

## INTRODUCTION

Multiple sclerosis (MS) is chronic neurodegenerative disease of the central nervous system with a wide range of symptoms including, but not limited to, impairments in mobility, cognitive function, visual acuity and fine motor skills<sup>1</sup>. More than 80% of people with multiple sclerosis (PwMS) are diagnosed with the relapsing-remitting MS (RRMS) and develop secondary progressive MS (SPMS) after 15-20 years<sup>2</sup>. Progressive MS is characterized by a critical accumulation of disability independent of relapses. About 15% of PwMS are diagnosed with primary progressive MS (PPMS) at disease onset<sup>2</sup>.

Clinical tools have been developed for standardized, quantitative and multidimensional assessment of disability in PwMS<sup>3</sup> such as the Expanded Disability Status Scale (EDSS)<sup>4</sup> and the revised 4-component MS Functional Composite (MSFC-4)<sup>5,6</sup>.

Inspired by the MSFC-4, MSCopilot®, a clinically validated software-as-a-medical-device (SaMD) facilitating real life self-assessment of MS through digital biomarkers (dBMKs) evaluates four functional parameters: walking capacity, low-contrast visual acuity, cognitive processing, and dexterity<sup>7,8</sup>.

Available for use by French patients and physicians, the first version of the application allowed the collection of self-reported and self-measured real-life data valuable in our understanding of MS and its progression.

## OBJECTIVE

This study aims at evaluating the ability of MSCopilot® digital tests to differentiate disability levels, as measured by the Expanded Disability Status Scale (EDSS) scores, in French patients having used the app during six years.

## METHODS

Data collected from adult MS patients having reported their EDSS scores while using MSCopilot® from October 2017 to September 2023 were analyzed according to their disability levels: low to mild (EDSS <4) and moderate to severe (EDSS ≥4). Patient baseline characteristics were described accordingly. DBMKs scores were calculated with results from the digital tests performed at home. Logistic regression models were fitted and validated to predict the patients' EDSS class from the biomarkers

