Project Title: Adapting Critical Time Intervention to Support Inpatient Medical Care Transition
NCT Number: NCT03637296
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Data Analysis Plan

Qualitative Feasibility Assessment (Aim 1): Our qualitative data analysis will be guided by grounded theory, which provides a rigorous, systematic approach to collecting and analyzing interview data. Grounded theory has yielded robust theoretical models of social behavior in health care settings (104). We will produce a fine-grained descriptive analysis of the barriers and facilitators of CTI in this patient population and then probe how the services operated to reduce readmission, promote completion of outpatient medical and mental health referrals, and enhance patient functioning. Transcripts of recorded interviews will be entered into Atlas.ti. We will use open, axial, and selective coding and the constant-comparative methods to generate codes and derived themes. To establish reliability, two study staff will independently code up to 10% of transcripts. Team meetings will be conducted to review Code assignments will be reviewed at team meetings and differences resolved via consensus. Successive coding sessions will continue until an agreement of 85% or greater in codes applied is reached at which point the research assistant will code the rest of the data.

We will use a thematic matrix (105,106) to integrate the analysis of the patients' and CTI team member/ administrator interviews. This matrix will enable us to compare side-by-side the themes derived from these interviews and to identify similarities and differences in the barriers to and facilitators of CTI that emerge from these interviews. We will use established procedures to enhance the trustworthiness of our analysis, including developing an audit trail documenting analytical decisions, triangulating data generated from patient and clinician interviews, conducting team de-briefing meetings and member checking presentations to study consultants, and staff meetings at study site to review emerging results and lessons learned (107).

Exploratory Quantitative Analyses (Aims 2-4). Data summaries will provide frequencies for categorical variables and means, medians, and ranges for continuous variables. We will assess data quality and examine distributional assumptions with graphical methods. To evaluate balance among groups achieved by randomization, we will compare baseline values of all variables across the 2 study arms using appropriate tests. Variables with imbalances will be covariates in outcome analyses.

General Procedures. All primary analyses of the effects of CTI for Aims 2 and 3 will be on an intent-to-treat (ITT) basis, including each participant in the group to which she or he is randomized, regardless of adherence to the CTI intervention and medical and mental health treatments received following hospital discharge. All hypotheses involving readmission and outpatient service outcomes will be tested using two-sided, 0.05-level tests. In all analyses, we will withhold multiple comparison corrections because we prefer to explore leads that may turn out to be wrong rather than miss possibly important findings (108,109).

Generalizability of Study Participants: For the CTI patients, we will assess the extent to which enrolled participants differ from individuals who were eligible on the basis of claims eligibility criteria but declined to permit sharing of their claims data. T-tests and chi-square tests will be used to compare participants and potentially eligible non-participants on all available demographics. In addition, attrition analyses will assess whether participants and dropouts from the Medicaid program differ on key demographic variables (informative dropout) and whether variables on which they differ interact with study group to affect service outcomes.