A Trial of "Opening Doors to Recovery" for Persons with Serious Mental Illnesses

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Methods

Participants

Enrollment will begin in December 2014 and continue until the target sample size is achieved, which is expected to take approximately three years. Adults with serious mental illnesses (SMI) will be recruited from three inpatient facilities: a state psychiatric hospital in Savannah, Georgia; a crisis stabilization unit (CSU) in Savannah; and a CSU in Brunswick, Georgia.

Eligibility criteria will include: (1) 18–65 years of age; (2) English speaking; (3) diagnosis of a psychotic or mood disorder (confirmed with the *Structured Clinical Interview for DSM-5 Disorders* (SCID-5);[1] (4) two separate inpatient admissions, each for ≥2 days, in the past 12 months; (5) absence of intellectual disability or dementia; (6) capacity to provide informed consent; (7) being discharged to reside within one of seven counties with case management (CM) services provided by the public mental health agency hosting the research; (8) not currently receiving assertive community treatment (ACT) or CM; and (9) eligible to receive CM; i.e., unable to complete daily living activities in at least two areas, despite caregiver or behavioral health staff support, and requires assistance in one or more areas of managing their illness.[2]

Interventions

Opening Doors to Recovery (ODR). The Community Navigation Specialist (CNS) team's process of community navigation is a broader function than traditional CM as it includes mapping and connecting clients to all available local resources, which requires being embedded in the community. The CNSs benefits from commitments of diverse collaborative ODR partners (who convene as part of a "Blue Ribbon Taskforce"), including local treatment providers, law enforcement, employers, and housing programs. Those enrolled in ODR consent to information sharing that allow the CNSs to overcome communication barriers in pursuit of their clients' recovery goals. One example of this is a novel Police–CNS Linkage System that allows law enforcement officers to talk directly to a CNS in the event of a police encounter—a component of ODR also being studied separately.[3,4] The CNS team's caseload will be capped at 40. Each CNS is expected to meet with the client at home or in community settings at least monthly, with the client having contact with at least one CNS weekly.

Case Management (CM). For the control group, we considered both traditional CM and intensive case management (ICM) to be different enough from ODR for the purposes of testing hypotheses. Because we are limited to what is available locally for the control group, patients will receive CM if being discharged to reside in six of the counties, and they will receive ICM if living in Chatham County, the most urban/populous county, which offers ICM services. CM services, as defined by the State mental health agency, focus on assisting the individual with: developing natural supports to promote community integration, identifying service needs, linking to services/resources, and coordinating services to maximize integration and minimize service gaps.[2] Outcome expectations include decreased hospitalizations and incarcerations, as well as increased housing stability, job-related activities, community engagement, and recovery.[2] CM is provided by a licensed practitioner, whose caseload does not exceed 50. Contact must be made with the individual ≥2 times per month, at least one of which must be in-person, in a non-clinic setting. ICM is very similar, but four in-person visits are required monthly, at least 60% of total contacts must be face-to-face, and at least 50% must be delivered in non-clinic/community-based settings.[2] An ICM team includes nine professionals, and the team's maximum case load is 200 (22 per team member).

Referral, Assessment, and Randomization

All procedures will be reviewed and approved by the university's and the State's Institutional Review Boards. Clinicians at the three sites will refer potentially eligible patients who will then be evaluated for their interest in taking part in the study and capacity to give informed consent. Trained research assessors will complete the initial/baseline assessment

within about a week before discharge. After eligibility screening, consent, and the assessment, the patient will be randomized at a 1:1 ratio to ODR or CM using a computer-generated algorithm. The study statistician will create the randomization list, by randomly alternating blocks of 2 or 4, and the resulting sequential treatment assignments will be sealed in opaque envelopes. After the patient is found to meet eligibility criteria, gives informed consent, and completes the baseline assessment, the research assessor will open the next envelope in the sequence and inform the ODR or CM provider of the treatment assignment.

Outcome Data Collection

Primary outcomes (hospitalizations and arrests). Hospitalization data will be collected from three sources: the Georgia Department of Behavioral Health and Developmental Disabilities (DBHDD, the State's mental health agency), the CSU in Savannah, and the CSU in Brunswick. Because DBHDD operates all state psychiatric hospitals, they have complete admission and discharge data for the study timeframe. However, DBHDD only collected CSU data beginning in January 2017; as such, the two CSUs serving as referral sites will also provide admission and discharge data for the full study period.

Arrest data will be provided by the Georgia Crime Information Center (GCIC), within the Georgia Bureau of Investigation (the lead state law enforcement agency), in the form of the participants' record of arrests and prosecutions (RAP sheets). GCIC receives monthly arrest reports from >600 state and local law enforcement agencies; this information is stored in GCIC's crime database and is summarized in the RAP sheet. To test our arrest-related hypotheses, we will extract all arrests for the 12 months after enrollment. Arrest data will be available for all participants.

Secondary outcomes (housing and recovery). Data collection for the two secondary outcomes will be collected in-person, though retention is expected to be difficult based on the serious psychosocial impairment of the study sample and experience in the initial study.[5] Two housing-related measures will be used. The *Housing Satisfaction Scale* (HSS)[6] has 19 items covering choice, safety, privacy, and proximity.[6–8] The *Housing Instability Index* (HII) is a sum of 10 items that ask participants about their housing situations over the past six months;[9] the time frame was adapted to four months for this study to match the follow-up timepoints.

To thoroughly assess recovery, we will examine five measures of constructs aligned with recent conceptualizations of recovery and the goals of ODR. First, the *Multnomah Community Ability Scale* (MCAS) is a 17-item instrument that measures social and community functioning, with documented good inter-rater and test-retest reliability, and validity.[10] We added five items covering several areas deemed important for the study's purposes. Second, the *Maryland Assessment of Recovery in People with Serious Mental Illness* (MARS) is a 25-item instrument addressing recovery experiences,[11] with documented excellent internal consistency and test-retest reliability, as well as construct validity and divergent validity.[12] Third, the *Herth Hope Scale* (HHS) is a 30- item measure widely used to assess hope,[13] and with well-documented psychometric properties. [14] Fourth, the *Empowerment Scale* (ES) is a 28-item measure assessing self-esteem, perceived power, optimism/control over the future, and related constructs, with documented reliability and validity.[15–17] Finally, the 21-item Community Navigation Scale was developed for the initial and current study—preliminary psychometric research suggests good internal consistency reliability and construct validity.[18]

Recovery Summary Score (RSS)

Because the recovery measures are likely to be highly correlated, we will derive a summary measure to conserve power, which we call the overall Recovery Summary Score (RSS), using principal component analysis (PCA) with possible rotation, and then calculating a patient-specific summary measure by standardizing each of the five measures and then averaging for each subject and timepoint.

Data Analyses

Between-group comparisons will rely on intention-to-treat analyses. Analyses involving hospitalizations and arrests will be performed using both binomial and Poisson generalized linear models for binary outcomes and counts, respectively. Analyses of change in housing and recovery measures will be performed using linear mixed models on all available data at each timepoint. Time in months will be used as a continuous predictor (growth curves) with measures at baseline, 4-, 8-, and 12-months. For the primary outcome analysis (12-month endpoint) the model structure will include group (ODR vs. CM), time, and group-by-time interactions, with a random intercept for subject. For those measures that indicate significant 2-group differences, we will compare ODR against ICM specifically, to further define effects (post-hoc analyses). For count/duration of hospitalizations and number of arrests, we will do conditional tests (comparing only those with non-zero values) to reduce the effects of zero inflation and get meaningful effect sizes across groups.

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