with heterogeneous characteristics. It is particularly well-suited for participants with a wide range of brain injuries and symptoms. The small number of participants is compensated for by multiple measurements of the primary outcome, with participants as their own controls [8]. Moreover, this model is suitable for studying interventions aimed at the acquisition of a new skill, with the expectation that the effect will be maintained beyond the end of the intervention [9].

The trial was approved by the EST I ethics committee and registered at ClinicalTrials.gov (NCT04253522). The experimental process lasted 12 weeks and included 3 phases: A (baseline), B (the intervention phase) and FU (the follow up phase). The intervention was introduced sequentially, and the duration of the baseline phase was randomized among the participants. Consequently, the duration of the baseline phase varied between 3, 4 and 5 weeks, depending on the order of randomization. Similarly, the follow-up phase lasted 5, 4 or 3 weeks, for an overall duration of 12 weeks. The experimental design is presented in Fig. 1. Throughout the 3 successive phases, each rehabilitation session lasted 45 min, 4 times a week, and was run by the same occupational therapist (OT). Phases A and FU consisted of standard OT with no specific cognitive remediation (eg, rehabilitation focusing on motor or sensory disorders). Phase B lasted 4 weeks for all participants. The intervention for phase B consisted of cognitive training using the Covirtua software coupled with a 20-minute tRNS session. tRNS involved the application of low-intensity electrical current of 1 mA according to current recommendations [10]. We used a high-definition (HD) montage, which has the advantage of inducing a focal stimulation [10]. It was applied using 1 central electrode positioned at the stimulating site over the right dorso-lateral prefrontal cortex, which is directly involved in executive functioning [11], and 4 return electrodes. The duration of the cognitive training was guided by the data from the systematic review by Zhang et al. [4] who reported that therapy duration was mainly 4 weeks at a frequency of 2 to 5 times per week.

Five groups of 3 participants with ABI were included (see Appendix A in the Supplementary material). One participant withdrew from the study because of family issues.

We assessed performance in everyday life situations with the Goal Attainment Scaling (GAS) score. This tool has been validated for use in clinical research [12] and is used here as the primary outcome (ie, the repeated measurement).

Three 5-level individualized goals were precisely defined for each participant at the inclusion visit before the start of phase A [13]. They

Abbreviations: ABI, acquired brain injury; EF, executive function; GAS, goal attainment scaling; HD, high-definition; IOA, inter-observer agreement; OT, occupational therapist; SCED, single-case experimental design; SMART, specific, measurable, achievable, realistic/relevant and timed agreement; tES, transcranial electrical stimulation; tRNS, transcranial random noise stimulation

¹ <https://www.covirtua.com>

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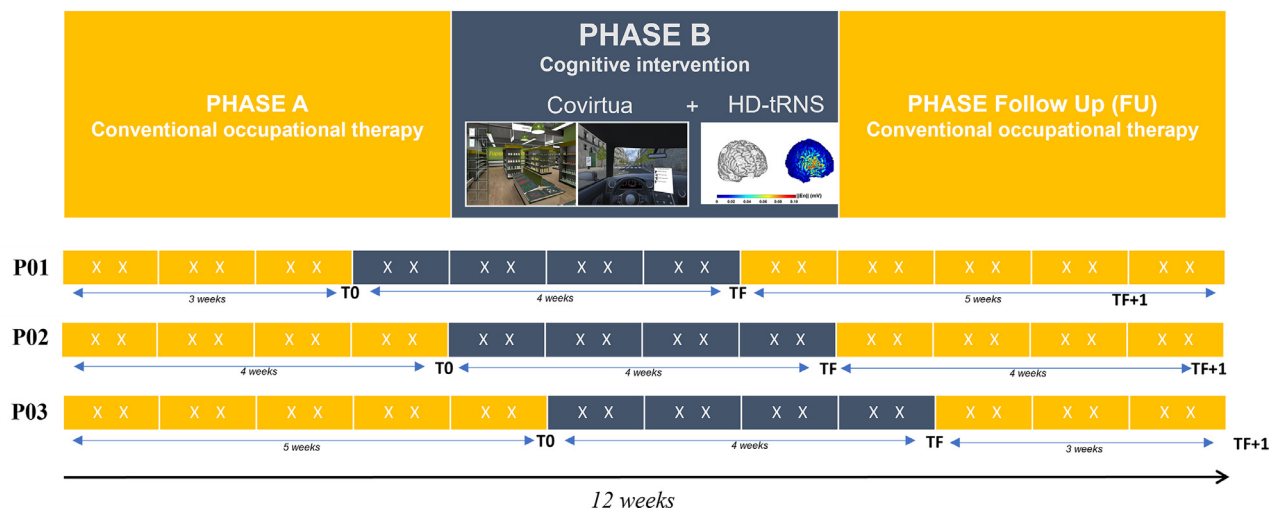


