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Exploring the impact of mindfulness on children with mental health diagnoses

Submission date
09/08/2024

Recruitment status
No longer recruiting

Registration date
15/08/2024

Overall study status
Completed

Last Edited
15/08/2024

Condition category
Mental and Behavioural Disorders

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[ ] Record updated in last year

Plain English summary of protocol
Background and study aims
This study aimed to measure the impact of mindfulness-based intervention (MBI) on a clinical student population when provided in general education classrooms for elementary and middle students.

Who can participate?
Kindergarten through eighth-grade students from two schools identified with one or more of the following: autism spectrum disorder, dyslexia, attention deficit hyperactivity disorder, oppositional defiant disorder, anxiety, specific learning disability, dyslexia, or emotional disturbance

What does the study involve?
Schools are randomly assigned to the MBI or control group. The Calm & Alert intervention will begin no earlier than the second week of school to allow children to acclimate to the new school year. Calm & Alert uses mind, body, and breath to foster resiliency and self-regulation in students. This mindfulness-based intervention, which also incorporates yoga movements, aims to develop skills in self-awareness, self-regulation, safety, focus, attention, active listening, following directions, respect, and positive thinking. The program consists of six lessons lasting approximately 20-30 minutes, each conducted once a week over six consecutive weeks. An additional week will be included for the preschool students to familiarize them with the routine, songs, and visuals. It will be adapted to the age and needs of the students in each classroom. It may include materials provided by the primary researcher, such as a mini Hoberman sphere (breathing ball), chime, mind/body/breath icons, two small mason jars (one with mud and one with clear water), yoga mats for students, picture of the spine, pictures of feelings (happy, sad, angry, scared, surprised, disgusted), and an on/off switch. The protocol is multisensorial, with successive opportunities to practice the explicit concepts taught throughout the lessons. Each class has a similar structure of songs, breathing, warm-ups, yoga poses, mindful games, and rest involving meditation with child-friendly language.

What are the possible benefits and risks of participating?
There is no compensation and no guaranteed benefits from participating in this study. Mindfulness-based interventions have been researched in several studies. There are no known

side effects of mindfulness-based interventions. There are potential risks of increased symptoms because mindfulness training can increase awareness of body sensations. Students will be doing gentle yoga with potential physical risks, such as pulled or strained muscles.

Where is the study run from?
Elizabethtown College (USA)

When is the study starting and how long is it expected to run for?
June 2023 to November 2023

Who is funding the study?
Investigator initiated and funded

Who is the main contact?
Helen Russell, helen.c.c.russell@gmail.com

Contact information

Type(s)
Public, Scientific, Principal investigator

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Additional identifiers

Protocol serial number
2086851-2

Study information

Scientific Title
Efficacy of a mindfulness-based intervention in schools with a clinical population

Study objectives
This study aimed to measure the impact of the Calm & Alert mindfulness-based intervention when provided in the general education classroom once weekly for six weeks for 10-30 minutes per session. Specifically, studying the changes in executive function, including self-regulation, and prosocial behavior for students identified with at least one of the following: ASD, dyslexia, ADHD, other health impairment (OHI), anxiety, specific learning disability, dyslexia, or emotional disturbance. This pilot study will add to the growing body of research regarding a Mindfulness-Based Intervention (MBI)’s impact on vulnerable youth populations and potential best practices

for implementation within the school setting. We hypothesized that the prosocial behavior and executive function would improve for those receiving the mindfulness-based intervention.

Ethics approval required
Ethics approval required

Ethics approval(s)
Approved 09/08/2024, Elizabethtown College IRB (One Alpha Drive, Elizabethtown, 17022, United States of America; +1 (0)717 361 1366 Dept. Ext. 1174; panchikd@etown.edu), ref: 2086851-2

Primary study design
Interventional

Study design
Pretest-posttest control cluster randomized trial

Study type(s)
Efficacy

Health condition(s) or problem(s) studied
Autism spectrum disorder, attention deficit hyperactivity disorder, other health impairment (IEP eligibility), specific learning disability (IEP eligibility criteria, dyslexia, emotional disturbance, anxiety

Interventions
Schools 1 & 2 were randomly assigned to the experimental and waitlist-control groups via hat draw. School 1 (n = 6) kindergarten and second-grade classrooms as well as School 2 (n = 13) third, fourth, and fifth classrooms, as well as a combined middle school study hall group, received the mindfulness intervention, Calm & Alert, for the initial 6 weeks.

The Calm & Alert intervention will begin no earlier than the second week of school to allow children to acclimate to the new school year. Calm & Alert uses mind, body, and breath to foster resiliency and self-regulation in students. This mindfulness-based intervention, which also incorporates yoga movements, aims to develop skills in self-awareness, self-regulation, safety, focus, attention, active listening, following directions, respect, and positive thinking. The program consists of six lessons lasting approximately 20-30 minutes, each conducted once a week over six consecutive weeks. An additional week will be included for the preschool students to familiarize them with the routine, songs, and visuals. It will be adapted to the age and needs of the students in each classroom. It may include materials provided by the primary researcher, such as a mini Hoberman sphere (breathing ball), chime, mind/body/breath icons, two small mason jars (one with mud and one with clear water), yoga mats for students, picture of the spine, pictures of feelings (happy, sad, angry, scared, surprised, disgusted), and an on/off switch. The protocol is multisensorial, with successive opportunities to practice the explicit concepts taught throughout the lessons. Each class has a similar structure of songs, breathing, warm-ups, yoga poses, mindful games, and rest involving meditation with child-friendly language.

Intervention Type
Behavioural

Primary outcome(s)

Executive function measured using Behavior Rating Inventory of Executive Functioning-2nd edition (BRIEF-2) teacher report at baseline and 1-week post-intervention

Key secondary outcome(s)
1. Prosocial behavior measured using the Strengths and Difficulties Questionnaire prosocial behavior subscale at baseline and 1-week post-intervention
2. Behavioral aspects of self-regulation measured using the Head-Toes-Knees-Shoulder Task at baseline and post-1 week (children in grades kindergarten to third grade only)

Completion date
22/11/2023

Eligibility

Key inclusion criteria
1. Aged 5 to 14 years
2. Having English fluency in spoken language
3. Having one of the following diagnoses or IEP/504 eligibility criteria ASD, ADHD, OHI, specific learning disability, dyslexia, emotional disturbance, anxiety diagnosis, or multiple disabilities or other health impairment due to at least one of the above (verified via educational records)

Participant type(s)
Learner/student

Healthy volunteers allowed
No

Age group
Child

Lower age limit
5 Years

Upper age limit
14 Years

Sex
All

Total final enrolment
33

Key exclusion criteria
1. Students whose first language was not English
2. Those who missed two or more sessions
3. Those who missed substantial portions of two or more sessions

Date of first enrolment
14/09/2023

Date of final enrolment
22/09/2023

Locations

Countries of recruitment
United States of America

Study participating centre
Appleton Village School
737 Union Road
Appleton
United States of America
04862

Study participating centre
Lincolnville Central School
523 Hope Road
Lincolnville
United States of America
04849

Sponsor information

Organisation
Elizabethtown College

ROR
https://ror.org/01y0mgq54

Funder(s)

Funder type
Other

Funder Name
Investigator initiated and funded

Results and Publications

Individual participant data (IPD) sharing plan
The datasets generated during and or analysed during the current study are available upon request by contacting Helen Russell (helen.c.c.russell@gmail.com).

IPD sharing plan summary
Available on request