ABC Mental Health: A behavioral study of K-12 teachers and school staff

Phase: N/A – a behavioral intervention

Funding Sponsor:

The *Eunice Kennedy Shriver* National Institute of Child Health and Human Development (NICHD)

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Principal Investigator:	Emily M. D'Agostino, DPH, MS, MEd, MA Assistant Professor of Orthopedics Director of Community-Engaged Research Practice Department of Orthopaedic Surgery Duke University School of Medicine [redacted]

STATEMENT OF COMPLIANCE

This study will be conducted in compliance with the protocol, International Council for Harmonisation (ICH) E6 (R2) guideline for Good Clinical Practice (GCP), and the applicable regulatory requirements from the United States Code of Federal Regulations (CFR), including 45 CFR 46 (Human Subjects Protection); 21 CFR 50 (Informed Consent), 21 CFR Part 54 (Financial Disclosure), and 21 CFR 56 (Institutional Review Board [IRB]); as well as international regulatory requirements, if applicable.

All individuals who are responsible for the conduct, management, or oversight of this study have completed Human Subjects Protection and ICH GCP Training.

STUDY PRINCIPAL INVESTIGATOR

The signature below documents the review and approval of this protocol and the attachments, and provides the necessary assurances that this clinical study will be conducted according to all stipulations of the protocol, including all statements regarding confidentiality and according to local legal and regulatory requirements and to the principles outlined in applicable United States (U.S.) and international regulations and ICH guidelines.

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Principal Investigator Name (Print or Type)

_____ _____

Study PI Signature Date

TABLE OF CONTENTS

LIST OF ABBREVIATIONS

CARE	Cultivating Awareness and Resilience in Education
CDC	Centers for Disease Control and Prevention
CFR	Code of Federal Regulations
CI	Confidence Interval
CoC	Certificate of Confidentiality
COVID-19	Coronavirus Disease 2019
DCRI	Duke Clinical Research Institute
DUHS	Duke University Health Systems
GCP	Good Clinical Practice
HIPAA	Health Insurance Portability and Accountability Act
ICH	International Council for Harmonisation
IRB	Institutional Review Board
NIH	National Institutes of Health
NICHD	National Institute of Child Health and Human Development
PI	Principal Investigator
PP	Per-protocol
U.S.	United States

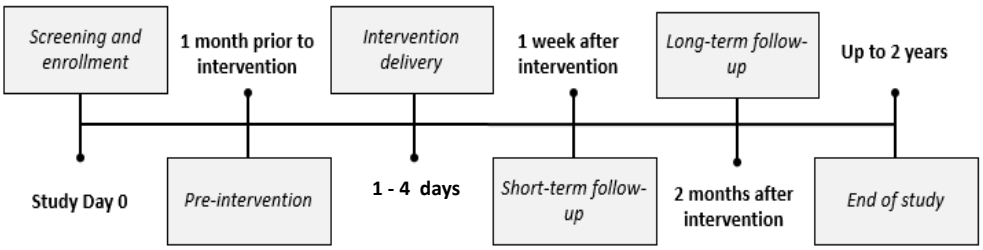
PROTOCOL HISTORY OF CHANGES

Version	Date	Summary of Changes
1.0	29 Sep 2022	N/A Original protocol

PROTOCOL SYNOPSIS

Protocol Title:	ABC Mental Health: A behavioral study of K-12 teachers and school staff
NCT #	Pending
Phase:	N/A, a behavioral intervention
Study Intervention:	Behavioral
Objectives:	Primary: Evaluate the impact of a teacher resilience program on mental health and well-being outcomes of K-12 teachers and staff Exploratory: Examine teacher and staff classroom instruction and behavior management
Study Design:	Prospective, multi-site
Study Population:	Kindergarten through 12th grade (K-12) school employees
Inclusion / Exclusion Criteria:	Inclusion Criteria: - Adult participant, defined as an adult (18 years or older) employed by a school working with youth in kindergarten through 12th grade. - Fluent in the English language Exclusion Criteria: N/A
Number of Participants:	Up to 1,000
Number of Sites:	Single coordinating site, direct-to-participant
Duration of Participation:	School employees will participate in the intervention up to 1 year; the study will last up to 2 years.

SCHEMATIC/DESCRIPTION OF STUDY DESIGN



1 KEY ROLES

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2 BACKGROUND INFORMATION AND RATIONALE

2.1 Background Information

2.1.1 Background of Child Mental Health During COVID-19

As of December 2020, the severe acute respiratory virus coronavirus 2 (SARS-CoV-2) has caused over 74 million confirmed cases of Coronavirus Disease 2019 (COVID-19) and over 1.6 million deaths globally.[1] Initially, children were thought to be minimally affected by this disease, representing < 2% of confirmed cases.[2] However, more recent studies describe increased incidence of multisystem dysfunction and some association to prior or concurrent SARS-CoV-2 infections in children.[3] Thus, spread of SARS-CoV-2 remains an issue. Viral spread and increased infections has spurred non-pharmaceutical measures in children's environment, especially schools. Strategies to limit the spread of infection has included closure of most public spaces, including school buildings. Students have been required to learn from their homes, and many lost access to meals and other services provided at schools and structures vital to their physical, mental, social, and emotional well-being.