Fig. 1. Multiple baseline design shown for 3 participants with 3 successive phases: A without cognitive intervention, B with intervention combining cognitive training (Covirtua) and transcranial random noise stimulation (tRNS) and FU (follow up) without cognitive intervention. Phase B Cognitive intervention: **Covirtua** functional tasks with example of shopping task in a supermarket (left) and following an itinerary (right). **HD-tRNS** montage with influence map over the white matter of the right dorsolateral prefrontal cortex. One central electrode positioned (F4) at the stimulating site and 4 other electrodes (F8; C4; FZ and FP2) as the return electrodes (extracted from NIC2 software v.2.0.10, Neuroelectronics®). The baseline duration varied for each participant between 3, 4 and 5 weeks. The intervention phase (B) lasted 4 weeks and the total duration of the experimental procedure lasted 12 weeks for all participants. X: corresponds to each GAS assessment, 24 measures in total for each goal.

were developed in collaboration with the participant, the OT in charge of the participant and the participant's caregiver. If necessary, the therapists used the Canadian Occupational Performance Measure [14] interview or the goal determination grid OT'HOPE A² [15]. The goals defined were Specific, Measurable, Achievable, Realistic/Relevant and Timed (SMART criteria) [16]. All objectives were assessed and scored twice a week (ie, 24 measurements) by an OT trained in the GAS methodology, independent from the participant's care and blind to the phase. The goals were evaluated either using patient- (or caregiver-) reported outcome measures, allowing for the assessment of the effect of the intervention in an ecological setting by indirect observation, or by direct observation of performance, which allowed for a more objective measurement of the participant's progress.

Inter-observer agreement (IOA) was assessed for at least 20% of the measures by an independent assessor blinded to the study phases, and the mean IOA was 82% (the details of the goals for each participant are provided in Appendix B in the Supplementary material).

In accordance with current recommendations [17,18], we carried out visual and statistical analyses of the changes in GAS scores. Regarding the visual inspection, we examined the differences in the trends between phases A and B to assess whether the intervention had a short-term effect (A vs. B) and an overall effect, 1 month after the end of the intervention (A vs. B+FU).

Detailed graphs of GAS "raw" scores are presented for all participants in Fig. 2.

We calculated the TAU-U described by Tarlow [18] or the baseline corrected version in case of a significant baseline trend³ between phases. The TAU-U characterizes the size of the treatment effect and was calculated for each participant and each goal, comparing phase A to phase B to assess short-term effects, and comparing phase A to phases B and FU together to assess the overall effect of the intervention. We did not directly compare phase A to phase FU because they were not adjacent, which is a mandatory condition for TAU-U analysis. A description of each goal and raw data for TAU-U are provided in Table 1.

Overall, in the short-term evaluation (A vs. B), 3 participants achieved at least 1 of their goals (P01, P03, and P12): P01 achieved 2 goals, and P03 and P12 each achieved 1 goal. Furthermore, the effect

was maintained 1 month after the end of the intervention (B vs. FU). A positive and significant overall effect was found for 8 participants who achieved at least 1 of their goals during the study (A vs. B+FU). P01, P02, and P06 achieved 2 out of 3 goals and P03, P07, P12, P13, and P14 achieved at least 1 of their goals 1 month after the end of the intervention. No significant improvement over time occurred for P05, P08, P9, P10, P11 or P15.

The purpose of this study was to evaluate the effectiveness of an individualized pseudo-ecological approach combined with HD-tRNS to improve the performance of activities of daily living in people with ABI and EF deficits. We found an improvement in activities of daily living mainly between phases A and B+FU for 8 participants. The lack of visible short-term effects might relate to the time required for the brain plasticity mechanisms induced by tRNS to take effect and improve behavioral performance, as previously observed in our recent work, albeit with healthy participants [19].

