Enhanced Care Planning and Clinical-Community Linkages to Comprehensively Address the Basic Needs of Patients With Multiple Chronic Conditions

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This grant builds on a previous efficacy trial sponsored by IES. The current study collects data during the sustainment year of participating teachers. The statistical analysis plan below denotes the intent to combine results with the previous grant which collected data from the implementation phase, which occurred before the sustainment phase. Participating teachers participated in both studies. The aims below describe the larger objective of analyzing data from both phases.

Aim 1: Determine if malleable baseline factors predict treatment fidelity and modifications to BEST in CLASS during implementation or sustainment. Informed by the DSF, we will evaluate if teacher (self-efficacy, burnout, attributions), intervention (usability), and school (climate, classroom atmosphere, classroom-level adversity) factors predict treatment fidelity and modifications to BEST in CLASS during implementation or sustainment.

Outcomes:
1. Treatment Integrity Instrument for Elementary Settings (TIES-A) to measure change in Program Adherence (Teacher level component) Change in the degree to which the 52 teacher sample adheres to the BEST in CLASS treatment during the post-baseline implementation phase from the prior efficacy trial, in comparison to the same sample's adherence during the present sustainment trial.
2. Treatment Integrity Instrument for Elementary Settings (TIES-C) to measure change in Program Competence (Teacher level component) Change in the competency with which the 52 teacher sample delivers to the BEST in CLASS treatment during the post-baseline implementation phase from the prior efficacy trial, in comparison to the same sample's competency during the present sustainment trial.

Aim 2: Determine if treatment fidelity or modifications to BEST in CLASS predict child outcomes during implementation or sustainment. Two cohorts of children at risk for EBD who meet inclusion criteria for BEST in CLASS will be assessed at two points during implementation (n=192) or sustainment (n=192). Multi-level modeling will be used to evaluate if treatment fidelity or modifications to BEST in CLASS predict improvement in child outcomes (disruptive behavior, social skills) during = implementation or sustainment.

Outcomes:
3. Social Skills Improvement System (SSIS) to measure change in student disruptive behavior problems (Student Level Component) The effect statistic showing change in teacher-reported problem behavior exhibited by the sustainment focal student sample from Fall (SU1) to Spring (SU4) of the sustainment year. Student disruptive behaviors will be measured by the Social Skills Improvement System (SSIS) total problems scale.
4. Social Skills Improvement System (SSIS) social skills scale to measure change in student prosocial behavior (Student level component) The effect statistic showing change in teacher-reported social skills exhibited by the focal student sample (78 enrolled) from Fall (SU1) to Spring (SU4) of the sustainment year. Student prosocial behaviors will be measured by the Social Skills Improvement System (SSIS) social skills scale.

Leadership
Drs. McLeod and Sutherland will provide oversight of the entire project including the development and implementation of project policies, procedures, and processes. Both Drs. McLeod and Sutherland will share equal responsibility for implementation of the Scientific Agenda, the Leadership Plan, and the Specific Aims of the proposed project. Additionally, the MPIs will be responsible for ensuring that systems are in place to adhere to US Laws and NIH policies including human subject research, data, and facilities. Drs. McLeod and Sutherland will share responsibility for all components of the proposed project. They will share equal responsibility for implementing the procedures related to participant recruitment and retainment for all Aims. Dr. McLeod will be primarily responsible for coding procedures

and management (both treatment integrity and qualitative), data management, and overseeing the training and monitoring of the coding teams. Dr. Sutherland will be primarily responsible for community engagement and data collection. Finally, Dr. McLeod will serve as contact PI and will assume fiscal and administrative management, responsibility for communication with NIH, and submission of annual reports.

Methodology Drs. McLeod and Sutherland will lead the methodology team. The team will be comprised of Drs. McLeod, Sutherland, and Chapman. Drs. McLeod, Sutherland, and Chapman are experts in the methodological and statistical approaches employed in the proposed study. Dr. Chapman will provide expert consultation on data analysis (e.g., how to address nesting), and interpretation for all Aims. The team will meet weekly throughout the duration of the project.

Data Analysis Strategy

Overview. The multilevel, interrupted time series design leverages an ongoing RCT, the BEST in CLASS Elementary Trial, to inform the development of a sustainment strategy for EBPs in school settings. The strategy will be based on key targets empirically identified by the project, specifically, the malleable features of BEST in CLASS, teachers, or schools that are associated with treatment fidelity and modifications to BEST in CLASS. A notable strength is that the teacher, intervention, and school targets have two relevant "baselines": one from the implementation phase and one from the sustainment phase. Thus, the sustainment strategy will target influential factors from the start of sustainment and factors from the start of implementation that predicted later sustainment. The design is straightforward, but the analyses have a few complexities that require consideration. As detailed next, the complexities are readily addressed by the proposed analyses.

Data structure. As is common for implementation and sustainment research, the data are nested. In the proposed models, nesting will be addressed using two simultaneous strategies. The first is to use standard mixed-effects regression models, for example, for the nesting of repeated measurements within children, repeated measurements within teachers, children within teachers. The second strategy addresses nesting when the number of upper-level units is too small for accurate estimates of random effects. This approach, which will apply to the nesting of teachers within schools and schools within research sites, uses fixed effect indicators to control for systematic differences across nesting units. The combined approach is highly flexible, readily implemented, and ensures accurate estimates for key model parameters. The specific data structures vary across Aims 1 and 2, and as such, they are detailed separately below.

