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Rachele Rosso[1], Alessandro Maglione[1], Ilario Ferrocino[2], Roberta Lanzillo[3], Cinzia Cordioli[4], Federica Masuzzo[1], Manuela Matta[1], Dora Tortarolo[5], Sandro Gepiro Contaldo[5], Marco Beccuti[5], Francesca Cordero[5], Marinella Clerico[1] and Simona Rolla[1]

[1]Department of Clinical and Biological Sciences, AOU San Luigi Gonzaga, University of Turin, [2]Department of Agricultural, Forestry and Food Sciences, University of Turin, [3]Department of Neurosciences, Reproductive Sciences and Odontostomatology, Federico II University, Naples, Italy, [4]Spedali Civili di Brescia, Multiple Sclerosis Centre, Brescia, Italy, [5]Department of Computer Science, University of Turin, Italy

Objective: The microbiome is modulated by genetic and environmental factors including lifestyle, diet, and drug intake. This study aimed to characterize the gut microbiome associated with MS in an Italian cohort and to identify associations with disease (MS onset or disease duration), dietary characteristics and therapy. The recently approved oral ones, represent significant advances in therapy. The oral route of administration clearly promotes patient satisfaction and increases therapeutic compliance. Here we specifically focused on people with MS (PwMS) receiving dimethyl fumarate (DMF) or Cladribine therapies. DMF acts by decreasing circulating lymphocytes counts and their migration into the central nervous system whereas Cladribine, a chemotherapy drug, acts as an immune-reconstitution therapy.

Methods: 60 PwMS were recruited in a multicenter follow-up study. Among them 30 pwMS started DMF therapy and 30 started Cladribine. Stool samples, clinical data and food diaries were collected at the recruitment and then at different time points in the follow-up.

Results: The gut microbiota was sequenced through a shotgun metagenomic sequencing strategy and α- and β-diversity were calculated. Abundances were compared between MS at the onset, MS with already established disease, before starting therapy and 1 and 12 months after. Specific taxa related to MS clinical features and treatment were identified. Association with nutrient intake was also evaluated.

Conclusions: The identification of the microbial populations and of their functional role within the microbiome during therapies will first, clarify if their beneficial effects act through modulation of gut microbiota that in turns modulate immune system, and second, will be fundamental to help neurologist in the treatment decisions within individual MS heterophenotypes.