Moreover, it can be assumed that the participants needed time to develop and implement the cognitive strategies necessary to achieve their goals, which occurred a few weeks after the intervention.

Nevertheless, it is important to highlight that with interventions that target cognitive improvement, the aim is to obtain persistent effects beyond the end of the intervention. This occurred for 8 participants who achieved at least 1 goal, demonstrating some performance stabilization.

In SCED, several factors can limit the detection of intervention effects, such as a tendency for improvement from the baseline. To overcome this problem, the SCED methodology suggests increasing the baseline period until stabilization is achieved (we chose participants in the chronic phase to limit possible spontaneous recovery effects).

The article follows the Single-Case Reporting Guideline in Behavioural Interventions (SCRIBE) recommendations [20] and the study was designed according to the SCED methodology standards (Appendix C in Supplementary materials).

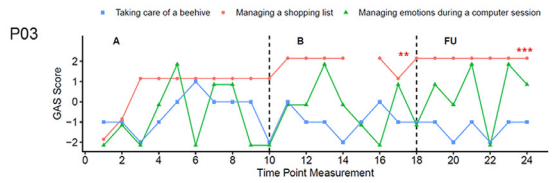
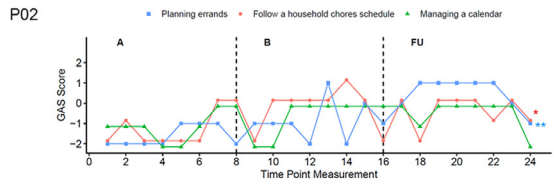
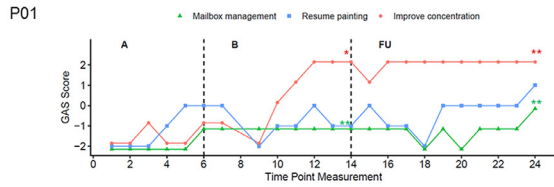
The SCED allowed exploration of this individualized pseudo-ecological approach through a participant-by-participant analysis of each GAS score, which provided an assessment of performance in everyday life. The GAS and SCED perfectly integrate the person-centered approach, which is particularly interesting for research in people with ABI.

Given the heterogeneity of the results, we cannot draw a conclusion on whether the effects of this intervention were positive. Further

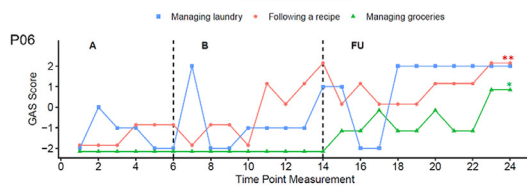
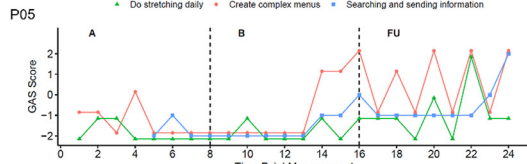
² <http://www.ot-hope.com>

³ <https://ktarlow.com/stats/tau>

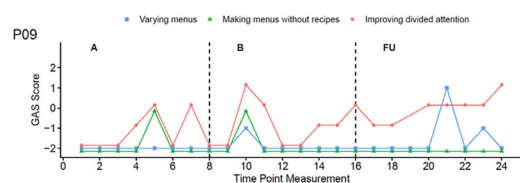
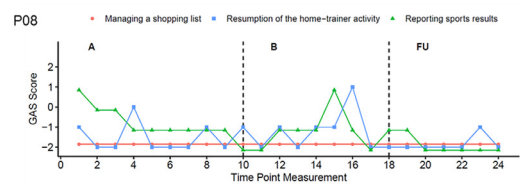
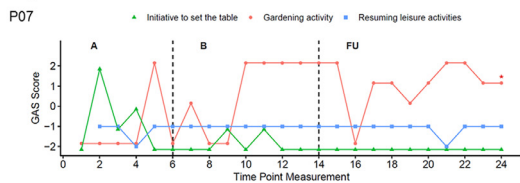
Group 1



