RESEARCH PARTICIPANT CONSENT FORM

Title:	Breathing Curriculum for Stress Reduction in High School Students: A Feasibility Randomized Controlled Trial
Protocol No.:	101
Sponsor:	Health and Human Performance Foundation
Investigator:	Tanya GK Bentley
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	USA
Study-Related Phone Number(s):	617-359-8407
Date:	January 20, 2021

DETAILED RESEARCH CONSENT

Your child is being invited to take part in a research study. A person who takes part in a research study is called a research participant.

In this consent form "you" generally refers to the research participant. If you are being asked as the legally authorized representative, parent, or guardian to permit the participant to take part in the research, "you" in the rest of this form generally means the research participant.

What should I know about this research?

- The research has been explained to you and this form summarizes the explanation.
- Taking part in this research is voluntary. Whether you take part is up to you.
- You can choose not to take part. There will be no penalty or loss of benefits to which you are otherwise entitled.
- You can agree to take part and later change your mind. There will be no penalty or loss of benefits to which you are otherwise entitled.
- If you don't understand, ask questions.
- Ask all the questions you want before you decide.

Why is this research being done?

The purpose of this research is to determine whether the implementation of a new stress-reduction curriculum in your school is possible and whether it may help reduce participants' stress levels. About 80 participants will take part in this research.

How long will I be in this research?

We expect that your taking part in this research will last 16 weeks, or approximately 4 months.

What happens to me if I agree to take part in this research?

If you agree to take part in this research, you will be asked to complete questionnaires about your demographics, your stress levels, and your experiences participating in the study. You will also be asked to do 1-2 minute seated breathing exercise that involves some regular breaths and some slow breathing. These questionnaires and the breathing exercise will be done twice per week in the 2 weeks prior to the study start, 1 time per week during the 6-week study implementation, and 1-2 times per week during the 8 weeks after study implementation. The questionnaires and the breathing exercise are expected to take less than 5 minutes each class period.

All questionnaires and the breathing exercise will be completed during regular class time in your English class. The study will evaluate different variations of the stress-reduction curriculum. All data collected and evaluated will be de-identified, which means that your identity will not be associated with any data collected for this study. There are no known safety risks to participating in this study.

You will be put into a study group by chance (like a coin toss/ like drawing straws). You have a one out of four chance of being placed in each group. You cannot choose your study group. During the research, you and the study investigator will not know which group you are in. Only the teacher will know which study group you are in. No one on the study analytic team will know your study group.

Once the study is completed and the results evaluated, you will be informed of the study findings about whether it was possible to successfully implement the curriculum and whether it may have reduced participants' stress levels.

What are my responsibilities if I take part in this research?

If you take part in this research, it will be your responsibility to:

- Report to your teacher or the study investigator if completing the questionnaires or breathing exercise ever makes you uncomfortable.
- Report to your teacher or the study investigator if you wish to withdraw from the study.
- Skip any questions or breathing exercises as desired.
- Follow the instructions provided by the teacher and the study team.
- Report to the teacher or study investigator if you have any changes in information included in the initial demographics and baseline questionnaire, including the addition or removal of your participation in another stress-reduction program or activity (e.g., yoga, mindfulness or meditation, etc.) outside of this curriculum.

Could being in this research hurt me?

There are no known potential risks of completing the study questionnaires and breathing exercise. Potential discomforts may include discomfort in considering one's stress levels for completing the questionnaires or sensations of discomfort in doing the 1-2 minute breathing exercise.

Will it cost me money to take part in this research?

Taking part in this research will not cost you any money.

Will being in this research benefit me?

We cannot promise any benefits to you or others from your taking part in this research. However, possible benefits to you include reduced stress in general and/or on a day-to-day basis. These benefits may last only during the study and/or may continue afterwards. Benefits to others include informing the feasibility and potential effectiveness of this curriculum so that it can be studied and implemented to help reduce stress among more students at this and/or other schools.

What other choices do I have besides taking part in this research?

This research is not designed to diagnose, treat or prevent any disease. Your alternative is to not take part in the research.

What happens to the information collected for this research?

Your research data may be shared with the individuals and organizations that conduct or watch over this research, including the research sponsor, people who work with the research sponsor, or the Institutional Review Board (IRB) that reviewed this research.

We may publish the results of this research. However, your name and other identifying information will remain confidential.

We protect your information from disclosure to others to the extent required by law. We cannot promise complete secrecy.

Deidentified data collected in this research might be used for future research or distributed to another investigator for future research without your consent.

Who can answer my questions about this research?

If you have questions, concerns, or complaints, or think this research has hurt you or made you sick, talk to the research team at the phone number listed above on the first page.

This research is being overseen by an Institutional Review Board ("IRB"). An IRB is a group of people who perform independent review of research studies. You may talk to them at (800) 562-4789, help@wirb.com if:

- You have questions, concerns, or complaints that are not being answered by the research team.
- You are not getting answers from the research team.
- You cannot reach the research team.
- You want to talk to someone else about the research.
- You have questions about your rights as a research participant.

What if I am injured because of taking part in this research?

Due to the nature of this study, it is not expected that you will get injured or get sick because of being in this research. However, if this does occur, tell your teacher or call the study investigator immediately.

Can I be removed from this research without my approval?

The person in charge of this research can remove you from this research without your approval. Possible reasons for removal include:

- The research is canceled by the IRB or the sponsor
- You are unable to complete the questionnaires or breathing exercise
- You are unable to attend classes on days in which the curriculum is implemented or the questionnaires and breathing exercise are administered.

We will tell you about any new information that may affect your health, welfare, or choice to stay in this research.

What happens if I agree to be in this research, but I change my mind later?

If you decide to leave this research, contact the research team so that the investigator can describe the procedures for orderly termination.

Will I be paid for taking part in this research?

You will not be paid for taking part in this research.

Statement of Consent:

Your signature documents your permission for you or the individual named below to take part in this research.

Signature of child participant's parent or individual authorized under state or local law to consent to the child participant's general medical care	Date
Printed name of participant	Date

All participants are required to assent by signing below.

- ❑ I (parent, legally authorized representative, or legal guardian) have explained the study to the extent compatible with the participant's capability, and the participant has agreed to be in the study.

Signature of person (parent, legally authorized representative, or legal guardian) obtaining assent	Date
Signature of participant providing assent	Date
Name of participant providing assent	
School email address of participant	English Class Period # of participant