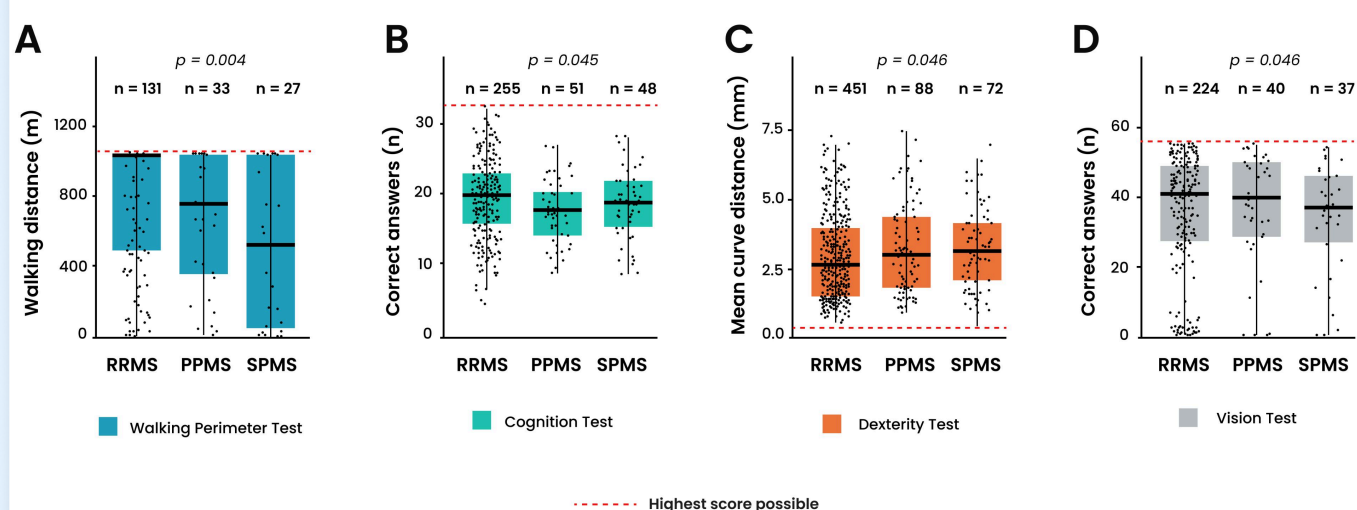
## RESULTS

	RRMS N=882	SPMS N=175	PPMS N=222	Total N=1279
Female, n (%)	660 (74.8)	111 (63.4)	131 (59.0)	902 (70.5)
Age, mean (SD)	40.0 (10.4)	47.5 (11.9)	44.5 (12.9)	41.8 (11.4)
Disease duration, mean (SD)	7.0 (7.2)	14.3 (9.6)	7.3 (10.8)	8.2 (8.6)
BMI, mean (SD)	25.1 (5.8)	24.6 (6.0)	24.7 (5.5)	25.0 (5.8)
EDSS score, mean (SD)	1.8 (1.9)	5.5 (1.0)	2.7 (2.2)	2.5 (2.2)
Walking disability, n (%)	414 (47.1)	156 (91.2)	161 (74.5)	731 (57.7)
Walking aid, n (%)	151 (17.6)	128 (73.5)	105 (49.1)	384 (30.8)

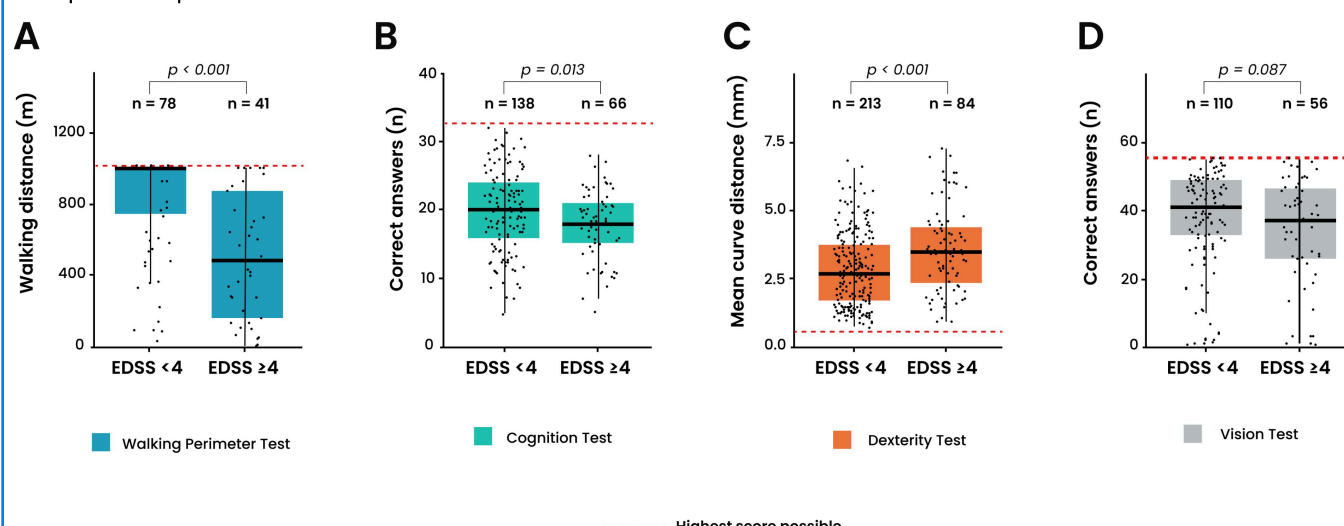
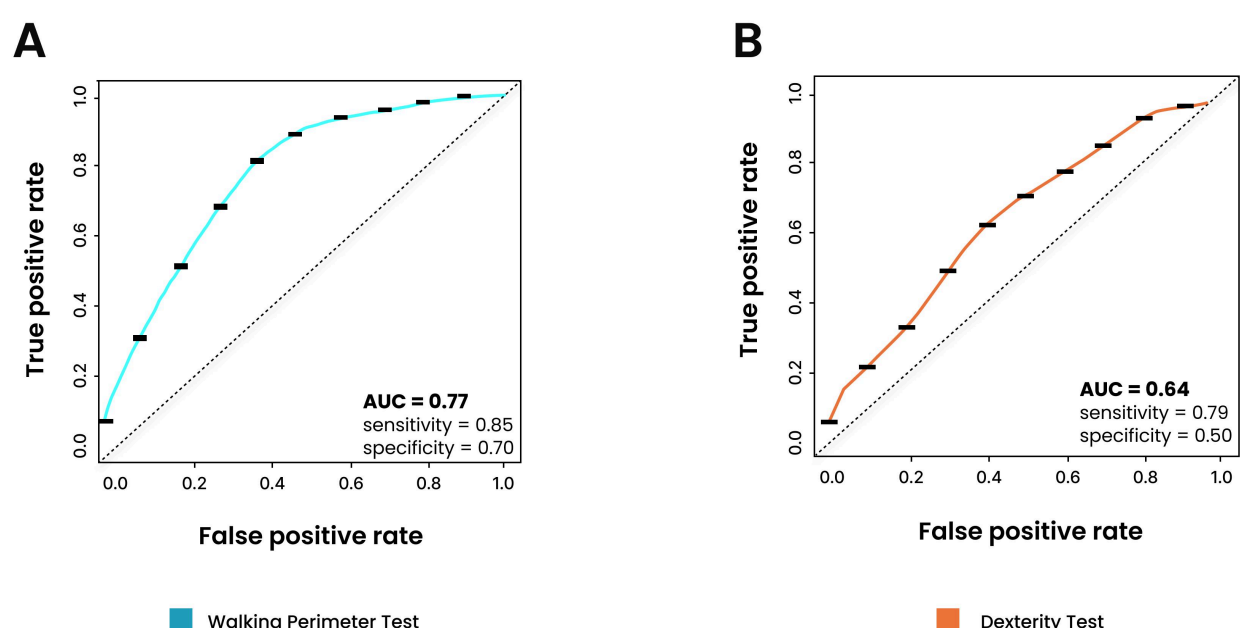
**Table 1. Baseline socio-demographics and disease characteristics per Multiple Sclerosis phenotypes of MSCopilot® French users from 2017 to 2023.** Patients reported their disease classification which included Relapsing Remitting MS (RRMS), Secondary Progressive MS (SPMS) and Primary Progressive MS (PPMS).

