

# **A questionnaire to collect unintended effects of Transcranial Magnetic Stimulation: A consensus based approach**

**Andreina Giustiniani, A. Vallesi, M. Oliveri, V. Tarantino, E. Ambrosini, M. Bortoletto, F. Masina, P. Busan, H. Siebner, L. Fadiga, G. Koch, L. Leocani, J. Lefaucheur, A. Rotenberg, A. Zangen, I. Violante, V. Moliadze, O. Gamboa, Y. Ugawa, A. Pascual-Leone, U. Ziemann, C. Miniussi, F. Burgio**

**IRCCS San Camillo Hospital - University of Palermo - Venice  
Department of Neuroscience & Padova Neuroscience Center - University of Padova - Padua  
Department SPPEF - University of Palermo - Palermo  
Department SPPEF - University of Palermo - Palermo  
Department of General Psychology - University of Padova - Padua  
Neurophysiology Lab - IRCCS Istituto Centro San Giovanni di Dio Fatebenefratelli - Brescia  
Neurophysiology Lab - IRCCS San Camillo Hospital - Venice  
Stuttering lab - IRCCS San Camillo Hospital - Venice  
Danish Research Centre for Magnetic Resonance, Centre for Functional and Diagnostic Imaging and Research - Copenhagen University Hospital - Copenhagen  
Department of Neuroscience and Rehabilitation, Section of Physiology - University of Ferrara - Ferrara  
Department of Neuroscience and Rehabilitation, Section of Physiology - University of Ferrara - Ferrara  
Department of Neurorehabilitation and Experimental Neurophysiology Unit, Institute of Experimental Neurology - IRCCS San Raffaele - Milan  
ENT Team - Faculty of Medicine, - Paris  
Department of Neurology and the Kirby Center for Neurobiology - Boston Children's Hospital and Harvard Medical School - Boston  
Laureate Institute for Brain Research - Laureate Institute for Brain Research - USA  
School of Psychology, Faculty of Health and Medical Sciences - University of Surrey - Guildford  
Institute of Medical Psychology and Medical Sociology - University Medical Center Schleswig Holstein - Kiel  
School of Psychology - University of Sydney - Sydney  
Department of Human Neurophysiology - Fukushima Medical University - Fukushima  
Berenson-Allen Center for Noninvasive Brain Stimulation and Division of Cognitive Neurology - Harvard Medical School - Boston  
Department of Neurology & Stroke - University of Tübingen - Tübingen  
Center for Mind/Brain Sciences - CIMeC - University of Trento - Rovereto  
Neuropsychologylab - IRCCS San Camillo Hospital - Venice**

**Aims:** Transcranial magnetic stimulation (TMS) has been widely used in both clinical and research practice. However, TMS might induce unintended sensations and undesired effects as well as serious adverse effects [1]. To date, no shared forms are available to report such unintended effects.

**This study aimed at developing a questionnaire enabling reporting of TMS unintended effects. Materials and Methods:** A Delphi procedure was applied which allowed consensus among TMS experts [2]. A steering committee nominated a number of experts to be involved in the Delphi procedure. Three rounds were conducted before reaching a consensus. Afterwards, the questionnaire was publicized on the International Federation of Clinical Neurophysiology website to

# A questionnaire to collect unintended effects of Transcranial Magnetic Stimulation: A consensus based approach

collect further suggestions by the wider scientific community. A last Delphi round was then conducted to obtain consensus on the suggestions collected during the publicization and integrate them in the questionnaire.

Results: The procedure resulted in a questionnaire, that is the TMSens\_Q, applicable in clinical and research practice

Discussion: The TMSens\_Q was developed through a Delphi procedure, implemented online, with the goal of reaching a consensus among experts in the field. The questionnaire could be used in research as well as in clinical settings. Reporting information about potentially undesired TMS effects in a standardized format will provide the unique opportunity to quantify the incidence of minor sensory effects, such as discomfort and unpleasant sensations induced by the stimulation, in addition to adverse effects, which are generally reported and collected in medical and research study record. Therefore, the use of this questionnaire might constitute an important starting point for future studies investigating the safety of new TMS protocols.

Conclusions: Routine use of the structured TMS questionnaire and standard reporting of unintended TMS effects will help to monitor the safety of TMS, particularly when applying new protocols. It will also improve the quality of data collection as well as the interpretation of experimental findings.  
research settings

## References:

- [1] Rossi S, Antal A, Bestmann S, Bikson M, Brewer C, Brockmüller J, et al. Safety and recommendations for TMS use in healthy subjects and patient populations, with updates on training, ethical and regulatory issues: Expert Guidelines. Clin Neurophysiol 2021. <https://doi.org/10.1016/j.clinph.2020.10.003>.
- [2] Hasson F, Keeney S, McKenna H. Research guidelines for the Delphi survey technique. J Adv Nurs 2000. <https://doi.org/10.1046/j.1365-2648.2000.t01-1-01567.x>.

**Tipo presentazione:** ORALE