PO104 PLACEBO AND NOCEBO RESPONSES IN RLS: A META-ANALYSIS

[1,2,3]Filipe B Rodrigues, [2,3,4]Gonçalo S Duarte, [2,3]Maria A Silva, [2,3,4]Ricardo M Fernandes, [2,3]Daisy Abreu, [5]Tiago Mestre, [2,3,4,6]João Costa, [7,8]Claudia Trenkwalder, [2,3]Joaquim J Ferreira. *[1]Huntington's Disease Centre, Institute of Neurology, University Collega London, UK; [2]Clinical Pharmacology Unit, Instituto de Medicina Molecular, Portugal; [3]Laboratory of Clinical Pharmacology and Therapeutics, University of Lisbon, Portugal; [4]Portuguese Collaborating Centre of the IberoAmerican Cochrane Network, Cochrane Portugal, Portugal; [5]Parkinson's disease and Movement Disorders Centre, University of Ottawa, Canada; [6]Center for Evidence-Based Medicine, Faculty of Medicine, University of Lisbon, Portugal; [7]Paracelsus-Elena Klinik, Centre of Parkinsonism and Movement Disorders, 34128 Kassel, Germany; [8]Department of Neurosurgery, University Medical Centre, Goettingen, Germany*

10.1136/jnnp-2017-ABN.134

Objective Our goals were to estimate the placebo and nocebo responses in restless legs syndrome (RLS).

Methods Databases were searched up to October 2015. Randomised, double-blind, placebo-controlled trials of RLS patient were included. 'Placebo response' was defined as the within-group change from baseline, using any scale measuring RLS severity or disability. 'Nocebo response' was defined as the proportion of patients experiencing adverse events in the placebo arm. Random-effects meta-analysis was used to pool data.

Results We included 5046 participants. Pooled placebo response effect size was −1.41 (95%CI:−1.56-−1.25), corresponding to −6.58 points in the International RLS Study Group Scale (IRLS). Pooled nocebo response was 45.36% (95%CI:40.47%–50.29%). The placebo and nocebo responses were greater in trials with longer duration, evaluating pharmacological interventions and idiopathic RLS, and in industry funded and unpublished studies. The placebo response was considerable smaller in objective as compared to subjective outcomes. In addition, the nocebo response increases proportionally with the placebo response, and has the same predictors.

Conclusions The magnitude of the placebo response in RLS is above the threshold of minimal clinical important difference, and the frequency of adverse events is also considerable. These results are relevant to inform the design and interpretation of future clinical trials.