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MS-FLOWER, an Ongoing U.S. Multicenter Pilot Study to identify challenges to MSCopilot® 's integration into Multiple Sclerosis standard clinical care

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INTRODUCTION

- Digital biomarkers (dBMKs) offer symptom tracking and objective functional testing to supplement standard clinic assessments by enabling people with Multiple Sclerosis (PwMS) to assess symptom progression remotely via smartphone sensors[1–4].
- MSCopilot®, a clinically validated software-as-medical-device (SaMD), and its digital biomarkers measure Multiple Sclerosis (MS) impact on walking, vision, cognition, and dexterity enabling symptoms' self-assessment. Clinicians can review these home-collected data through a dashboard, enhancing personalized care and decision-making[5,6].
- Prior studies have shown that MSCopilot® scores correlate with the Expanded Disability Status Scale (EDSS) and revised 4-item MS Functional Composite (MSFC-4) scores, however, integrating such a tool into routine clinical practice presents some practical and organizational challenges[5,6].
- MS-FLOWER (NCT06922942) is a U.S. multicenter pilot study designed to evaluate the feasibility, usability, and workflow integration of MSCopilot® in routine care, identifying barriers and optimization opportunities prior to large-scale deployment.

OBJECTIVE

This interim analysis reports initial clinicians and patients assessments following MSCopilot® training and first app use.

METHODS

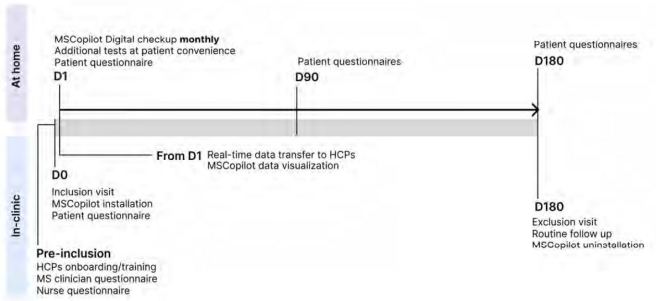

Figure 1. MS-FLOWER study design. Participants recruited by trained clinicians are to use MSCopilot and complete regular use-related questionnaires for six months. MSCopilot includes five digital tests assessing the mobility, finger dexterity, cognition and vision of people with Multiple Sclerosis.

RESULTS

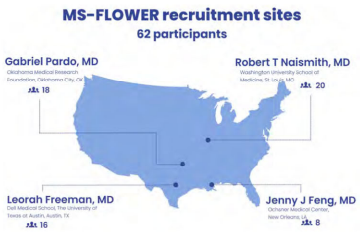

Figure 2. MS-FLOWER recruitment sites. Participants were recruited over a record 6-week period from four sites across the United States of America.

HCPs	N = 8
Female, *n* (%)	6 (75)
Male, *n* (%)	2 (25)
Age, *mean* (SD)	45.3 (10.4)
Specialty	
Neurologist, *n* (%)	7 (88)
Advanced MS provider, *n* (%)	1 (12.5)
Years of practice	
≤10, *n* (%)	3 (37.5)
11-20, *n* (%)	2 (25.0)
21-30, *n* (%)	2 (25.0)
31-40, *n* (%)	1 (12.5)
Healthcare facility type	
Public hospital, *n* (%)	1 (12.5)
Private clinic, *n* (%)	2 (25.0)
Other, *n* (%)	5 (62.5)
Experience with monitoring digital tools	
Yes, *n* (%)	6 (75.0)
No, *n* (%)	2 (25.0)

Table 1. Baseline characteristics of the clinicians trained during the MS-FLOWER study.

Patients	N = 62
Female, *n* (%)	47 (75.8)
Male, *n* (%)	15 (24.2)
Age, *mean* (SD)	45.3 (11.2)
BMI, mean (SD)	29.4 (8.8)
EDSS score, *median (min-max)*	2 (0-6.5)
MS phenotypes	
RRMS, *n* (%)	57 (92.0)
Non-active SPMS, *n* (%)	1 (1.6)
Active SPMS, *n* (%)	2 (3.2)
PPMS, *n* (%)	2 (3.2)
Employment status	
Employed, n (%)	42 (67.7)
Self-employed, *n* (%)	5 (8.1)
Unemployed, *n* (%)	4 (6.5)
Retired due to MS, *n* (%)	9 (14.5)
Unable to work, *n* (%)	2 (3.2)

Table 2. Baseline characteristics of the patients participating to the MS-FLOWER study.

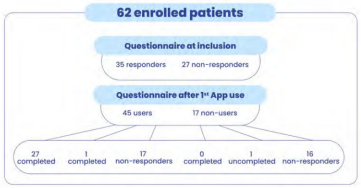

Figure 3. Flowchart of questionnaires completion by MS-FLOWER participants following study inclusion and MSCopilot first use.

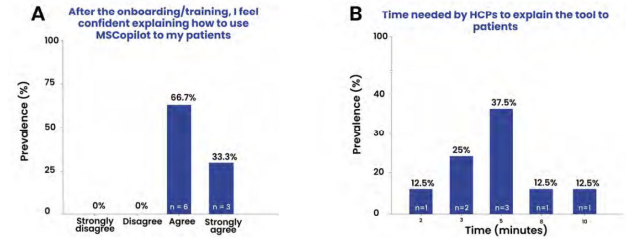

Figure 4. Explaining MSCopilot to patients: clinicians confidence and duration.

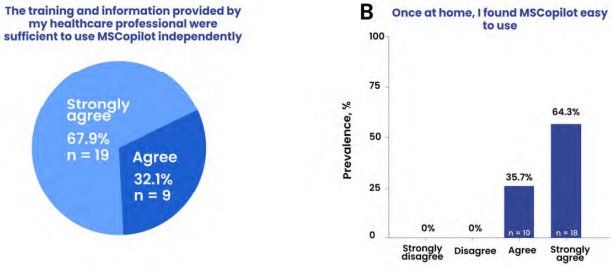

Figure 5. MSCopilot ease of use: from clinicians' explanations to remote use by patients.

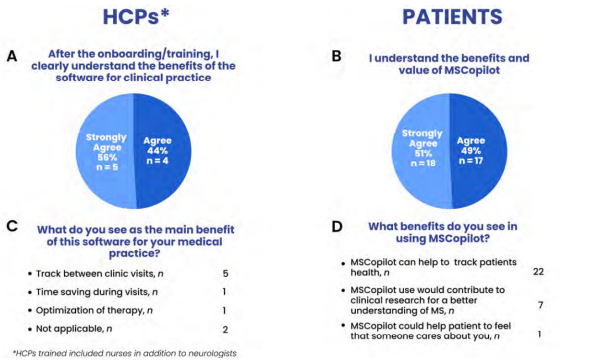

Figure 6. Perceived benefits of using MSCopilot: clinicians and patients perspectives.

CONCLUSIONS

- Clinical integration of MSCopilot® could enhance disease monitoring, optimize clinical workflows, and improve patient engagement in MS management.
- MS-FLOWER shows that MSCopilot is easy to explain and use which is critical for a broader adoption of digital biomarkers in routine care, supporting personalized, data-driven management of PwMS in the U.S.

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