

Engagement and Recruitment in the MOBILITY (Metformin for Overweight and OBese chILdren with blpolar spectrum disorders Treated with second-generation antipsYchotics) Study

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Methodological Question

- Methods to improve clinician and patient/family engagement and recruitment in a pragmatic clinical trial (PCT).

Introduction

- Second generation antipsychotics (SGAs) are efficacious for treatment of bipolar spectrum disorders (BPD).
- SGA-induced weight gain may lead to medication non-adherence in youth with BPD.
- Metformin (MET) has been shown to mitigate weight gain associated with SGAs in clinical trials, but data on widespread use of MET in care-as-usual settings is lacking.
- MOBILITY (Metformin for Overweight and OBese chILdren with blpolar spectrum disorders Treated with second-generation antipsYchotics) is a multi-site, randomized PCT to assess the comparative effectiveness of MET plus a simple healthy lifestyle intervention (LIFE) vs. LIFE alone on patient-centered outcomes.
- Given its PCT design, this trial offers unique methodological problems and solutions for engaging clinicians, patients, and families in research in real-world settings.

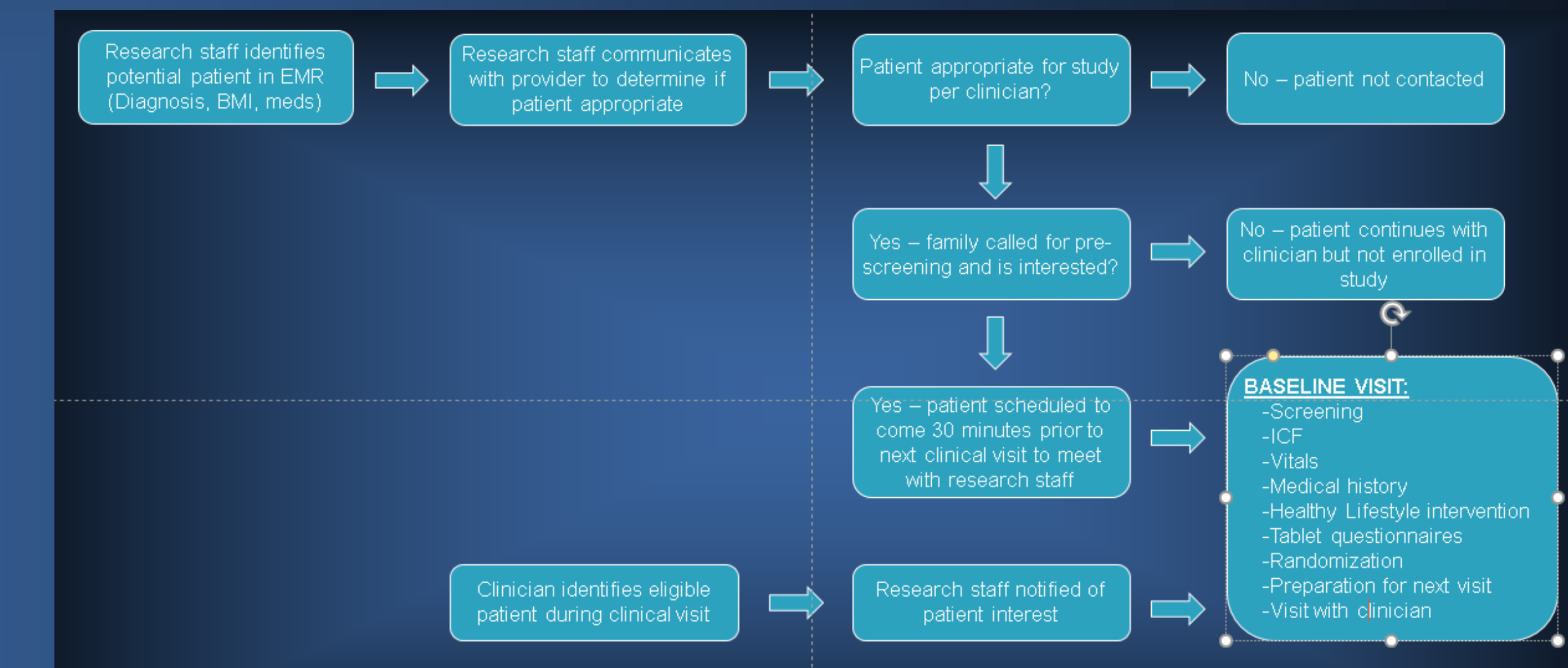
Methods

- Novel approaches were utilized to engage clinicians and patient/families in the PCT design of the MOBILITY trial.
- Issues unique to sites provided opportunities to address clinician engagement and improve general recruitment as well as enhance enrollment for ethnic minorities, SGA treatment-naïve patients, those transitioning from inpatient to outpatient settings, and those transitioning into adult care.

Results

- 715 patients randomized at 55 sites in 27 months
- Select sites were able to recruit up to three new patients per month
- One site recruited 17 patients in first three months
- Techniques effective in enhancing clinician engagement:
 - Early communication
 - Buy-in from stakeholders including institutional leaders and clinician champions to serve as change agents
- Methods successful in enhancing and encouraging clinician involvement:
 - Providing supported clinical time for required research training
 - One-to-one direct electronic or personal communication with clinicians
 - Flexibility around clinician schedules
 - Research staff screened schedules weekly for potential patients and communicated with providers about patient suitability
- Patient and family recruitment was enhanced by:
 - Education regarding patient-centered outcomes research
 - Emphasis on flexibility
 - Personal engagement with their individual providers
- Well-coordinated patient visits were ensured by:
 - Patients asked to arrive 15 minutes before each appointment to allow time for research related activities with research staff
 - Research activities (excluding informed consent which was always obtained before the first study visit) were conducted before, during, and after clinical visits to ensure that clinicians could conduct their regular clinical duties

Approach to Patient Enrollment



Conclusions

- Novel approaches in a multi-site patient-centered PCT created opportunities for engagement of both patients/families and clinicians leading to high levels of enrollment.

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Disclosures

One or more authors report potential conflicts which are described in the program

