

# Exploring the impact of mindfulness on children with mental health diagnoses

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		<input type="checkbox"/> Protocol
<b>Registration date</b> 15/08/2024	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
<b>Last Edited</b> 15/08/2024	<b>Condition category</b> Mental and Behavioural Disorders	<input type="checkbox"/> Individual participant data
		<input type="checkbox"/> 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

**Contact name**  
Dr Helen Russell

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## Additional identifiers

**Clinical Trials Information System (CTIS)**  
Nil known

**ClinicalTrials.gov (NCT)**  
Nil known

**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

### **Study design**

Pretest-posttest control cluster randomized trial

### **Primary study design**

Interventional

### **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****Lincolnvile Central School**

523 Hope Road

Lincolnvile

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

### Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
<a href="#">Participant information sheet</a>	Participant information sheet	11/11/2025	11/11/2025	No	Yes