



DigiToms Study: Preliminary Findings on Konectom™ Digital Outcome Assessments in MS

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OBJECTIVE

- To report interim results on the reliability and convergent validity of smartphone-based Konectom digital outcome assessments measuring neurological function in people living with multiple sclerosis (PwMS).

CONCLUSIONS

- Preliminary results of the DigiToms study showed good to excellent reliability and convergent validity of Konectom digital outcome assessments with conventional clinical outcome assessments.
- These findings support the potential of Konectom to provide outcomes that are important measures of disease burden in PwMS measured in a free-living environment.

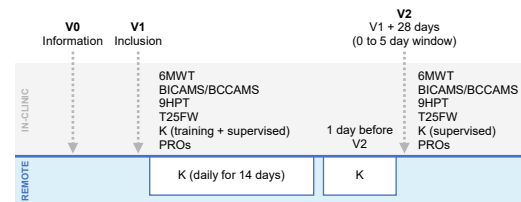
Introduction

- The development and deployment of digital health tools has the potential to facilitate the remote monitoring of people living with multiple sclerosis (PwMS), potentially improving care and leading to better outcomes.¹
- Konectom is a mobile application intended to be used as a self-assessment and patient-reported outcome tool to quantify neurological impairments (motor and cognitive functions) in PwMS.²
- The Konectom application includes a Cognitive Processing Speed (CPS) Test, Manual Dexterity Tests (pinching, drawing, and grip force), and ambulation tests (U-turn Test [UTT], Static Balance Test [SBT], and 6-Minute Walk Test [6MWT]).

Methods

- The DigiToms study (NCT04756700) includes PwMS aged 18–64 years with Expanded Disability Status Scale (EDSS) score ≤ 6.0.
- The overall study design is presented in Figure 1.
- Further evaluation of Konectom CPS Test reaction time features in relation to standard measures of cognition and disability in PwMS is presented in poster P35.
- Participants performed Konectom assessments at 2 clinical visits (4 weeks apart), as well as remotely between the 2 visits.
 - In the first 2 weeks, the use of Konectom is mandatory every day (mandatory period); in the following 2 weeks, use is optional (optional period).
- Test-retest reliability was assessed using intraclass correlation coefficient (ICC).
- Association between conventional clinical outcome assessments and Konectom digital outcome assessments (DOAs) was assessed using Spearman's rank (ρ), Pearson's correlation (r), or generalized linear model, whichever appropriate.

Figure 1. Overall DigiToms Study Design



9HPT = 9-Hole Peg Test; BCCAMS = Brief Computerized Cognitive Assessment for MS; BICAMS = Brief International Cognitive Assessment for MS; K = Konectom app tests; PRO = patient-reported outcome; T25FW = Timed 25-Foot Walk; V = visit

Results

- At the interim data cut (18 August 2021), 40 PwMS had completed the study.
 - Mean (SD) age was 41.9 (9.4) years, and 82.5% of PwMS were female (Table 1).
 - Median (interquartile range) EDSS score was 2.0 (1.5).

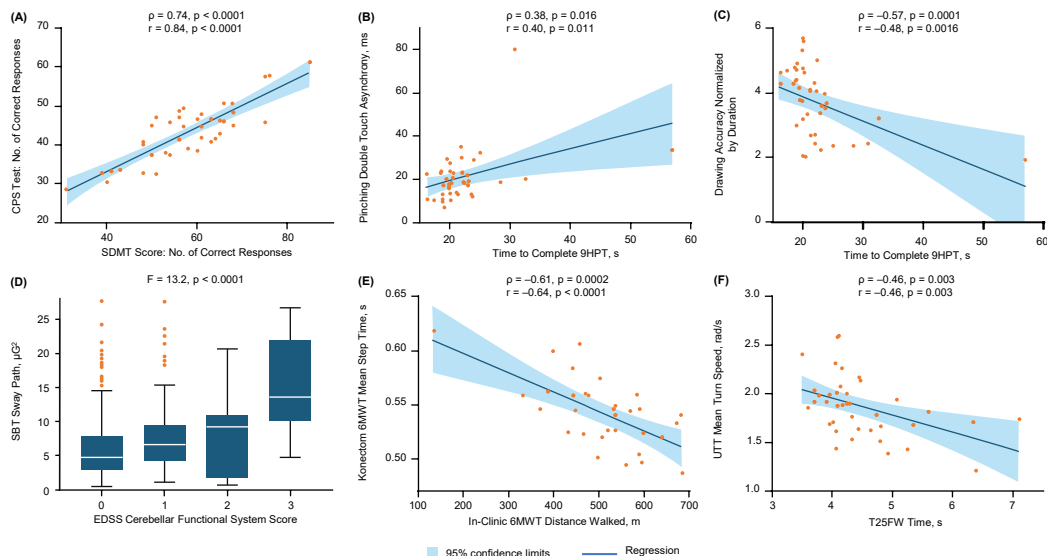
Table 1. Patient Demographics and Baseline Characteristics