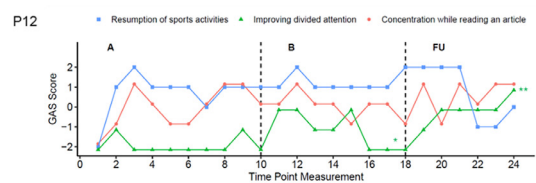
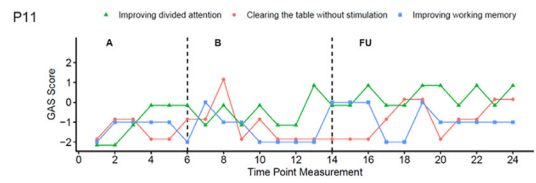
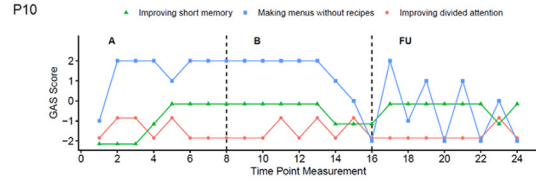
Group 2



Group 3



Group 4



Group 5

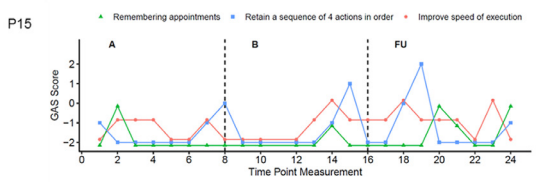
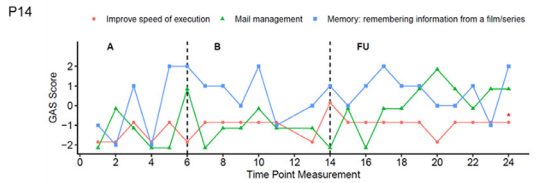
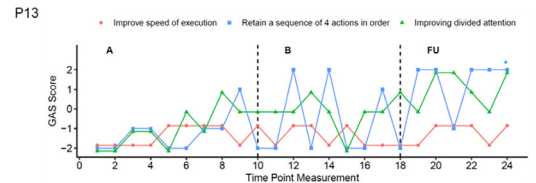


Fig. 2. Change in Goal Attainment Scale (GAS) scores for all participants across each phase: baseline (A), intervention (B) and follow up (FU). GAS scores. -2: initial level; -1: progress but goal not achieved; 0: goal achieved as expected; +1: goal achieved better than expected; +2: most favorable outcome. For each participant, 3 goals are represented by a different color (red, blue and green). Tau-U p-values: * $P < 0.05$; ** $P < 0.01$; *** $P < 0.001$.

Table 1
Descriptive data for each objective and results of statistical analyses for all patients.

