

# MSCOPILOT® A NEW MULTIPLE SCLEROSIS SELF-ASSESSMENT DIGITAL SOLUTION: RESULTS OF A COMPARATIVE STUDY VERSUS STANDARDS TESTS. A RANDOMIZED CLINICAL TRIAL

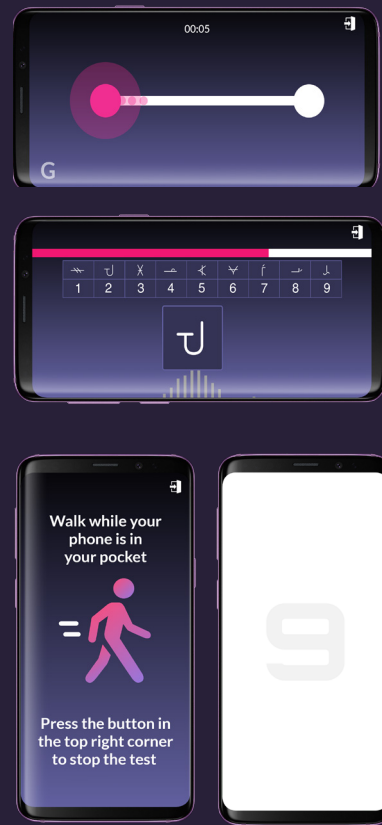
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## INTRODUCTION

Assessing patients' disability in MS requires to perform time-consuming and expensive batteries of tests at the hospital.

MSCopilot® is a software medical device designed for the self-assessment of patients with multiple sclerosis (PwMS), combining 4 tests: walking, dexterity, cognition and low contrast vision. MSCopilot® processes the data collected by the smartphone sensors and uses algorithms to generate scores for each test and allows remote monitoring of PwMS by their clinicians.



## OBJECTIVES

To evaluate the ability of MSCopilot® to identify PwMS with Expanded Disability Status Scale (EDSS) score ranging from 0 to 7 against healthy controls (HC) as compared to Multiple Sclerosis. Functional Composite (MSFC) and the correlation between MSCopilot® and MSFC z-scores

## METHODS

Multicentre, controlled, randomized, cross-over, open-label study, in 140 PwMS and 76 Healthy Controls (HC). Participants performed standard tests {Time 25-Foot Walk (T25FW), 9-Hole Peg Test (9HPT), Paced Auditory Serial Addition Task (PASAT), Symbol Digit Modalities Test (SDMT), Sloan Low-Contrast Letter Acuity Test (SLCLAT)} and digital tests {walking (MWT), dexterity (MCT), cognition (MAT), vision (MVT)} and vice versa. 46 PwMS performed the same tests at day 30±3 (2 visits) to assess their reproducibility.

## STUDY DESIGN

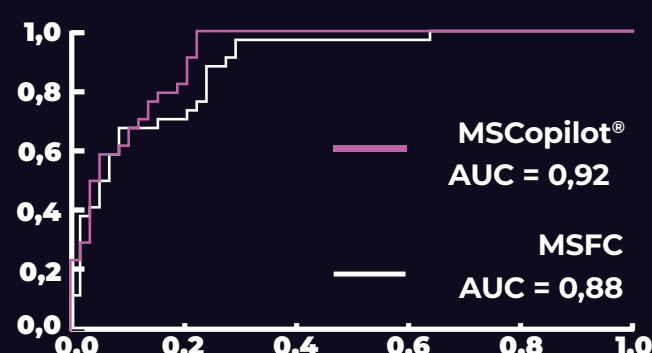


## PRIMARY ENDPOINT

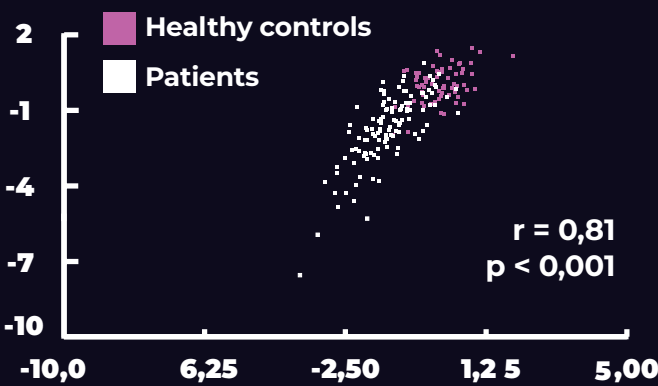
Performance of MSCopilot® versus MSFC for the identification of PwMS against HCs, quantified using area under the curve (AUC).

Correlation of MSCopilot®-3tests with MSFC-3tests (PASAT) z-scores.

ROC CURVE, MSCOPILOT® vs MSFC (N=92, p=0.33)



CORRELATION MSCOPILOT® vs MSFC (N=185)



PATIENTS DISTRIBUTION (N = 140) BY GENDER, MS TYPE, AND EDSS SCORE.

