

Exploring the impact of mindfulness on children with mental health diagnoses

Submission date 09/08/2024	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered
		<input type="checkbox"/> Protocol
Registration date 15/08/2024	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
Last Edited 15/08/2024	Condition category Mental and Behavioural Disorders	<input type="checkbox"/> Individual participant data
		<input checked="" 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

Contact details
430 Keating Rd
Warren
United States of America
04864
+1 (0)2078444850
helen.c.c.russell@gmail.com

Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
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

Secondary study design

Cluster randomised trial

Study setting(s)

School

Study type(s)

Efficacy

Participant information sheet

Not available in web format, please use contact details to request a participation information sheet

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 measure

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

Secondary outcome measures

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)

Overall study start date

01/06/2023

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

Age group

Child

Lower age limit

5 Years

Upper age limit

14 Years

Sex

Both

Target number of participants

34

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

Sponsor details

One Alpha Drive
Elizabethtown
United States of America
17022
+1 (0)717 361 1366
hamplek@etown.edu

Sponsor type

University/education

Website

<https://www.etown.edu/index.aspx>

ROR

<https://ror.org/01y0mgq54>

Funder(s)**Funder type**

Other

Funder Name

Investigator initiated and funded

Results and Publications**Publication and dissemination plan**

Planned publication in a peer-reviewed journal

Intention to publish date

05/10/2024

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