Piloting a Mobile Platform in Multiple Sclerosis Patients Taking Oral Disease-Modifying Therapies

Devin S. Mullin, BS[1], Cindy Gonzalez, MPH[1], Taylor J. Saraceno, BS[1], Kelsey Rankin, BA [2], Eyal Bartfeld, DMD, PhD,[3] Brian C. Healy, PhD[1], Riley Bove, MD[2] and Tanuja Chitnis, MD[1],
(1)Partners Multiple Sclerosis Center, Brigham and Women's Hospital, Boston, MA, (2)University of California San Francisco, San Francisco, CA, (3)Irody, Inc., Boston, MA

INTRODUCTION

BACKGROUND

- One of the current major challenges in multiple sclerosis (MS) care is the accurate monitoring of patient symptoms and status because annual or biannual clinic visits provide only limited information.
- There is increasing interest regarding "real-time" data collection platforms, such as smartphones, as they provide the opportunity to collect more frequent, granular information.

OBJECTIVE

- To investigate the feasibility of a mobile application to collect clinical data from patients with MS and to examine the impact of mobile pop-up reminder on oral disease-modifying therapies (DMTs) adherence.

METHODS

PARTICIPANTS

A total of 60 MS patients were recruited from the Partners MS Center, Brigham and Women's Hospital. Including those:

- With a diagnosis of clinically definite MS according to the 2010 McDonald criteria
- Taking or starting either teriflunomide, fingolimod, or dimethyl fumarate
- 18-60 years of age and using a smartphone
- Enrolled in the Comprehensive Longitudinal Investigation of Multiple Sclerosis at the Brigham and Women's Hospital (CLIMB) study, an ongoing observational study collecting data since the year 2000

Among the 60 MS patients recruited, 10 were excluded for three main reasons (see Figure 1.)

PILL REMINDERS

- Patients were 1:1 randomized in two groups: receive medication reminders on their smartphones or no reminder and followed for 6 months.

DAILY QOL

- During the 6 month period, subjects also completed items related to quality of life (QOL), mood, fatigue, cognition, and MS-specific symptoms on their mobile device.
- In particular, subjects rated their QOL daily on a 1-10 scale and every 8 days answered questions related to mood, fatigue, cognition, and MS symptom severity using their mobile device.

STATISTICAL ANALYSIS

Categorical variables were described by counts and percentages and continuous variables by mean and standard deviation (SD). To compare the pill count method (pill bags brought vs self-reported) between the those who received medication reminders on their smartphones vs those who did not, we used a chi-squared test. To compare the binary pill count (≤4 pills vs >4 pills) between the two groups, we used Fisher's exact test. To compare the numeric pill count (range 0-35), we used the Mann-Whitney U test. Significance levels were evaluated at an alpha level of <0.05. Statistical analyses were performed using the SAS 9.4 software (SAS Inc., Cary, NC).

RESULTS-I

Figure 1. Flow diagram of study participant

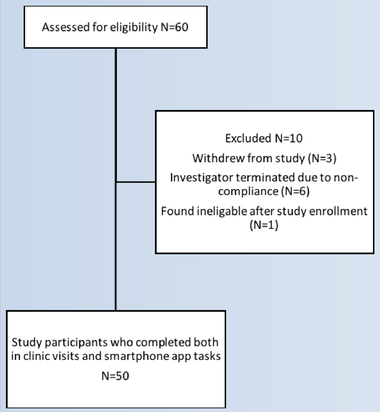


Table 1. Demographic characteristics of study subjects, stratified by randomization status

Variables	Randomized Yes	Randomized No	p-value
N (%)	26 (52.00%)	24 (48.00%)	
Age at baseline visit (mean ± SD)	42.30±11.10	42.31±9.59	0.9985[a]
Disease duration at baseline visit (mean ± SD)	15.64±7.95	13.46±7.22	0.3209[a]
Male, n(%)	6(23.08%)	6(25.00%)	0.8736[b]
White race, n(%)	18(69.23%)	23(95.83%)	0.0244[c]
Not Hispanic or Latino, n(%)	25(96.15%)	23(95.83%)	0.9998[c]
EDSS at baseline visit (mean ± SD)	2.19±1.18	2.00±1.64	0.5726[d]
Disease category at baseline visit, n(%)			
Relapsing-Remitting	26(100.00%)	23(95.83%)	0.4800[c]
Secondary Progressive	0(0.00%)	1(4.17%)	
DMT, n(%)			
Aubagio	2(7.69%)	0(0.00%)	0.5475[c]
Gilenya	16(61.54%)	14(58.33%)	
Tecfidera	8(30.77%)	10(41.67%)	

Legend: EDSS=expanded disability status scale, DMT=disease modifying therapy; [a]Means were compared with a two-sample t-test; [b]Proportions were compared via a chi-square test for contingency tables; [c]Proportions were compared via a Fisher's exact test for contingency tables; [d]Rank scores were compared via the Mann-Whitney U test.