		EDSS < 3,5		Total
		n(%)	3,5 ≤ EDSS < 7	
RRMS*	Men	13(13)	17(17)	30(29)
	Women	41(40)	31(30)	72(71)
	Total	54(53)	48(47)	102(73)
PMS**	Men	8(21)	16(42)	24(63)
	Women	5(13)	9(24)	14(37)
	Total	13(34)	25(66)	38(27)
Total	Men	21(15)	33(24)	54(39)
	Women	46(33)	40(28)	86(61)
	Total	67(48)	73(52)	140(100)

\*RRMS = Relapsing-Remitting Multiple Sclerosis  
\*\*PMS = Progressive Multiple Sclerosis

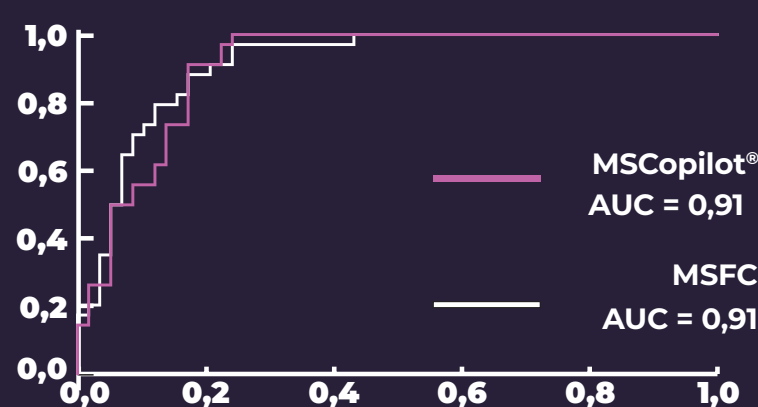
## SECONDARY ENDPOINTS

Correlation of MSCopilot®-3tests with revised MSFC-3tests (SDMT) z-scores.

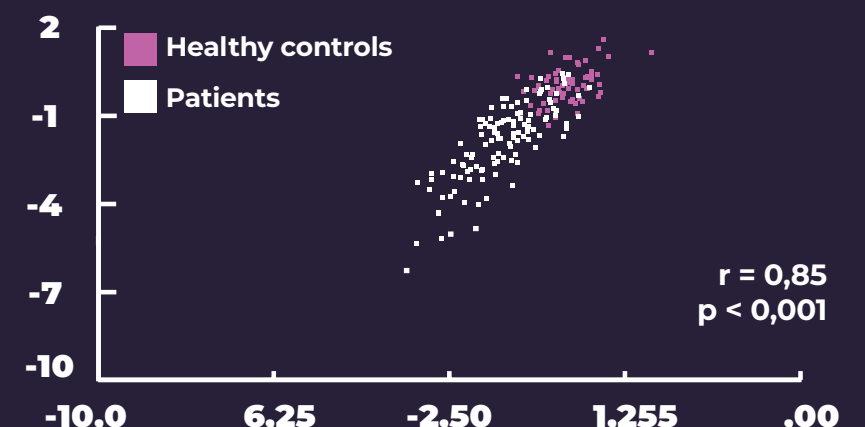
Correlation of MSCopilot®-4tests (vision) with MSFC4 (PASAT + vision) z-scores and revised MSFC-4tests (SDMT+vision) z-scores.

Reliability was calculated among the 46 PwMS who performed 2 visits.

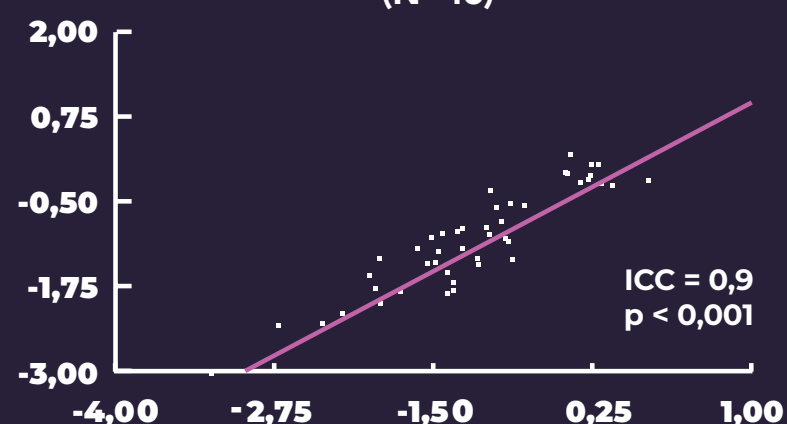
ROC CURVE, MSCOPILOT®-4 TESTS (vision) vs MSFC- 4 TESTS REVISED (SDMT+vision) (N=92, p=0.8)



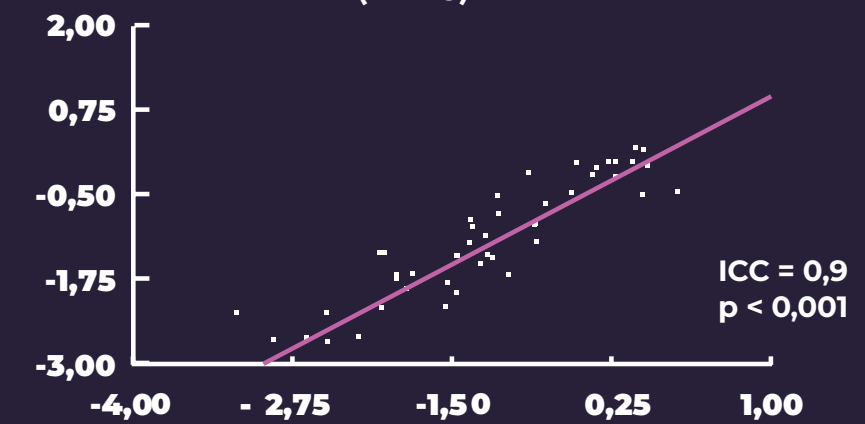
CORRELATION MSCOPILOT®-4 TESTS (vision) vs MSFC-4 TESTS REVISED (SDMT+vision) (N=185)



RELIABILITY MSCOPILOT®-3 TESTS Z-SCORES (N=46)



RELIABILITY MSCOPILOT®-4 TESTS (vision) Z-SCORES (N=46)



## CONCLUSION

**Non-inferiority of MSCopilot® ability to identify PwMS against HCs as compared to MSFC was demonstrated. Strong correlations between digital and standard scores were found.**

**These results suggest that MSCopilot® could be used in clinical practice for the monitoring of MS disability progression.**

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