Conducting a Multi-Site, Community-Based, Pragmatic Research Trial: Study Design, Recruitment Barriers, and Initial Sample Characteristics of Mobility

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INTRODUCTION

- Second generation antipsychotics (SGAs) are effective for bipolar spectrum disorders
- Weight gain is the most problematic side effect and often leads to medication non-adherence
- Recent clinical trials suggest metformin (MET) may mitigate weight gain associated with SGAs, but there is a significant gap in the evidence base and widespread use of MET
- Pragmatic clinical trials (PCTs) are randomized trials that seek to compare the effectiveness of two or more interventions in real-world clinical settings
- PCTs focus on patient-centered outcomes and seek to inform decisions made by clinicians and patients about the relative advantages and disadvantages of interventions
- MOBILITY (Metformin for overweight and OBese chILdren with bIpolar spectrum disorders Treated with second-generation antipsYchotics) is a PCT to assess the comparative effectiveness of MET plus a simple healthy lifestyle intervention (LIFE) vs. LIFE alone on patient-centered outcomes

OBJECTIVES

- To understand the difference between PCTs and traditional explanatory trials
- To describe study design, recruitment barriers, and initial sample characteristics

METHODS

- Overweight/obese youth ages 8–19 years with current or past diagnosis of bipolar spectrum disorder who are continuing or starting treatment with SGAs were randomized in 1:1 ratio to either MET + LIFE
- The primary outcome measure is to assess overall and subgroup-specific impact of MET + LIFE versus LIFE alone on short- and long-term weight and metabolic health
- Differences in study design, barriers to recruitment and retention, and baseline sample characteristics were analyzed

RESULTS

- 507 patients consented and 491 randomized as of 5/10/17
- Recruitment barriers: high cancellation and no-show rates, lack of support staff, limited provider time, and referral outside of MOBILITY sites
- Retention barriers: transitions in care from inpatient to outpatient or day hospital settings

CONCLUSIONS

- Conducting a multisite patient-centered pragmatic trial is much different from an explanatory trial with respect to study design, implementation, and barriers to recruitment and retention
- The initial demographic data show a diverse clinical sample and attest to the pragmatic nature of this trial

Demographic and clinical characteristics at baseline (N=438)

	Mean (SD) or n (%)
Age, yrs.	13.7 (2.6)
Sex, female	226 (52%)
Race	
Caucasian	277 (63%)
African-American	106 (24%)
Mixed	40 (9%)
Unknown or not reported	9 (2%)
Asian	4 (1%)
Native American	2 (<1%)
Ethnicity, hispanic	53 (12%)
Weight	
Overweight (85% ≤ BMI% < 95%)	149 (34%)
Obese (BMI% ≥ 95%)	289 (66%)
BMI percentile	95.5 (3.9)
Lifetime bipolar/mood diagnosis	
Mood Disorder NOS/Other Specified Mood Disorder	198 (45%)
Bipolar I	85 (19%)
Disruptive Mood Dysregulation Disorder	83 (19%)
Bipolar NOS	37 (8%)
Bipolar II	16 (4%)
Cyclothymic Disorder	1 (<1%)
Prior or current SGA use	391 (89%)
Aripiprazole	237 (61%)*
Risperidone	196 (50%)*
Quetiapine	124 (32%)*
Ziprasidone	45 (12%)*
Olanzapine	39 (10%)*
Lurasidone	19 (5%)*
Paliperidone	17 (4%)*
Asenapine	6 (2%)*
Clozapine)	3 (1%)*
Other	4 (1%)*
Prior or current psychostimulant use (n=391)	262 (67%)
Prior or current mood stabilzer use (n=378)	117 (31%)

*Percentages based on patients who have used SGAs

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