RESULTS-II

Figure 2. Daily QOL App

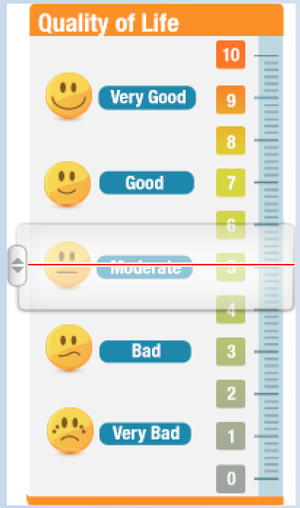
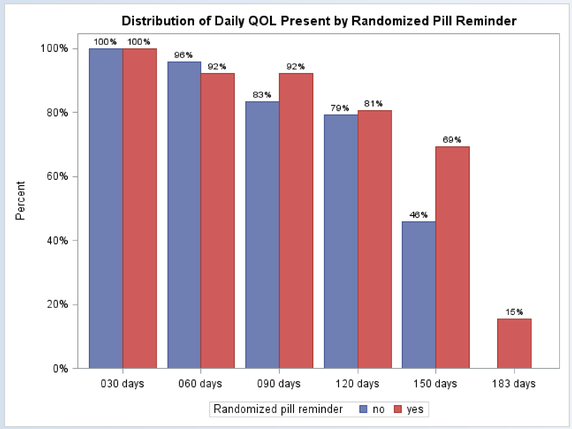


Figure 3. Distribution of Daily QOL Present by Randomized Pill Reminder



RESULTS-III

Table 2. Pill counts and methods, stratified by randomized pill reminder

Variables	Randomized Yes	Randomized No	p-value
Pill count method, n(%)[1]			
Pill bag brought in	15(57.69%)	11(45.83%)	0.3796[a]
Patient reported	7(26.92%)	9(37.50%)	
Pill Count (bag & self-reported), n(%)[1]			
≤4 pills	18(69.23%)	18(75.00%)	0.6653[b]
>4 pills	4(15.38%)	2(8.33%)	
Pill Count (bag & self-reported), n(%)[1]			
0	10(38.46%)	12(50.00%)	0.2940[c]
1	2(7.69%)	1(4.17%)	
2	0(0.00%)	2(8.33%)	
3	4(15.38%)	1(4.17%)	
4	2(7.69%)	2(8.33%)	
5	1(3.85%)	0(0.00%)	
6	0(0.00%)	1(4.17%)	
10	0(0.00%)	1(4.17%)	
14	1(3.85%)	0(0.00%)	
23	1(3.85%)	0(0.00%)	
35	1(3.85%)	0(0.00%)	

Legend: [a]Proportions were compared via a chi-square test for contingency tables; [b]Proportions were compared via a Fisher's exact test for contingency tables; [c]Rank scores were compared via the Mann-Whitney U test; [1]42 subjects had reported pill count method and were included in this analysis, 8 subject had unknown values and were excluded.

CONCLUSION

- Our study demonstrates that a mobile application is a feasible and acceptable intervention for MS patients.

FUTURE DIRECTIONS

- Potential future study directions are to investigate the predictors of oral DMT adherence with or without pill reminders and compare smartphone daily QOL data with Partners MS Center clinic QOL data.

DISCLOSURES

- Mullin, Saraceno, Rankin: nothing to disclose.
- Gonzalez receives salary support from Verily.
- Bartfeld is employed by Irody, Inc., who provided the technology platform for this study.
- Healy has served as a consultant for Biogen Idec and receives research support from Merck Serono, Novartis, Genzyme, and Google Life Sciences.
- Bove has served as a consultant for Sanofi-Genzyme, Roche-Genentech and Novartis.
- Chitnis has received research support from EMD Serono, Octave and Verily; consulting fees from Bayer, Novartis and Roche-Genentech. She serves on clinical trials advisory board for Novartis, Sanofi-Genzyme, and Roche-Genentech.

SUPPORT

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Poster Number: SX04
Contact:
dmullin@partners.org