	EDSS <4 N=421	EDSS ≥4 N=169	Total N=590
Female, n (%)	278 (66.0)	95 (56.2)	373 (63.2)
Age, mean (SD)	39.9 (11.0)	47.8 (11.8)	42.2 (11.8)
Disease duration, mean (SD)	7.4 (7.5)	13.5 (9.5)	9.6 (8.8)
BMI, mean (SD)	24.5 (4.8)	24.6 (5.1)	24.6 (4.9)
Walking disability, n (%)	182 (44.1)	156 (94.5)	338 (58.4)
Walking aid, n (%)	59 (14.5)	123 (73.2)	182 (31.7)

**Table 2. Baseline socio-demographics and disease characteristics per disability levels of MSCopilot® French users from 2017 to 2023.** Patients reported their EDSS' scores which were classified, in this analysis, as low to mild disability when EDSS was below 4 and as moderate to severe when the EDSS score was equal or superior to 4.



**Figure 1. MSCopilot® digital biomarkers evaluated walking perimeter, cognition, dexterity and vision in Multiple Sclerosis patients according to their disease phenotype.** Digital tests, Walking perimeter (A), Cognition (B), Dexterity (C) and Vision (D), were taken at home in unsupervised conditions.



**Figure 2. MSCopilot® digital biomarkers evaluated walking perimeter, cognition, dexterity and vision in Multiple Sclerosis patients according to their disability levels: EDSS <4 and EDSS ≥4.** Digital tests, Walking perimeter (A), Cognition (B), Dexterity (C) and Vision (D), were taken at home in unsupervised conditions.

**Figure 3. ROC curves demonstrate that MSCopilot® walking perimeter and dexterity digital tests can discriminate patients' disease severity based on their EDSS scores using biomarker data.** Logistic regression models confirmed that digital biomarker scores, for the Walking perimeter (A) and Dexterity (B) tests, could classify patients by disease severity, EDSS<4 or EDSS≥4, achieving good area under the curve (AUC) values

## CONCLUSIONS

- MSCopilot® digital tests effectively differentiated disease disability levels consistent with EDSS scores in a real-world setting.
- This analysis demonstrates the reliability of the software and supports its use in routine clinical care for people with Multiple Sclerosis.

