

ODEI Study Statistical Analyses Plan

Title: The Opening Doors to Early Intervention Study (ODEI)

NCT Number: NCT03625115

Document Date: July 3rd, 2024

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Aim 1: To test the effectiveness of the Opening Doors to Early Intervention Program on EI service use and child developmental status among poor minority children residing in an urban community.

- a. *Hypothesis 1a:* A greater proportion of children who are randomized to the intervention will complete EI referrals than children in the control condition at 12 months.

Analysis: Chi square analysis on the difference in completion of MDE by study arm and logistic regression on the difference in MDE completion by arm, controlling for sex, age, and primary care site.

- b. *Hypothesis 1b:* Among children eligible for EI services, children randomized to the intervention will initiate EI services at a greater rate & receiving a longer duration of EI services than children in the control condition.

Analysis: Chi square test on the difference in EI service initiation by arm and logistic regression, controlled for sex, age, and primary care site. Survival analysis with a Kaplan-Meier curve of EI duration of services by arm.

- c. *Hypothesis 1c:* As a result, children who are randomized to the intervention will have more favorable developmental outcomes than children in the control condition at 12 months.

Analysis: Logistic regressions to determine the difference in cognitive and language BSID III scores by arm, controlling for sex, age, and primary care site.

Variable Definitions:

- Completion of EI Referrals: Completion of Multidisciplinary Evaluation (MDE)
- Initiating EI services: Date of first early intervention service
- Duration of EI services: The time between the EI service initiation and discharge from early intervention OR 12 months from randomization (if discharge date is unavailable)
- Developmental outcomes: Language and cognitive composite scores from BSID III assessment.

Aim 2: To assess whether parent engagement mediates the effects of the Opening Doors to Early Intervention Program.

- a. *Hypothesis 2a:* Parent engagement will mediate the association between program participation and completion of EI referrals and participation in EI services (duration).

Analysis: Test the association between study arm at 3 months and EI referral completion and the association between EI parent engagement at 3 months (mediator) and EI referral completion. If both associations are significant, complete a mediation analysis of the association between study arm and completion of EI referrals, mediated by parent EI engagement.

- b. *Hypothesis 2b:* Completion of EI referrals and participation in EI services (dosage) will mediate the association between program participation (duration), parent engagement, and child developmental status

Analysis of EI referral completion and child development status: Test the association between EI engagement at 3 months and Bayley language & cognitive T scores and the association between MDE completion (mediator) and EI engagement at 3 months. If both associations are significant, complete a mediation analysis of the association between EI engagement at 3 months and Bayley language and cognitive T scores, mediated by EI referral completion.

Analysis of program participation and child development scores: Test the association between program participation and Bayley language & cognitive T scores and the association between referral completion (mediator) and program participation. If both associations are significant,

ODEI Study Statistical Analyses Plan

complete a mediation analysis of the association between program duration and Bayley language and cognitive T scores, mediated by referral completion.

Variable Definitions:

- Program participation: participation in ODEI intervention
- Completion of EI Referrals: Completion of Multidisciplinary Evaluation (MDE)
- Initiating EI services: Date of first early intervention service
- Duration of EI services: The time between the EI service initiation and discharge from early intervention OR 12 months from randomization (if discharge date is unavailable)
- Developmental outcomes: Language and cognitive composite scores from BSID III assessment.
- Parent engagement: total score from 2 subscales on parent engagement (Buy-In/Receptivity to EI and Advocacy/Navigating the EI Process)

Aim 3: To explore whether the home learning environment, parental health literacy, or poverty moderate the effects of the Opening Doors to Early Intervention Program on child developmental status.

a. *Aim 3a:* To explore whether differences in developmental scores between intervention and control groups varies by the richness of home learning environment

Analysis: Logistic regressions to determine the difference in cognitive and language BSID III scores by arm, controlling for STIM-Q scores, sex, age, and primary care site.

c. *Aim 3b:* To explore whether differences in elemental scores between intervention and control groups varies by the health literacy level of parents

Analysis: Logistic regressions to determine the difference in cognitive and language BSID III scores by arm, controlling for SAHL parent scores, sex, age, and primary care site.

d. *Aim 3c:* To explore whether differences in developmental scores between intervention and control groups varies by family income level

2. *Analysis:* Logistic regressions to determine the difference in cognitive and language BSID III scores by arm, controlling for parent income, sex, age, and primary care site.

Variable Definitions:

- Developmental outcomes: Language and cognitive composite scores from BSID III assessment.
- Richness of home learning environment: z-scores scores of STIMQ -I/T Home Environment Questionnaire
- Health literacy levels of parent: scores of Short Assessment of Health Literacy (SAHL)
- Family income level: parent reported income