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Burden-of-Illness in people with progressive MS: Insights from the MACSiMiSE-BRAIN clinical trial

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Introduction: Data on the economic burden within specific patient populations are essential to guide healthcare planning and treatment evaluation. Progressive MS (PMS) has limited treatment options and a significant impact on individuals, caregivers and society. Addressing both clinical and societal aspects, the MACSiMiSE-BRAIN clinical trial—a multicentre, randomized placebo-controlled study in Flanders, Belgium—investigates the neuroprotective and remyelinating effects of metformin as add-on therapy in people with non-active PMS and provides a valuable opportunity to assess the cost-of-illness in this specific population.

Objectives/Aims: To estimate the societal cost and resource use associated with non-active PMS in the MACSiMiSE-BRAIN cohort, providing insights into the burden faced by this subgroup of MS patients and supporting future cost-effectiveness evaluations, including that of metformin.

Methods: The trial includes patients aged 18–70 years with non-active PMS and EDSS 2.0–6.5. Patient/caregiver-reported questionnaires gather information on demographics, healthcare use, informal care, productivity loss, symptoms, and health-related quality of life (HRQoL) at regular intervals for 96 weeks. Descriptive statistics and exploratory association analyses are used to examine baseline data collected at study entry. Cost categories include direct (non-)medical costs and productivity-related indirect costs. Costs will be estimated using standard unit prices and the human capital approach.

Results: Between December '23 and March '25, a total of 112 patients have been randomized across five centres in Flanders and are currently in follow-up (mean age 52y, 56% female). The median EDSS score was 5.2; 24% of participants were not receiving disease-modifying therapy. Fatigue and cognitive difficulties were reported by 97% and 54% of patients, respectively. Among the 96% below retirement age (67y), only 42%

were employed- 36% full-time and 64% part-time, with MS cited as the reason in 82% of part-time cases. Employment status was associated with EDSS (OR = 0.6, 95% CI 0.44–0.82, p = .001), and 64% of workers reported reduced productivity, primarily due to mobility limitations and fatigue. Further analyses of healthcare use, resource consumption, HRQoL and cost patterns are ongoing and will be included.

Conclusion: This study offers valuable data on the societal burden of non-active PMS. Findings will support future health economic evaluations, including the cost-effectiveness analysis of metformin in the MACSiMiSE-BRAIN trial, and may inform future reimbursement policies.

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