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Yoga and mindfulness programming evaluation for middle school students

Submission date
03/06/2020

Recruitment status
No longer recruiting

Registration date
25/06/2020

Overall study status
Completed

Last Edited
19/07/2023

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
Anxiety and depression are mental disorders that cause excessive worry and sadness for people and get in the way of their daily lives. Young people are having anxiety and depression more than they used to in the past, and they need ways to help them feel better so that they can enjoy their lives and be successful at school and in life. Yoga is a way of moving and breathing to bring the body and mind together for relaxation. Mindfulness is a way of paying attention to the present moment in a purposeful way. Yoga and mindfulness are skills that can be taught to young people to help them cope with stress and difficult feelings. One way of providing yoga and mindfulness to young people is through activities at school. The aim of this study is to understand whether providing yoga and mindfulness at school to young people could help reduce their feelings of anxiety (worry) and depression (sadness).

Who can participate?
Students enrolled in the participating middle school

What does the study involve?
Participants are randomly allocated to either yoga and mindfulness activities in small groups or a waitlist control group. Activities include eight sessions of small group yoga and mindfulness (Monday, Tuesday, Thursday, or Friday) at the same time in the morning (8:05 to 9:05 AM during the school day). Symptoms of anxiety and depression are measured before the intervention, after completion of the intervention, and at the end of all the programming.

What are the possible benefits and risks of participating?
The benefits are to understand the usefulness of providing yoga and mindfulness programming to students based on whether their symptoms are affected by the programming. The risks are minimal and include potential breach of confidentiality in case any of the anonymized data may be sensitive.

Where is the study run from?
Tulane University (USA)

When is the study starting and how long is it expected to run for?
September 2018 to January 2019

Who is funding the study?
Investigator initiated and funded

Who is the main contact?
Dr Alessandra Bazzano
abazzano@tulane.edu

Contact information

Type(s)
Scientific

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Dr Alessandra Bazzano

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Type(s)
Public

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Additional identifiers

Study information

Scientific Title
Yoga and mindfulness programming evaluation for middle school students: a randomized controlled trial

Acronym
YMP

Study objectives
Yoga and mindfulness programming reduces symptoms of depression and anxiety.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Reviewed and deemed not human subjects research due to consisting of secondary analysis of de-identified data on 10/06/2019 by the Tulane University Human Subjects Protection Office Internal Review Board (Tulane University, HRPO 1440 Canal Street, Suite 1705, TW-8436 New Orleans, LA 70112, USA; +1 (0)504 988 2665; irbmain@tulane.edu), ref: 20191259

Primary study design
Interventional

Study design
Single-center cluster randomized controlled trial

Study type(s)
Prevention

Health condition(s) or problem(s) studied
Prevention of symptoms of anxiety and depression in early adolescents

Interventions
The school administration uses randomizer.org for group randomization with no blinding to either yoga and mindfulness activities in small groups or a waitlist control condition. Activities include eight sessions of small group yoga and mindfulness (Monday, Tuesday, Thursday, or Friday) and at the same time in the morning (8:05 to 9:05 AM during the school day). The total duration of the intervention and follow-up is September 2018 - March 2019.

Intervention Type
Behavioural

Primary outcome(s)
1. Symptoms of anxiety measured using the Screen for Child Anxiety Related Disorders (SCARED) scale at baseline (prior to intervention) in September 2018, after completion of intervention in December 2018, and at the end of all the programming in March 2019
2. Symptoms of depression measured using the Patient Health Questionnaire revised for adolescents (PHQA) at baseline (prior to the intervention in September 2018), after completion of the intervention in December 2018, and at the end of all the programming in March 2019

Key secondary outcome(s)
There are no secondary outcome measures

Completion date
05/01/2019

Eligibility

Key inclusion criteria
Students enrolled at the specific middle school where administrators evaluated their yoga and mindfulness programming

Participant type(s)
Healthy volunteer

Healthy volunteers allowed
No

Age group
Child

Sex
All

Total final enrolment
86

Key exclusion criteria
Unwilling to participate

Date of first enrolment
10/01/2018

Date of final enrolment
11/01/2018

Locations

Countries of recruitment
United States of America

Study participating centre
Tulane University
School of Public Health and Tropical Medicine
1440 Canal St.
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United States of America
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Sponsor information

Organisation
Tulane University

ROR
https://ror.org/04vmvtb21

Funder(s)

Funder type
Other

Funder Name
Investigator initiated and funded

Results and Publications

Individual participant data (IPD) sharing plan
The participant-level data (original SCARED and PHQA forms used to collect data) are the property of the school, and access must be requested through email to the principal investigator Alessandra Bazzano (abazzano@tulane.edu) who will transfer the request to the school. The school wish to remain anonymous at this time to protect students' privacy. All students involved in the study provided assent and their parents' consented, with two students' families opting out when provided informed consent and assent by the school.

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		24/09/2022	19/07/2023	Yes	No