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Response to letter to the editor: Safety of transcranial direct current stimulation: Evidence based update 2016

Dear Editor,

We respond to concerns raised by Godinho et al. about the Bikson et al. tDCS safety review [1]. As stated in the opening sentence, our report provided an update "based on published Serious Adverse Effects in human trials and irreversible brain damage in animal models". Further, we carefully defined the scope of the review, "In this review, tDCS safety indicates the absence of a Serious Adverse Effect including brain tissue injury related to tDCS application." We developed precise criteria for a Serious Adverse Effect. A systematic review of all adverse events, including minor side effects that may affect the acceptability and tolerability of tDCS (as suggested by Godhino et al.) was outside the scope of our review, and addressed elsewhere including recently by our coauthors [2].

Adverse event underreporting occurs in most medical fields. We dedicated our assessment to published reports specifically of Serious Adverse Events, assuming reporting a Serious Adverse Event (e.g. hospitalization) is more reliable than mild well-known tDCS side effects (e.g. itching). Speculation regarding unpublished adverse events was not incorporated into our evidence-based approach. Causality was explicit to our definition of Serious Adverse *Effect* namely: "based on scientific judgment is determined to be caused or aggravated by the application of direct current to the head."

Exact methodology to estimate the volume of tDCS sessions was indicated in the relevant section, but safety considerations were based on the complete tDCS literature as assessed by authors with domain expertise. We underscore that our conclusions are derived from, and are explicitly limited to, stated definitions - such that the discourse by Godinho et al. does not affect the validity of our methodology. To the extent that Godinho et al. do not provide evidence for a Serious Adverse Effect by tDCS, the review conclusion is unchanged.

-Marom Bikson, Pnina Grossman, Greg Kronberg, Paulo Sérgio Boggio, Andre R. Brunoni, Leigh Charvet, Felipe Fregni, Brita Fritsch, Bernadette Gillick, Roy H. Hamilton, Benjamin M. Hampstead, Adam Kirton, Helena Knotkova, David Liebetanz, Anli Liu, Colleen Loo, Michael A. Nitsche, Janine Reis, Jessica D. Richardson, Alexander Rotenberg, Peter Turkeltaub, Adam Woods.

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