Registry of Efficacy and Effectiveness Studies

Study Title:
Focus on Learning, Interaction, and Play (FLIP) at Recess

Registry ID: 7780.1v1

Version History

The first version of this entry was published on August 3, 2021 3:36:25 PM EDT
Currently viewing this version.

Section I: General Study Information

PI name: Matthew Brock
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Primary Funding Source(s):
Institute of Education Sciences
National Center for Special Education Research

Award Number(s):
R324A200110

IRB Name:
Focusing on Learning, Interaction, and Play at (FLIP) Recess for Students with Severe Disabilities

IRB Approval Date:
2020-07-31

IRB Approval Number:
2020B0158

Other Registration Name:
-

Other Registration Date:
-

Other Registration Number:
-

Study Start Date:
2021-09-01

Study End Date:
2026-06-30

Intervention Start Date:
2022-01-03

Timing of entry:
Prior to implementation of the intervention

Brief Abstract:
Purpose: For most elementary students, recess is a favorite time of the school day that is full of rich opportunities to play and socialize with friends. For students with severe disabilities (i.e., students with intellectual disability, autism, and/or multiple disabilities who qualify for their state's alternate assessment), recess often looks very different. These students are typically on the periphery, rarely interacting or playing with their peers. Instead of a much-needed time to develop social competence and build social connections, recess is a missed opportunity.

Intervention: Our proposed solution, FLIP Recess, is a promising and feasible intervention for building social competence and social connections for students with severe disabilities. This approach involves a combination two intervention components—peer-mediated intervention and social skills instruction. These two strategies work together. Through peer-mediated Pivotal Response Training (PRT) at recess, staff who supervise recess coach peers without disabilities to interact and support students with severe disabilities—increasing opportunities for these students to interact and play with peers. Through classroom-based social skills instruction, teachers systematically teach students social skills that will prepare them to be successful as they interact and play with peers. Results from two pilot studies have shown promising increases in social skills, social interactions, and peer play; and demonstrated that teachers and staff can feasibly implement the intervention with fidelity.

Research Design and Method: In this initial efficacy study, we will use a 2-level randomized cluster trial to test the effects of teacher-implemented FLIP Recess relative to a waitlist (business-as-usual) condition. We will randomize 36 elementary schools from four school districts in central Ohio to an intervention or waitlist condition. These four districts serve students from a combination of urban, suburban, and rural communities. We will recruit 8 students with severe disabilities in grades 1-5 from each school, for a total sample size of 288 students. We will test the efficacy of the intervention on proximal (i.e., peer interactions, targeted social skills, and play with peers at recess) and distal outcomes (i.e., social competence and social connections). We will measure social competence using the Social Skills Improvement Scales and the Autism Social Skills Profile, and social connections using classroom peer network analysis of peer nomination data. We will measure proximal outcomes through direct assessment at recess. In addition, we will measure the degree to which these outcomes maintain in the short-term (i.e., the semester after the intervention is over), and we plan to apply for follow-up funding to measure longer-term impacts.

Data Analytic Strategies: Our analysis for the primary research questions will involve multi-level analysis that accounts for students being clustered within schools, and we will analyze the degree to which severity of intellectual disability and/or autism symptomology moderate the efficacy of the intervention in these models. We also will use Structural Equation Modeling (SEM) to analyze the plausibility of our theory that proximal outcomes mediate distal outcomes. In addition, we will use the ingredients method of cost analysis in order to fully document the economic cost of FLIP Recess in opportunity cost terms.

Keywords:
recess, severe disabilities, social interactions, play, social skills, autism, intellectual disability, multiple disabilities, alternate assessment, elementary, peers,

Comments:
-

Section II starts on the next page.

Section II: Description of Study

Type of Intervention:
Practice

Topic Area of Intervention:
Early Childhood Education, Social and Behavioral Context for Academic Learning, Special Education

Number of intervention arms:
1

Target school level:
1, 2, 3, 4, 5

Target school type:
Rural, Suburban, Urban

Location of Implementation:
United States: United States : Midwest

Further description of location:
Ohio

Brief Description of Intervention Condition:
Our proposed solution, FLIP Recess, is a promising and feasible intervention for building social competence and social connections for students with severe disabilities. This approach involves a combination two intervention components—peer-mediated intervention and social skills instruction. These two strategies work together. Through peer-mediated Pivotal Response Training (PRT) at recess, staff who supervise recess coach peers without disabilities to interact and support students with severe disabilities—increasing opportunities for these students to interact and play with peers. Through classroom-based social skills instruction, teachers systematically teach students social skills that will prepare them to be successful as they interact and play with peers.

