# DISCOntinuation of disease-modifying therapies in MS (DISCOMS) Extension – Study Design and Baseline Demographics

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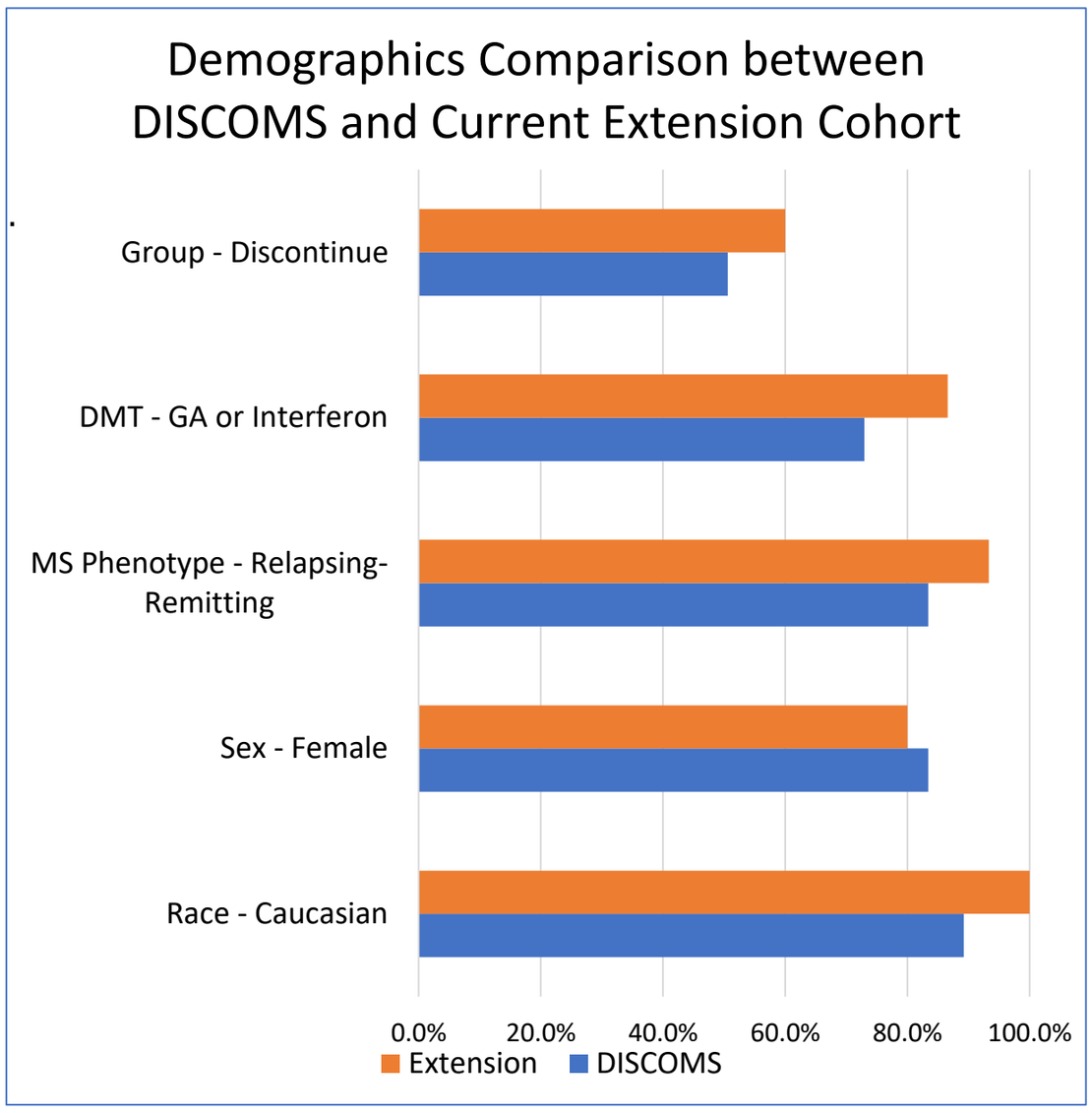
**Introduction**: Natural history of multiple sclerosis (MS) changes with age, with fewer new relapses and MRI scan changes over time. How long it is beneficial to use, and whether it is safe to discontinue, disease-modifying therapy (DMT) over time remains unclear. Prior surveys show most patients are unwilling to consider stopping DMT, and studies with longer post-discontinuation data would be optimal. We performed the DISCOMS study, a randomized (1:1 continue or discontinue DMT), controlled, rater-blinded 24-month study of 260 patients continuously taking DMT who were 55+ years old, and were without relapse for ≥5 years and new brain MRI lesions for ≥3 years. This was designed to determine if there is no greater risk of new relapses or brain MRI scan changes, and no increased risk of disease progression or worsening of patient quality of life, in those discontinuing compared to staying on DMT.

**Objective**: Complete a controlled, blinded extension of DISCOMS by performing a single visit 36-54 months post-enrollment.

**Aims:** Compare clinically significant and patient-relevant outcomes in those who have discontinued vs continued DMTs, to determine if risk of new relapses or brain MRI lesions, disability progression (by the Extended Disability Status Scale - EDSS), or cognition, quality of life and other patient-reported outcomes (PROs) are no worse in those discontinuing.

**Methods**: From 9 of the original 19 original participating sites, we will enroll 100 patients who have completed DISCOMS; did not reach the primary endpoint of a relapse or brain MRI lesion during the original trial; and retained original randomized assignment throughout. Participants will be included regardless of whether they have developed new disease activity after completion of the original study. All will undergo one study visit at 36-54 months after original enrollment in DISCOMS. Primary endpoint in the extension will be time to relapse or new brain MRI abnormality due to MS. Secondary endpoints include time to EDSS change, mean change in SDMT, and mean changes in PROs over time.




**Results**: To date, we have enrolled 15 in the Extension trial. Baseline demographic and MS phenotype data is similar in both studies (Graph). Mean baseline EDSS was 3.3±1.8 in DISCOMS and 2.2±1.0 so far in the extension patients. The percent randomized to discontinue DMT was 50.6% in DISCOMS and 60.0% of those enrolled thus far in the extension study. Over 70% of enrollees were still using injectable interferons or glatiramer acetate prior to randomization in both studies.

**Conclusions**: These trials will provide valuable data on durability of disease inactivity, and potential risks, after discontinuing MS DMTs. Enrollment data to date suggests baseline data for enrollees in the primary and extension will be very similar to each other.

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