

Yoga and mindfulness programming evaluation for middle school students

Submission date 03/06/2020	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered
		<input type="checkbox"/> Protocol
Registration date 25/06/2020	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
Last Edited 19/07/2023	Condition category Mental and Behavioural Disorders	<input type="checkbox"/> 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

Contact name
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Type(s)
Public

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Additional identifiers

EudraCT/CTIS number

Nil known

IRAS number**ClinicalTrials.gov number**

Nil known

Secondary identifying numbers

Nil known

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

Study design

Single-center cluster randomized controlled trial

Primary study design

Interventional

Secondary study design

Cluster randomised trial

Study setting(s)

School

Study type(s)

Prevention

Participant information sheet

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

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 measure

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

Secondary outcome measures

There are no secondary outcome measures

Overall study start date

01/09/2018

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

Age group

Child

Sex

Both

Target number of participants

88

Total final enrolment

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

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Sponsor information

Organisation

Tulane University

Sponsor details

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Sponsor type

University/education

Website

<https://tulane.edu/>

ROR

<https://ror.org/04vmvtb21>

Funder(s)

Funder type

Other

Funder Name

Investigator initiated and funded

Results and Publications

Publication and dissemination plan

Planned publication in peer-reviewed journal. De-identified participant level data will be made available as required by WHO/ICMJE requirements.

Intention to publish date

31/07/2020

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