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Efficacy of home and school-based interventions for students with disruptive behavior

Submission date
26/04/2016

Recruitment status
No longer recruiting

Registration date
28/04/2016

Overall study status
Completed

Last Edited
17/01/2022

Condition category
Mental and Behavioural Disorders

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[X] Results
[ ] Individual participant data

Plain English summary of protocol

Background and study aims
The aim of this study is to compare the effectiveness of two interventions for students with disruptive behaviour disorders: a home-based intervention to support parents (homeBase) and a school-based intervention to support students and teachers (First Step NEXT).

Who can participate?
Children in kindergarten (5 years old) through 3rd grade (10 years old) with disruptive behaviour disorders, and their parents and teachers

What does the study involve?
Participating children are randomly allocated to one of four interventions: First Step NEXT only, HomeBase-only, both First Step NEXT and homeBase, or usual care. Teachers of children allocated to First Step NEXT only or First Step NEXT plus homeBase receive expert training in the First Step NEXT program and ongoing in-class support from a behavioral coach. Parents of children allocated to homeBase only or First Step NEXT plus homeBase receive up to six 60-minute home visitation sessions with a behavioural coach. Teachers of children allocated to homeBase only do not receive any training or support from a behavioral coach, but they are asked to complete a log to identify typical services received. Parents of children allocated to First Step NEXT only do not receive any training or support from a trained behavioral coach, but they attend the initial parent-teacher-coach meeting, complete the daily parent-teacher home note, and are asked to complete a log to identify typical services received. Teachers and parents allocated to usual care do not receive any support from behavioral coaches or our research team, but they are asked to complete the log. The child's behaviour is assessed before and after the interventions and at 6-months follow-up. Focus groups are also conducted with parents, teachers, support staff and school administrators.

What are the possible benefits and risks of participating?
There are several benefits. Both children and caregivers selected for this study may have improved health and mental wellbeing from participating in the services provided through this study. The results from this study could provide evidence for the continued use of this

intervention with other children and families. The study's results could also help schools provide effective and appropriate services in the future. There is an ultimate benefit to society in creating an effective early intervention program. The main risk is that participants may feel uncomfortable in answering personal questions.

Where is the study run from?
University of Louisville (USA)

When is the study starting and how long is it expected to run for?
January 2015 to January 2019

Who is funding the study?
Institute of Education Sciences (USA)

Who is the main contact?
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Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
R324A150179

Study information

Scientific Title

Efficacy of enhanced first step to success intervention for tertiary-level students with disruptive behavior

Study objectives
We hypothesize that there will be a significant additive effect indicating the students assigned to the school-plus-home condition will demonstrate significantly greater change on the outcomes compared to the students receiving only one or none of the intervention components. We also expect that students randomized to conditions receiving the school module will demonstrate greater improvement in functioning within the school setting as compared to students randomized to the home-only or usual care conditions (i.e., the unique effect of the school module on the school setting). Conversely, we hypothesize children and parents in triads randomized to conditions receiving the home module will demonstrate greater improvement in functioning within the home setting as compared to children and parents in triads randomized to the school-only or usual care conditions (i.e., the unique effect of the home module on the home setting).

Ethics approval required
Old ethics approval format

Ethics approval(s)
University of Louisville Human Protection, 27/05/2015, IRB # 15.0315

Study design
Randomised controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
School

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use the contact details below to request a patient information sheet

Health condition(s) or problem(s) studied
Disruptive behavior disorders

Interventions
A comparative effectiveness study examining the impact of a home-based intervention to support parents (homeBase) and a school-based intervention to support students and teachers (First Step NEXT) for students with disruptive behavior disorders who require tertiary-level support. We will systematically vary the levels of two factors, First Step NEXT (factor 1) and homeBase (factor 2).

Participants are randomly assigned to one of four conditions:
1. First Step NEXT only
2. HomeBase-only
3. First Step NEXT -plus-homeBase
4. Usual care

Intervention Type
Behavioural

Primary outcome measure
1. Social competency - Social Skills Improvement System Rating Scales (baseline, post test, and 6-month follow up)
2. Problem behavior - Child Behavior Checklist (externalizing subscale) and FAST parent-child observation system (baseline, post test, and 6-month follow up)
3. Parenting practices - FAST parent-child observation system (baseline, post test)
4. Academic engaged time - Systematic Screening for Behavior Disorders (Academic engaged time observation system) (baseline, post test)

Secondary outcome measures
1. Parent motivation and perceptions of parenting - Parent motivation scale (baseline, post test, and 6-month follow up)
2. Student teacher relationships - Student-teacher Relationship Scale
3. Teacher classroom management efficacy- Teacher efficacy scale (classroom management subscale)

Overall study start date
07/01/2015

Completion date
01/01/2021

Eligibility

Key inclusion criteria
1. Male and female students
2. Kindergarten (5 years old) through 3rd grade (10 years old)
3. Must pass first two gates of the Systematic Screening for Behavior Disorders screening and exceed the borderline threshold on the externalizing subscale of the CBCL (PRF)

Participant type(s)
Other

Age group
Child

Lower age limit
5 Years

Upper age limit

10 Years

Sex
Both

Target number of participants
400

Total final enrolment
379

Key exclusion criteria
Severe developmental delays

Date of first enrolment
09/01/2015

Date of final enrolment
11/01/2018

Locations

Countries of recruitment
United States of America

Study participating centre
University of Louisville
United States of America
40292

Sponsor information

Organisation
Institute of Education Sciences (USA)

Sponsor details
555 New Jersey Avenue NW
Washington DC
United States of America
20208

Sponsor type
Government

ROR

https://ror.org/04et59085

Funder(s)

Funder type
Government

Funder Name
Institute of Education Sciences

Alternative Name(s)
IES Research, Institute of Education Sciences (IES) of the U.S. Department of Education, Institute of Education Sciences, U.S. Department of Education, Institute of Education Sciences (IES), IES

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United States of America

Results and Publications

Publication and dissemination plan
To be confirmed at a later date

Intention to publish date
01/07/2021

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study will be stored in a publicly available repository.
Repository name/weblink: openICPSR (https://www.openicpsr.org/openicpsr/project/145801/version/V1/view)
Type of data: underlying data file
When the data will become available and for how long: available now indefinitely.
What access criteria the data will be shared including with whom: curated data are available only to ICPSR members at no cost and to non-members for a fee.

IPD sharing plan summary
Stored in publicly available repository

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		06/12/2021	13/01/2022	Yes	No