Participants	Goals	A vs. B	A vs. B+FU	
Group 1	P01	1 : Mailbox management 2 : Resume painting 3 : Improve concentration	TAU-U = 0.85; P = 0.004 BC-TAU-U = -0.75; P = 0.004 TAU-U = 0.62; P = 0.021	TAU-U = 0.65; P = 0.002 BC-TAU-U = -0.64; P < 0.001 TAU-U = 0.69; P = 0.001
	P02	1 : Planning errands 2 : Follow a household schedule 3 : Managing a calendar	TAU-U = 0.42; P = 0.096 TAU-U = 0.45; P = 0.075 TAU-U = 0.35; P = 0.189	TAU-U = 0.56; P = 0.004 TAU-U = 0.43; P = 0.032 TAU-U = 0.37; P = 0.067
	P03	1 : Taking care of a beehive 2 : Managing shopping list 3 : Managing emotions during a computer session	TAU-U = -0.16; P = 0.506 BC-TAU-U = 0.80; P = 0.001 TAU-U = 0.21; P = 0.361	TAU-U = -0.26; P = 0.183 BC-TAU-U = 0.87; P < 0.001 TAU-U = 0.27; P = 0.150
Group 2	P05	1 : Do stretching daily 2 : Create complex menus 3 : Searching and sending information	TAU-U = 0.13; P = 0.648 TAU-U = 0.13; P = 0.629 TAU-U = 0.14; P = 0.343	TAU-U = 0.30; P = 0.138 TAU-U = 0.35; P = 0.072 TAU-U = 0.34; P = 0.123
	P06	1 : Managing laundry 2 : Following a recipe 3 : Managing groceries	TAU-U = 0.24; P = 0.371 TAU-U = 0.41; P = 0.120 TAU-U = 0.00; P = 1	TAU-U = 0.37; P = 0.056 TAU-U = 0.53; P = 0.005 TAU-U = 0.44; P = 0.027
Group 3	P07	1 : Initiative to set the table 2 : Gardening activity 3 : Resuming leisure activities	TAU-U = -0.32; P = 0.256 TAU-U = 0.52; P = 0.061 TAU-U = 0.47; P = 0.111	TAU-U = -0.44; P = 0.034 TAU-U = 0.44; P = 0.025 TAU-U = 0.36; P = 0.092
	P08	1 : Managing shopping list 2 : Resumption of the home-trainer activity 3 : Reporting sports results	TAU-U = 0.00; P = 1 TAU-U = 0.10; P = 0.690 TAU-U = -0.22; P = 0.361	TAU-U = 0.00; P = 1 TAU-U = -0.04; P = 0.864 TAU-U = -0.41; P = 0.038
	P09	1 : Varying menus 2 : Making menus without recipes 3 : Improving divided attention	TAU-U = 0.26; P = 0.382 TAU-U = 0.00; P = 1.703 TAU-U = 0.18; P = 0.496	TAU-U = 0.26; P = 0.220 TAU-U = -0.11; P = 0.655 TAU-U = 0.32; P = 0.121
Group 4	P10	1 : Improving short memory 2 : Making menus without recipes 3 : Improving divided attention	BC-TAU-U = -0.734; P = 0.001 TAU-U = -0.141; P = 0.609 TAU-U = 0.000; P = 1.050	BC TAU-U = -0.686; P < 0.001 TAU-U = -0.341; P = 0.081 TAU-U = -0.130; P = 0.560
	P11	1 : Improving divided attention 2 : Clearing the table without stimulation 3 : Improving working memory	BC-TAU-U = -0.756; P = 0.002 TAU-U = 0.185; P = 0.614 TAU-U = 0.000; P = 1.050	BC TAU-U = -0.638; P = 0.000 TAU-U = 0.148; P = 0.473 TAU-U = 0.142; P = 0.494
	P12	1 : Resumption of sports activities 2 : Improving divided attention 3 : Concentration while reading an article	TAU-U = 0.316; P = 0.194 TAU-U = 0.474; P = 0.047 TAU-U = 0.021; P = 0.962	TAU-U = 0.176; P = 0.384 TAU-U = 0.601; P = 0.002 TAU-U = 0.157; P = 0.439
Group 5	P13	1 : Improve speed of execution 2 : Retain a sequence of 4 actions in order 3 : Improving divided attention	TAU-U = -0.125; P = 0.643 TAU-U = 0.045; P = 0.883 BC-TAU-U = 0.599; P = 0.004	TAU-U = 0.000; P = 1.027 TAU-U = 0.406; P = 0.043 BC-TAU-U = -0.632; P < 0.001
	P14	1 : Improve speed of execution 2 : Mail management 3 : Improve memory	TAU-U = 0.540; P = 0.065 TAU-U = 0.020; P = 1 TAU-U = 0.114; P = 0.715	TAU-U = 0.52; P = 0.013 TAU-U = 0.250; P = 0.208 TAU-U = 0.119; P = 0.563
	P15	1 : Remembering appointments 2 : Retain a sequence of 4 actions in order 3 : Improve speed of execution	TAU-U = 0.000; P = 1.078 TAU-U = -0.053; P = 0.890 TAU-U = 0.135; P = 0.651	TAU-U = 0.140; P = 0.530 TAU-U = 0.008; P = 1 TAU-U = 0.232; P = 0.272

Bold: objectives that showed an effect of the intervention. BC-TAU-U: Baseline Corrected TAU-U. The effect size is considered small if TAU-U < 0.2; medium if 0.2 < TAU-U < 0.6; large if 0.6 < TAU-U < 0.8 and very large if TAU-U > 0.8.
TAU-U p-values: *P < 0.05; **P < 0.01; ***P < 0.001.

investigations are needed: 1) to determine responder and non-responder profiles, and 2) to target activities of daily living for which the transfer of knowledge would be most effective, if at all.

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Declaration of competing interest

None.

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Rennes in December 2022, and at the International Society of Physical and Rehabilitation Medicine (ISPRM) conference in Lisbon in July 2022. Moreover, 2 posters were presented at the Federation of European Neuroscience Societies (FENS) in Paris in July 2022 and at the SOFMER conference in Le Havre in October 2023.

Supplementary materials

Supplementary material associated with this article can be found in the online version at doi:10.1016/j.rehab.2024.101892.

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