Reviewer's report

Title: Evaluating the Effectiveness of Reasoning Training in Military and Civilian Chronic Traumatic Brain Injury Patients: Study Protocol

Version: 4 Date: 13 December 2012

Reviewer: Philippe Azouvi

Reviewer's report:

This manuscript presents an interesting and ambitious project. The authors have planned to include a large number of patients (n=100), which is quite far above the number of patients included in previous studies on rehabilitation of executive functions.

The study design is fine: the authors will use a randomized protocol, adjusted for severity and cause of injury (military versus civilian). Outcome will be assessed blindly. A follow-up is planned three months after the end of the trial. The training program and the comparison treatment are well presented and are relevant to the aim of the study. Outcome measures are adequate and relevant to the objective of the study, and the use of fMRI is a major strength of this study.

Overall, my feeling is that this is a very ambitious and high-quality protocol.

I have however a few questions / comments:

1. Outcome measures are relevant, but they are essentially laboratory-based neuropsychological tests, while recent studies and reviews emphasized the fact that ecological measures might be more sensitive to cognitive rehabilitation than laboratory measures (Kennedy et al., 2008; Spikman, Boelen, Lamberts, Brouwer, & Fasotti, 2010). I am aware of the fact that the authors have also planned to use the CIQ and a life satisfaction scale, but these scales do not exactly address the same aspects than ecological tests (such as the Multiple Errands Test or the Executive Secretarial Task) or behavioral scales (such as the Dysexecutive Questionnaire) measuring executive functions in everyday life.

2. The authors do not address the question of feasibility. They plan to include a large series of patients, but we know that it is very difficult to engage patients in such a long-lasting protocol in a single-center study. So, it would be interesting to have more information on this issue: how many eligible patients are seen in their clinic per year? What is the expected time schedule of the study?

3. Inclusion criteria are not very clear to me, and the terms “mild” and “moderate” TBI are used in a confusing way: the authors actually seem to refer to mild or moderate disability (as an outcome measure). However, this terminology usually refers to initial injury severity measures. They should clarify what relates to initial severity (mild, moderate or severe TBI based on the GCS and/or PTA) and what refers to an outcome measure (disability categories assessed with the GOS-E:...
severe disability, moderate disability, or good recovery).

4. Also, a related point is the question of “mild” TBI: I wonder whether patients with mild TBI who are expected to have only minor problems in daily life, will be ready to engage in a 24-week protocol. Moreover, they might be a high risk of a ceiling effect for these patients. Additionally, the authors do not tell us why they decided not to include patients with severe TBI, who may also be susceptible to benefit from this treatment?

5. A PTSD scale will be used in the screening procedure, but the authors do not tell us whether patients with PTSD will be included or not in the protocol?

6. Minor point: Overall, the paper is well written; however some of the neuropsychological outcome measures (VSLT, Pictures analogies task) are presented after the “testing-imaging counterbalancing procedures” section. I think that the paper would be easier to read, particularly for readers who are not familiar with these tests if the testing procedure was presented first, and the counterbalancing afterwards.

References


Level of interest: An article of outstanding merit and interest in its field

Quality of written English: Acceptable

Statistical review: No, the manuscript does not need to be seen by a statistician.

Declaration of competing interests:

I declare that I have no competing interests.