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Official Study Title:
Adaptation and Implementation of an ASD Executive Functioning Intervention in Children's Mental Health Services

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Objectives

Tailoring evidence-based interventions for delivery in community-based mental health services for youth with autism spectrum disorder (ASD) has the potential to increase quality of care and improve child outcomes. Results from the current study will serve as the foundation for large-scale hybrid implementation and effectiveness trials and a generalizable approach for different service systems of care and clinical populations. Youth with ASD represent a growing population with significant service needs. Prominent among these needs are high rates of co-occurring psychiatric conditions that contribute to increased functional impairments and often necessitate mental health services. Executive functioning deficits are associated with ASD as well as common co-occurring conditions (e.g., attention-deficit/hyperactivity disorder) and an evidence-based intervention has been developed and tested to address executive functioning within the school context. There is an urgent need to implement indicated evidence-based interventions for youth with ASD receiving care in community mental health settings. Interventions that optimally "fit" the mental health services context as well as the complex and co-occurring mental health needs of these youth have the potential to improve key clinical outcomes for this high priority population.

Objectives

Specific objectives are to (1) conduct a need and context assessment to inform the systematic adaptation an executive functioning evidence-based intervention; (2) systematically adapt the clinical intervention and develop a corresponding implementation plan, together entitled "Executive Functioning for Enhancing Community-based Treatment for ASD," (EFFECT for ASD); and (3) conduct a feasibility pilot test of EFFECT for ASD in community mental health settings.

Methods

This mixed-methods developmental study will apply the Exploration, Preparation, Implementation, Sustainment implementation framework and a community-academic

partnership approach to systematically adapt and test an evidence-based executive functioning intervention for youth with ASD for delivery in community mental health settings. See Dickson et al., 2020 in the 'References module' for a detailed description of all methods throughout the multi-aim study.

Statistical Plan

Descriptive analyses and examination of qualitative themes related to perceptions of the feasibility, acceptability, and appropriateness of *Unstuck and On Target* will be used to evaluate intervention effectiveness and implementation outcomes. For quantitative implementation outcome measures, criteria for determining sufficient feasibility, acceptability, and appropriateness will be applied, including examination of mean-level ratings on relevant measures and whether mean scores are greater than or equal to ratings indicating perceived feasibility, acceptability and/or appropriateness (e.g., ≥4 on Feasibility and Acceptability of Interventions measures, ≥4 on subscales on the Perceived Characteristics of Intervention Scale). Scores will also be compared to prior relevant literature. For example, fidelity scores will also be analyzed and compared to prior trials of *UOT* to determine if providers achieve similar fidelity levels, indicating appropriate uptake and fidelity. Finally and informed by current recommendations and prior work[93], objective measures of outcomes (e.g., recruitment and enrollment, proportion of sessions completed, attrition) will also be examined. Intervention effects analyses will also be conducted, including Group (intervention vs. control) x Time (pre to post), will be conducted to examine changes in outcome measures over time; analyses will be conducted using recommended procedures (e.g., maximum likelihood) to adjust for missing data and non-normality of outcome variables. Informed by similar pilot feasibility trials, the targeted sample size (n=26) allows for dropout rates similar to that of prior pilot studies in the same setting while also meeting the threshold for sufficiently precise parameter estimates. Per current recommendations, direction of effects and effect size estimation will be examined given the small sample size. Consistent with a Type III Scale-Out, this pilot study adapts an evidence-

based intervention for a new population and delivery systems and will borrow statistical strength by comparing findings to prior studies regarding evidence of *UOT.* As such, we anticipate an effect size that approximates the medium effect observed in the *UOT* randomized-clinical trial[30] (average Cohen's d= .55).