Variable	Interim Study Population (N = 40)
Age, y, mean (SD)	41.9 (9.4)
Female, n (%)	33 (82.5)
Educational level, n (%)	
No A-Level/High School Diploma	5 (12.5)
A-Level/High School Diploma	8 (20.0)
Bachelors Degree	19 (47.5)
Masters Degree or higher	8 (20.0)
Disease duration, y, mean (SD)	11.4 (8.5)
EDSS, median (IQR)	2 (1.5)
Disease subtype, n (%)	
Relapsing-remitting MS	38 (95.0)
Secondary progressive MS	2 (5.0)
Number of relapses in prior 12 months, median (IQR)	0 (0)
SDMT score, mean (SD)	57.8 (11.1)
Time to complete 9HPT, s, mean (SD)	22.2 (6.6)
T25FW time, s, mean (SD)	4.5 (0.8)
6MWT distance, m, mean (SD)	500.2 (115.0)

6MWT = 6-Minute Walk Test; 9HPT = 9-Hole Peg Test; EDSS = Expanded Disability Status Scale; IQR = interquartile range; MS = multiple sclerosis; SDMT = Symbol Digit Modalities Test; T25FW = Timed 25-Foot Walk

- Significant correlations were observed between conventional clinical outcome assessments at baseline visit and a set of Konectom features (selected based on previously reported findings¹) (Figures 2A-F):
 - CPS Test correct responses versus Symbol Digit Modalities Test (SDMT) score ($r = 0.84$, $p < 0.0001$)
 - Pinching double touch asynchrony versus time to complete 9HPT ($r = 0.40$, $p = 0.011$)
 - Drawing accuracy normalized by duration versus time to complete 9HPT ($r = -0.48$, $p = 0.0016$)
 - SBT sway path versus EDSS cerebellar functional system score ($F = 13.2$, $p < 0.0001$)
 - Konectom 6MWT mean step time versus in-clinic 6MWT distance walked ($r = -0.64$, $p < 0.0001$)
 - UTT mean turn speed versus T25FW time ($r = -0.46$, $p = 0.003$).
- Test-retest reliability (ICC) of Konectom DOAs was good to excellent (0.48–0.86) for all the tests (Table 2).

Figure 2. Plots Showing Correlations Between Konectom DOAs and Conventional Clinical Outcome Assessments at Baseline Visit: (A) CPST Correct Responses vs. SDMT Score; (B) Pinching Double Touch Asynchrony vs. Time to Complete 9HPT; (C) Drawing Accuracy Normalized by Duration vs. Time to Complete 9HPT; (D) SBT Sway Path vs. EDSS Cerebellar Functional System Score; (E) Konectom 6MWT Mean Step Time vs. In-clinic 6MWT Distance Walked; (F) UTT Mean Turn Speed vs. T25FW



6MWT = 6-Minute Walk Test; 9HPT = 9-Hole Peg Test; CPS = cognitive processing speed; DOA = digital outcome assessment; EDSS = Expanded Disability Status Scale; GLM = generalized linear model; SBT = Static Balance Test; SDMT = Symbol Digit Modalities Test; T25FW = Timed 25-Foot Walk; UTT = U-Turn Test

Table 2. Test-Retest Reliability (ICC) of Konectom DOAs

	PwMS, n	Observations, n	Estimated ICC (95% CI)	Estimated Coefficient of Within-Subject Variance (95% CI)
CPS Test correct responses	39	319	0.86 (0.79, 0.91)	0.11 (0.10, 0.12)
Pinching double touch asynchrony	38	532	0.73 (0.63, 0.81)	0.35 (0.29, 0.42)
Drawing accuracy normalized by duration	38	506	0.78 (0.68, 0.85)	0.14 (0.13, 0.16)
SBT sway path	37	482	0.48 (0.35, 0.61)	0.53 (0.44, 0.63)
6MWT mean step time	33	441	0.57 (0.44, 0.69)	0.04 (0.04, 0.05)
UTT mean turn speed	38	571	0.59 (0.47, 0.70)	0.13 (0.12, 0.14)

6MWT = 6-Minute Walk Test; CPS = Cognitive Processing Speed; DOA = digital outcome assessment; ICC = intraclass correlation coefficient; PwMS = people living with multiple sclerosis; SBT = Static Balance Test; UTT = U-Turn Test