Brief Description of Comparison Condition:
In schools randomly assigned to the waitlist condition, teachers and staff will not receive any support, training, or materials from our research team until after all project data collection is complete. We anticipate that the adults who supervise recess will not provide any social support to students with severe disabilities.

Comparison condition:
Business-as-usual

Comments:
-

Section III: Research Questions

Confirmatory research questions:

Question 1:
What are the effects of FLIP Recess on social connections and social competence for elementary students with severe disabilities?

Question 2:
What are the effects of FLIP recess on (a) rate of peer interaction, (b) time engaged in appropriate play with peers, and (c) use of social skills at recess for elementary students with severe disabilities?

Exploratory research questions:
Question 1:
What are the effects of FLIP recess on (a) rate of peer interaction, (b) time engaged in appropriate play with peers, and (c) use of social skills at recess for elementary students with severe disabilities

Question 2:
To what degree does student intellectual functioning and autism symptom severity moderate the efficacy of FLIP Recess on the outcome variables?

Question 3:
To what degree do differences in implementation fidelity moderate the efficacy of FLIP Recess on the outcome variables?

Question 4:
Is it plausible that the relation between the intervention and the distal variables (i.e., social competence and social connections) is mediated by the rate of peer interaction, time engaged in appropriate play with peers, and use of social skills at recess?

Question 5:
To what degree do social networks change for peers who participate in the peer-mediated intervention?

Question 6:
How do stakeholders perceive the social validity of FLIP Recess?

Comments:
-

Section IV-A: Study Design (Selection)

Study Design:
Randomized Trial (RT)

Comments:
-

Section IV-B: Study Design (Input)

Study Design: Input

Unit of random assignment of intervention:
School

Assignment within sites or blocks:
Yes

Define the sites or blocks:
School

Probability of assignment to treatment the same across sites or blocks:
Yes

Probability of assignment to treatment:
.5

Unit outcome data measured:
Student

Intermediate clusters between unit of random assignment and unit of measurement:

Comments:
-

Design Classification

Based on the responses above, this study has been classified as:
RT: Multisite (Blocked) Cluster Randomized Trial

Section V: Sample Characteristics

Approximate number of students per school: 8

Approximate number of schools in the comparision condition within each school: 8

Approximate number of schools in the intervention condition within each school: 8

Number of schools: 36

Yes - students with severe disabilities; We define students with severe disabilities as those students who (a) have an education label of intellectual disability (ID), autism spectrum disorder (ASD), or multiple disabilities (MD); and (b) are eligible for their state's alternate assessment for students with the most significant cognitive disabilities. Yes - students with aggressive or violent behaviors No No No No

Comments:
-

Section VI: Outcomes (Input)

Confirmatory question 1: Outcome Measure 1

Outcome domain: Student Social, Emotional, & Behavior - social connections and social competence
Minimum detectable effect size: 0.39-0.49
Outcome measure: Social Skills Improvement Systems (SSIS)
Scale of outcome measure: Continuous
Normed or state test: Yes
Same outcome measure in treatment and comparison groups: Yes

Confirmatory question 1: Outcome Measure 2

Outcome domain: Student Social, Emotional, & Behavior - social connections and social competence

Minimum detectable effect size: 0.39-0.49

Outcome measure: Social Network Analysis

Scale of outcome measure: Ordinal

Normed or state test: No

Test-retest reliability:

Internal consistency:

Inter-rater reliability:

Same outcome measure in treatment and comparison groups: Yes

Confirmatory question 2: Outcome Measure 1

Outcome domain: Student Social, Emotional, & Behavior - peer interactions, time engaged in play, use of social skills

Minimum detectable effect size: 0.39-0.49

Outcome measure: Direct Observation of Peer Interaction

Scale of outcome measure: Continuous

Normed or state test: No

Test-retest reliability:

Internal consistency:

Inter-rater reliability:

Same outcome measure in treatment and comparison groups: Yes

Confirmatory question 2: Outcome Measure 2

Outcome domain: Student Social, Emotional, & Behavior - peer interactions, time engaged in play, use of social skills

Minimum detectable effect size: 0.39-0.49

Outcome measure: Direct Observation of Time Engaged in Play

Scale of outcome measure: Continuous

Normed or state test: No

Test-retest reliability:

Internal consistency:

Inter-rater reliability:

Same outcome measure in treatment and comparison groups: Yes

Confirmatory question 2: Outcome Measure 3

Outcome domain: Student Social, Emotional, & Behavior - peer interactions, time engaged in play, use of social skills

Minimum detectable effect size: 0.39-0.49

Outcome measure: Direct Observation of Use of Social Skills

Scale of outcome measure: Continuous

Normed or state test: No

Test-retest reliability:

Internal consistency:

Inter-rater reliability:

Same outcome measure in treatment and comparison groups: Yes

Section VII: Analysis Plan

Baseline data collected prior to start of intervention:
Yes

Description of baseline data:
WASI-2, CARS, 3 Recess Observations, SSIS, ASSP, Peer nominations of social network connections, Parent-reported out-of-school social contact

Covariates you plan to include in the model:
Gender, Race

Covariates you plan to include in the model:
Free and Reduced Lunch Status

Analytic model:
<p>Preliminary Analysis. Before conducting any inferential analysis, we will examine data for baseline equivalence, attrition, and missing data. Baseline equivalence. We will test for baseline group differences on all dependent variables using a simple t-test. In the event that there are statistically significant baseline differences, we will include additional demographic variables in our model that might explain these differences. Attrition. Based on our prior studies testing this intervention (Amadi et al., in preparation; Brock et al., 2018), we anticipate very low attrition at the student level. Based on our strong commitment from the four school districts and our prior work in these schools, we also anticipate very low attrition at the school level. Nevertheless, descriptive analysis will be conducted to document overall attrition and differential attrition between groups. If attrition does occur, predictors of attrition will be added to the efficacy model. Missing data. We have taken a number of steps to ensure that we will have very little missing data, including (a) providing incentives for teachers to complete measures, (b) providing incentives for parents to complete measures, and (c) planning for a wide observation window so that we can make-up observations if a student is absent. Because we anticipate very little missing 21 data and that data will be missing at random, we anticipate that it will be appropriate for us to accept the assumptions of Maximum Likelihood (ML) that is part of our analytic plan. However, in the unlikely event that we have a significant amount of missing data or missing data are nonrandom, we will adopt a different approach (e.g., multiple imputation). Research Questions (RQ) 1-3: Main treatment effects. We will use multi-level analysis to estimate the effects of FLIP Recess on (a) social connections and social competence (confirmatory analysis of distal outcomes; RQ 1); (b) interactions and social skills at recess (confirmatory analysis of proximal outcomes; RQ 2); and (c) a global measure of social competence and peer interaction outside of school (exploratory analysis of generalized effects, RQ3). Treatment group will be a level-2 (school-level) predictor. We will use the approach described in the paragraphs below for each outcome variable across research questions 1-3. Before running full multi-level models, we will calculate intraclass correlations (ICCs) for each of our dependent variables, which is the proportion of the total variance than can be attributed to mean differences across schools. We will estimate the null model (Yij = γ 00 + u0j + rij) and calculate the ICC using this formula: ρ = τ2 /(σ2 + τ2) = τ2 /#### 2. In our power analyses, we estimated that ICCs would be between .10 and .20. After we have partitioned the variance into two levels, we will enter a school-level covariate, Wj (i.e., percent of students receiving free or reduced lunch) to account for variance between schools. In our power analyses, we estimated that this covariate would account for 20- 50% of the variance between schools. In addition, we will enter condition, Tj (i.e., FLIP Recess or Waitlist) in order to estimate differences in the outcome variables that can be attributed to the intervention. The complete model, including the treatment effect and the level-2 covariate is: Level 1: Yij = β0j + rij Level 2: β0j = γ00 + γ01Tj + γ02Wj +u0j Effect size. In order to calculate an effect size that accounts for clustering in schools, we will divide the coefficient for the treatment by the pooled standard deviation. Research Question 4: Student characteristics as moderators. To estimate the degree to which the intervention moderates the effects of student characteristics (i.e., autism symptom severity and intellectual functioning) on outcome variables,

