Principal Investigator (PI):

Cheryl L. Somers, PhD Wayne State University, Division of Theoretical and Behavioral Foundations Phone: (313) 577-1670 Email: <u>c.somers@wayne.edu</u>

Key Information

This project is research and participation is voluntary. The aim of this project is to research the possible benefits of school-based mindful movement, breathing, and cognitive reframing activities for adolescent students. The research project will last for approximately 10 weeks, with teachers facilitating mindful movement, breathing, and cognitive reframing activities within the normal structure of their class time. There are no foreseeable risks or discomforts associated with participation. The expected benefits will include possible reduction in challenging behaviors, expanding upon school-based emotional coping skills, and helping students and teachers decrease stress levels while at school. There are no alternative procedures for the study.

Purpose

You are being asked to allow your child or ward to be in a research study of that focuses on the development of a new mental, behavioral, and emotional health resource for middle school students called Teens Work It because he/she is in middle school and may benefit. This study is being conducted at Wayne State University. The estimated number of study participants to be enrolled at Wayne State University is about 500. Please read this form and ask any questions you may have before agreeing to be in the study.

In this research study, we are developing and evaluating the implementation process of Teens Work It Out, as well as the outcomes of the pilot intervention. The program will consist of three elements that the classroom teacher will be trained to facilitate: 1) yoga poses that can be done in a classroom chair, 2) mindfulness techniques for relaxation (e.g., deep breathing and guided imagery) and, 3) cognitive reframing strategies (e.g., reversing self-blame thoughts and focusing on the good). The total time for completing all 3 short bursts of movement and activity will be no longer than 15 minutes from start to finish and will be broken up across different days of the week. Activities will be done during regular advisory/homeroom time, and they will not miss any core academic instruction. Experts in the fields of mental health and physical activity are working to develop Teens Work It Out, and will train teachers before they bring it into the classroom. Teachers will also receive information about trauma and social development that will help them to respond differently to students who are struggling in class. The ultimate goal is that student stress symptoms will decrease and they express intent to apply these strategies in their daily lives. We are interested in evaluating the class engagement components of this resource and student opinions about the yoga, mindfulness, and coping strategies. We are also interested in understanding student emotions and body awareness to see if this resource helps reduce overall feelings of stress, happiness in school, school climate, feelings of support, and so on.

Study Procedures

If you/ your child/ward agree to take part in this research study, he/she will be asked to complete short surveys before and after the program, providing feedback on overall thoughts of the TWIO program and their use of the three categories of strategies. In between, the program gives them the opportunity to learn new mindfulness techniques in the areas of stretching/movement, breathing/relaxation, and thinking about problems in their lives. The surveys should not take more than 20-30 minutes each and will only be administered at the beginning and end of the study. The questions will ask about the program itself as well as how they feel about school, themselves (e.g., self-esteem), peers and teachers, etc. If students feel uncomfortable in any way, then they may chose not to participate in either of these evaluation activities. In order for student identity to be protected, the questionnaires will be given an alpha-numeric code and will be kept in a locked office at Wayne State University. A select group of students (about 16) will be chosen, or can volunteer, to participate in focus groups to help inform the research study.

Benefits

The possible benefits to your child or ward for taking part in this research study are that students will learn coping and stress reduction strategies; additionally, they will be able to provide valuable feedback for the research team overall, which in turn will help when implementing this resource at additional schools. All of this helps society figure out how best to choose programs in schools that help teens reduce and cope with stressors.

Risks

By taking part in this study, there are minimal risks associated. However, students may experience the slight anxiety during the mindfulness and cognitive portion, or doing yoga/movement activities in front of peers. However, none of the activities will ask students to share out with the class, report on sensitive topics, abuse, communicable diseases, or illegal activities. There may be risks involved from taking part in this study that are not known to researchers at this time.

Costs

Participation in this study will be of no cost to students as the resource is being provided for free to classroom teachers and the school.

Compensation

You or your child or ward will not be paid for taking part in this study.

Confidentiality:

All information collected about your child during the course of this study will be kept confidential to the extent permitted by law. Your child or ward will be identified in the research records by a code name or number. Information that identifies your child personally will not be released without your written permission. However, the study sponsor, the Institutional Review Board (IRB) at Wayne State University, or federal agencies with appropriate regulatory oversight [e.g., Food and Drug Administration (FDA), Office for Human Research Protections (OHRP), Office of Civil Rights (OCR), etc.) may review your records.

When the results of this research are published or discussed in conferences, no information will be included that would reveal your child's identity.

Voluntary Participation /Withdrawal:

Taking part in this study is voluntary. You have the right to choose not to allow your child or ward to take part in this study. Your child or ward is free to only answer questions that he/she wants to answer. You are free to withdraw your child from participation in this study at any time. Your decisions will not change any present or future relationship with Wayne State University or its affiliates, or other services you or your child are entitled to receive.

The PI may stop your child's participation in this study without your consent. If your child has any side effects that are very serious or if your child becomes ill during the course of the research study your child may have to drop out, even if you would like to continue. The PI will make the decision and let you know if it is not possible for your child to continue. The decision that is made is to protect your child's health and safety, or because it is part of the research plan that people who develop certain conditions or do not follow the instructions from the study doctor may not continue to participate.

Questions

If you have any questions about this study now or in the future, you may contact Dr. Cheryl Somers at the following phone number (313) 577-1670. If you have questions or concerns about your rights as a research participant, the Chair of the Institutional Review Board can be contacted at (313) 577-1628. If you are unable to contact the research staff, or if you want to talk to someone other than the research staff, you may also call the Wayne State Research Subject Advocate at (313) 577-1628 to discuss problems, obtain information, or offer input.

Participation

By completing the survey, you and your teen are each agreeing that he/she/they may participate in this study.

IRB-23-10-6217 10/18/2023 - 10/17/2026

APPROVAL PERIOD

WAYNE STATE UNIVERSITY INSTITUTIONAL REVIEW BOARD