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Translating an Efficacious Illness Management Intervention for Youth with Poorly Controlled Asthma to
Real World Settings

2/12/24

Study Protocol with Statistical Analysis Plan

The study is a randomized effectiveness trial to test the effectiveness of an adapted, evidence-based multisystems intervention to improve health outcomes of youth with poorly controlled asthma when delivered by community health workers. Participants will be recruited from the emergency department (ED) at a large urban pediatric hospital. Participants will be randomly assigned to receive Reach for Control (RFC), an intensive, multisystemic intervention focused on improving asthma management, or Managing Asthma Through Case Management in Homes (MATCH), a program endorsed by the state health department as a model program for persons with poorly controlled asthma. Randomization occurs immediately after baseline data collection using a permuted block algorithm with blocks of varying size to ensure equivalence across treatment condition. A repeated measures design (baseline, 6 months, 12 months and 18 months) will be used in the effectiveness trial to test the effectiveness of RFC in improving hospital utilization (primary outcome) compared to MATCH.

Eligible participants will be aged 12 years, 0 months-16 years 11 months, with persistent, poorly controlled asthma and 2 or more ED visits or hospitalizations in the previous 12 months. Also, the youth must reside in a family setting where the primary caregiver is willing to participate in data collection and treatment (versus residential facility or group home). Consistent with an effectiveness trial, youth will not be excluded based on ethnicity, but the ED at the study site serves primarily Black families as Detroit has the highest percentage of Blacks of any city in the U.S. according to 2010 Census data (85%). Also consistent with an effectiveness trial, exclusion criteria are kept to a minimum. No exclusions will be made due to co-morbid mental health problems (i.e. ADHD, conduct disorder, depression, anxiety disorder), with the exception of thought disorder (i.e. schizophrenia, bipolar disorder, autism) or developmental delay sufficient to prevent independent asthma care or comprehension of study measures. Data are collected by trained research staff and include questionnaires and interviews.

Study Interventionists in both treatment arms are hired and overseen by the collaborating community partner, Kids Health Connection (KHC). KHC provides a range of services to promote the health of children in their catchment area, including a focus on children with poorly controlled asthma. MATCH is the standard of care provided by KHC to youth with asthma. Several structures and processes will be used to facilitate CHW fidelity to RFC protocols when interacting with families. These include manualization of key components of the RFC program, intensive training of CHW staff, individual supervision each week with an experienced agency supervisor, and one hour of group supervision with supervisor and an expert consultant. During the COVID-19 pandemic, the intervention was delivered via telehealth in both treatment arms.

To test the effectiveness of RFC to improve the primary outcomes at each follow-up period, data will be analyzed for the intent-to-treat sample (all randomized participants). Factors that differ between groups will be included as covariates in subsequent analyses. The primary hypothesis concerning the effectiveness of RFC versus MATCH will be addressed through generalized linear mixed modeling for count outcomes. The group x contrast interactions will test the intervention effect at immediate post intervention, and 6 and 12 months later.