we will enter autism symptom severity and intellectual functioning as level-1 covariates. Below is an example of the randomintercept model with autism symptom severity included as a level-1 covariate. To assess variation across schools in this treatment moderation effect, we will also test a model that includes a random effect for Β1j (i. e., including u1j) Level 1: Yij = β0j + β1(AUTij) + rij Level 2: β0j = γ00 + γ01Tj + γ02Wj + u0j Β1j = γ10 + γ11Tj Research Question 5: Implementation fidelity as a moderator. To assess the degree to which implementation fidelity can explain differential effects we will conduct three different analyses. First, we will focus on the entire sample using the adherence/quality measure of the peer-mediated component of the intervention. This will be collected for both groups, because it is conceivable that the adults or peers in the waitlist group may sometimes engage in some of the behaviors associated with the peer-mediated intervention, and this measurement will enable us to characterize treatment differentiation. We will analyze the effect of the total adherence/quality score, and additional analyses will focus on the subtotal for the items that capture only adult behavior, and the subtotal of items that capture only peer behavior. This will enable us to analyze the degree to which overall implementation fidelity of the peer-mediated component, adult 22 behavior, and peer behavior impact treatment outcomes. Second, we will focus on only the treatment group using the adherence/quality measure of the social skills component. We will analyze the degree to which treatment fidelity for the social skills component explains variability of effects within the treatment group. Third, we focus on exposure /dose by using number of minutes each student received social skills instruction to predict treatment outcomes. This will enable us to address the degree to which variability of effects across groups can be attributed to time spend in social skills instruction. We will examine effects of implementation fidelity at both the individual child and the school level. If no school-level differences are warranted, we will remove school from the model and examine if there are interactions between the child-level fidelity measure and the effects of the student-on level predictors. Research Question 6: Mediation. We will conduct Structural Equation Modeling (SEM) using MPlusV8.3 to analyze the degree to which it is plausible that the proximal outcomes (i.e., interactions, targeted social skills, and play at recess) mediate the distal outcomes (i.e., social status and social competence). These paths are illustrated in the Theory of Change (see Figure 2 on page 4). We will account for clustering of students within schools by computing adjusted standard errors using TYPE = COMPLEX in conjunction with the CLUSTER option. Research Question 7: Descriptive analysis of changes in peer networks for peers who provide support. Using descriptive statistics we will summarize (a) the change in the total number of connections in the networks of each of these peers; (b) the subset of connections at pre-test that were lost at post-test; and (c) the subset of new connections at post-test that were not present at pre-test. Research Question 8: Descriptive and qualitative analysis of stakeholder feedback. We will analyze qualitative focus group data using a constant-comparative approach (Corbin & Strauss 2008). Using an iterative process, we will code transcripts for themes that emerge across respondents, and revise our coding framework as new themes emerge. We will analyze quantitative data from Likert-type items on surveys by summarizing descriptive statistics (e.g., means, standard deviations, ranges). Cost analysis. The cost expert consultant will conduct cost analysis using the ingredients method of cost analysis (Levin et al., 2018) in order to fully document the economic cost of FLIP Recess in opportunity cost terms. This consultant will review quantitative and qualitative data on implementation fidelity gathered in the first wave of the intervention to develop instruments for gathering cost data during subsequent waves, including interview protocols for participants and questions to add to fidelity observation protocols. Observers and other members of the research team will then gather data on the amount and characteristics of personnel, facilities, materials and equipment, and other resources required to produce the measured effect of the program in 15 treatment schools in Years 2-4, and contrast that with analysis of exposure and dosage of alternative programming in the Business-as-Usual schools to determine incremental costs and treatment contrast. Ingredients will then be paired with national average market prices based upon nationally representative surveys, such as the National Compensation Survey by the Bureau of Labor Statistics, to obtain a representative and generalizable estimate of total and per-student program costs. When total costs are obtained, the consultant will then analyze them according to who pays for or provides each cost— what is required of the school, district, intervention sponsor, and other entities—as well as different

components of the intervention, including training for teachers, planning time, video equipment and costs associated with producing videos, teacher time implementing the program, and any potential cost savings due to shifting away from other potentially costlier or less effective interventions in the comparison group. The 23 costs will then be paired with the primary measures of effectiveness to create cost-effectiveness ratios for each outcome; these will not be divided by component, as the effectiveness cannot be causally attributed to any particular component of the intervention.</p>

Plan to handle cases with missing outcome data:
Impute missing outcome data

Process description:
Because we anticipate very little missing data and that data will be missing at random, we anticipate that it will be appropriate for us to accept the assumptions of Maximum Likelihood (ML) that is part of our analytic plan. However, in the unlikely event that we have a significant amount of missing data or missing data are nonrandom, we will adopt a different approach (e.g., multiple imputation).

Planned multiple comparisons adjustment, confirmatory question 1 (Student Social, Emotional, & Behavior):
No

Planned multiple comparisons adjustment, confirmatory question 2 :
No

Comments:
-

Section VIII: Additional Information

Links:
No links have been added yet.

Files:
No Files have been added yet.

Comments:
-