Modeling building, estimation, and significance testing. The mixed-effects regression models will be implemented using the lme4 package in R software. All outcomes are continuous, though the distributions will be inspected and confirmed prior to modeling. Should non-linear sampling distributions be required (e.g., Bernoulli, negative binomial, ordinal), the models will be implemented using adaptive quadrature in SuperMix. Significance testing will be based on the Wald test statistic, and 95% CIs will be computed to gauge the magnitude and precision of all effects. Planned contrasts will be specified using R's multcomp package to obtain all comparisons of interest. Across Aims, dummy-coded fixed effect indicators will be included for schools and sites. Also, the models will include teacher-level indicators to control for systematic differences by grade. For each predictor of interest, prior to modeling, the level of measurement will be carefully considered, and ICCs will be computed to confirm the appropriate level(s) for scoring and modeling. To aid interpretation, each baseline factor will be centered around its grand mean prior to model entry.

Evaluation of Specific Aims

Aim 1. Determine if malleable baseline factors predict treatment fidelity and modifications to BEST in CLASS during implementation or sustainment. The outcomes for Aim 1—treatment fidelity (TIES Adherence and Competence Scales) and fidelity-consistent modifications (TIES Adherence

and Competence "Purity" Scales; are structured with four repeated measurements (level-1) nested within two phases (level-2; i.e., implementation phase, sustainment phase) nested within teachers (level-3). This is possible because all teachers have repeated measurements in both phases, permitting a single, simultaneous model to test (1) associations within the implementation phase, (2) associations within the sustainment phase, and (3) differences in associations across phases. Fixed effect indicators will control for differences by schools, sites, and grades, and a dummy-coded indicator will differentiate measurements in the implementation and sustainment phases. Change over time will be modeled according to linear and quadratic (if indicated) polynomials. The focal predictors are malleable baseline factors, including teacher (self-efficacy, burnout, attributions), intervention (usability), and school (climate, classroom atmosphere, classroom adversity) factors. For each predictor, there are two scores: a baseline score from the implementation phase and a baseline score from the sustainment phase. The model will necessarily exclude a main effect for the sustainment baseline score because it cannot predict the prior implementation phase outcomes (i.e., the reference phase). However, implementation baseline scores will be considered as predictors of outcomes across both the implementation and sustainment phases. The results will identify key factors that at the start of implementation or the start of sustainment were predictive of sustainment outcomes. The results will inform development of the sustainment strategy. Of note, standard formulations of models for discontinuous and piecewise change can be used to provide more targeted tests for change across the two phases. For example, this could test whether treatment fidelity and modifications to BEST in CLASS change during implementation, whether the overall levels differ for implementation and sustainment, and whether the slope for sustainment differs from the slope for implementation.

Aim 2. Determine if treatment fidelity or modifications to BEST in CLASS predict child outcomes during implementation or sustainment. The outcomes for Aim 1—treatment fidelity (TIES Adherence and Competence Scales) and modifications to BEST in CLASS (TIES Adherence and Competence "Purity" Scales;)—are structured with four repeated measurements (level-1) nested within two phases (level-2; i.e., implementation phase, sustainment phase) nested within teachers (level-3). This is possible because all teachers have repeated measurements in both phases, permitting a single, simultaneous model to test (1) associations within the implementation phase, (2) associations within the sustainment phase, and (3) differences in associations across phases. Fixed effect indicators will control for differences by schools, sites, and grades, and a dummy-coded indicator will differentiate measurements in the implementation and sustainment phases. Change over time will be modeled according to linear and quadratic (if indicated) polynomials. The focal predictors are malleable baseline factors, including teacher characteristics (self-efficacy, burnout, attributions), intervention characteristics (usability), and school characteristics (climate, classroom atmosphere, classroom adversity). For each predictor, there are two scores: a baseline score from the implementation phase and a baseline score from the sustainment phase. The model will necessarily exclude a main effect for the sustainment baseline score because it cannot predict the prior implementation phase outcomes (i.e., the reference phase). However, implementation baseline scores will be considered as predictors of outcomes across both the implementation and sustainment phases. The results will identify key factors that, at the start of implementation and/or the start of sustainment, were predictive of sustainment outcomes. The results will inform development of the sustainment strategy.

Of note, standard formulations of models for discontinuous and piecewise change can be used to provide more targeted tests of change in outcomes across the two phases. For instance, a two-level model with eight repeated measurements (level-1; four per phase) nested within teachers (level-2), an overall slope term, a phase indicator, and a slope term from the start of sustainment could test whether treatment fidelity and modifications change during implementation, whether the overall levels differ for implementation and sustainment, and whether the slope for sustainment differs from the slope for implementation. Alternatively, each outcome could be evaluated in a separate model for the implementation and sustainment phases, where the structure would reduce to two levels (i.e., repeated measurements within teachers).