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 0-3), 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

<table>
<thead>
<tr>
<th>Variables</th>
<th>Randomized Yes</th>
<th>Randomized No</th>
<th>p-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age</td>
<td>Median (IQR)</td>
<td>Median (IQR)</td>
<td></td>
</tr>
<tr>
<td>Baseline EDSS</td>
<td>3.00 (1.00)</td>
<td>3.00 (1.00)</td>
<td></td>
</tr>
<tr>
<td>Relapsing MS</td>
<td>12 (46.15%)</td>
<td>10 (41.67%)</td>
<td></td>
</tr>
<tr>
<td>Secondary Progressive MS</td>
<td>7 (26.92%)</td>
<td>5 (20.83%)</td>
<td></td>
</tr>
<tr>
<td>Women's MS Partners</td>
<td>26 (52.00%)</td>
<td>24 (48.00%)</td>
<td></td>
</tr>
</tbody>
</table>

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

<table>
<thead>
<tr>
<th>Variables</th>
<th>Randomized Yes</th>
<th>Randomized No</th>
<th>p-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pill bag brought in</td>
<td>100 (100%)</td>
<td>90 (75.00%)</td>
<td></td>
</tr>
<tr>
<td>Pill bag not brought in</td>
<td>0 (0.00%)</td>
<td>30 (25.00%)</td>
<td></td>
</tr>
<tr>
<td>Pill count (≤4 pills)</td>
<td>70 (70.00%)</td>
<td>30 (25.00%)</td>
<td></td>
</tr>
<tr>
<td>Pill count (&gt;4 pills)</td>
<td>30 (30.00%)</td>
<td>40 (33.33%)</td>
<td></td>
</tr>
</tbody>
</table>

DISCLOSURES

• Mullin, Saraceno, Rankin: nothing to disclose.

• Gonzales 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.

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.

SUPPORT

We would like to thank the Consortium of Multiple Sclerosis Centers for their support with this project.

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