Completion Rates Maintained During the COVID-19 Pandemic in a Large Community-Based Pragmatic Clinical Trial

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INTRODUCTION

- MOBILITY (Metformin for overweight and OBese chILdren with bIpolar spectrum disorders Treated with second-generation antipsYchotics) is a pragmatic clinical trial to assess the comparative effectiveness of metformin (MET) plus a simple healthy lifestyle intervention (LIFE) vs. LIFE alone on patient-centered outcomes.
- The primary outcome is to assess overall and subgroup-specific impact of MET + LIFE versus LIFE alone on short-term (6 month) and long-term (24 month) weight and metabolic health.

METHODS

- We examined visit completion rates of patients due for a study visit on 4/1/20 and performed in the remote care visit window 4/1/20-12/31/20 by visit type (month 6, month 24, other visit) and institution type (community vs academic) to in-person visits from coinciding preceding enrollment period, 4/1/19-12/31/19.

RESULTS

- The retention rate was not significantly different in 2020 (intra-pandemic=49.3%) as compared to 2019 (pre-pandemic=47.1%) in a repeated measures logistic regression model (OR=1.04 [95% CI: 0.82, 1.32], p=0.75).

- In a moderator analysis of visit type, the main effect for visit type was significant (p<0.01; OR=10.5 [95% CI: 6.0, 18.4] for M6 vs. M24; OR=5.1 [95% CI: 3.8, 6.8] for other visits vs. M24; and OR=2.1 [95% CI: 1.2, 3.5] M6 vs. other visits). Averaged over both time points, retention at M6 > other visits > M24. There was a significant time x visit type interaction (p=0.02) with the M6 retention decreasing (OR=0.34 [95% CI: 0.12, 0.92], p=0.03) and the M24 retention close to significantly increasing (OR=1.55 [95% CI: 0.95, 2.52], p=0.08) from 2019 to 2020.

- In a moderator analysis of institution, the main effect for institution was borderline significant (p=0.054; OR=1.29 [95% CI: 0.99, 1.68] for marginally greater retention at academic vs. community clinics), without any time x institution interaction (p=0.76).

CONCLUSIONS

- Visit completion rates were maintained after the onset of the pandemic through the use of virtual research methodology. Making virtual visits available in clinical effectiveness research enabled us to continue collecting data in this community-based, pragmatic, real-world study of youth with bipolar-spectrum disorders with the same degree of subject/visit retention, despite COVID-19 and the shift from in-person to remote clinical visits.

The time difference in retention was not significant between 2019 in-person visits and 2020 remote visits

Averaged over both time points, retention at Month 6 > other visits > Month 24

Visit completion rates were maintained after the onset of the pandemic through the use of virtual research methodology.

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2020 Remote Visits		Visit type			Institution Type	
	Number of Active Patients on 4/1/20	M6	M24	Other visits	Academic	Community
Due for visit on 4/1/20	602	61	195	346	365	237
Visit perfomed from 4/1/20 - 12/31/20	297	39	50	208	187	110
Retention (%)	49.3	63.9	25.6	60.1	51.2	46.4

2019 In-Person Visits		Visit type			Institution Type	
	Number of Active Patients on 4/1/19	M6	M24	Other visits	Academic	Community
Due for visit on 4/1/19	620	45	213	362	378	242
Visit perfomed from 4/1/19 - 12/31/19	292	38	40	214	189	103
Retention (%)	47.1	84.4	18.8	59.1	50.0	42.6

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