Considering the potentially detrimental effect of school building closures on students and families, school leaders across North Carolina sought partnerships with scientists, physicians, and public health specialists from Duke University and the University of North Carolina to better understand the science and data about COVID-19 and K-12 schools. Together, through the ABC Science Collaborative, school leaders and scientists monitored data from school districts choosing to gradually return to school buildings. Scientists interpreted the data and identified that contrary to existing assumptions, schools with mitigation strategies in place were not the

source of infection spread; in fact, data suggested that school buildings were likely safer than surrounding communities. ABC scientists published these results and discussed them with local, state, national, and international leaders. Ultimately, the results led to policy changes and guidance that changed the paradigm of children returning safely to school amidst a global pandemic. Perhaps most importantly, the collaboration between schools and scientists resulted in actionable, on-the-ground plans for safe school return that took into account the unique features and needs of each school district and local community.

Now that school buildings have reopened and K-12 students have returned, another crisis for children and families persists – COVID-19-related impacts on mental health. Health systems and schools have seen suicides skyrocket, schools are facing unprecedented classroom behavioral disruptions, and students with anxiety and depression have risen significantly. According to the Adolescent Behaviors and Experiences Survey (ABES) collected by the CDC in 2021, 37% of high school students reported experiencing poor mental health, and 44% indicated persistently feeling sad or hopeless during the pandemic.[4] Schools and school systems are once again requesting support.

2.1.1 Background of Professional Development Workshop and Evaluation

In addition to the direct pandemic-mediated impact on children, teachers' attitudes can impact their students' mental health.[5] We also suspect school staff may play a role in students' mental health. Thus, Cultivating Awareness and Resilience in Education (CARE) has been proposed as a potential professional development workshop to help improve teachers' and staff's mental health, well-being, effectiveness and student wellness. CARE provides teachers and staff with tools and resources to reduce stress, prevent burnout, enliven teaching, and help students thrive socially, emotionally, and academically. The program will be presented in one to four face-to-face training sessions, spread out over one to four months, and provides post-training resources as additional support. CARE blends instruction with experiential activities, reflection, and discussion. Tools used by the program include mindful awareness practices, emotion, and caring skills training to support more equitable and caring classrooms. Research showed CARE workshops help improve emotional awareness, self-regulation,[6] well-being, cardiovascular health,[7] efficacies, mindfulness, and burnout/time-related stress.[8] Improving teachers' ability to handle their own stress allows them to provide better emotional support to their students and may also help reduce schools' teacher attrition.[9]

As part of this study, people who participate in CARE will be asked to answer questionnaires about demographic information, mental health, well-being, classroom instruction, and behavior management prior to the workshop and two times after completing the workshop. The ABC Science Collaborative is providing this professional development workshop as a service that participating schools offer to all teachers and staff. Those that want to participate in pre- and post-intervention assessments will be consented prior to doing so. Participation in the intervention and assessment completion is optional.

2.2 Scientific Rationale

This study will examine the mental health and well-being of school teachers and staff after providing professional development to address teacher and staff self-efficacy, burnout, anxiety, depression, and stress. This behavioral intervention approach is necessary because the mental health of teachers, school staff, and children has declined since the beginning of the COVID-19 pandemic.

Teachers and staff can play a pivotal role in students' lives by developing supportive relationships and a classroom climate that promotes positive developmental outcomes and is

more conducive to learning. The ability of teachers and staff to play this role is compromised by the highly stressful emotional situations they encounter in the school environment that can lead to burnout. Teachers that exhibit burnout create learning environments that may cause harmful effects on students, especially those already at risk of mental health problems.[5] This behavioral intervention may help teachers and staff apply concepts to reduce stress, and aid teachers improve classroom management and climate that could positively impact children's mental health. Specifically, a growing body of evidence has demonstrated a positive relationship between teacher well-being, school climate, and student outcomes, such as learning, growth, and mental health. Moreover, we can help promote student mental health and young people's ability to cope with daily stresses by supporting school personnel and promoting their self-efficacy to teach effectively, manage behavioral disruptions, avoid burnout, and reduce their levels of anxiety, depression, and stress. This intervention therefore adopts a "whole-school approach" to support teacher and staff and student wellness.[10]

2.3 Potential Benefits

Direct benefit may include reduced stress and improved performance in teachers and staff. The intervention may benefit the mental health and well-being of teachers and staff participating in the intervention, as well as the mental health of children.

2.4 Known Potential Risks

This study is minimal risk, with the only identifiable risk being the potential loss of confidentiality.

Potential Risk of Loss of Confidentiality:

Loss of confidentiality is a potential risk. There is a potential risk of loss of confidentiality with identifiable data collected directly from the participant. Every effort will be made to protect the participants' protected health information as well as other identifying information, but this cannot be guaranteed.

3 OBJECTIVES AND OUTCOME MEASURES

	Objective	Outcome Measures	Endpoints
Primary:	Evaluate the impact of a teacher resilience program on mental health and well-being outcomes of K-12 teachers and staff	CARE assessments, including Teachers' Sense of Efficacy Scale, Maslach Burnout Inventory, Symptoms of anxiety Generalized Anxiety Disorder 7 (GAD7), Symptoms of depression - Patient Health Questionnaire 8 (PHQ-8), Perceived Stress Scale (PSS)	Change in CARE assessments after the intervention compared to before
Exploratory:	Examine teacher and staff classroom instruction and behavior management	Experiences with the CARE for Teachers and Staff Professional Development Program[1]	Teacher and staff perceptions of changes in classroom instruction and behavior management after professional development (post-test only)

4 STUDY DESIGN

4.1 Overall Design

Study design: This is a prospective behavioral intervention. The intervention is a professional development program for K-12 teachers and staff. The primary objective is to evaluate the impact of a professional development intervention on school teacher and staff mental health and well-being outcomes, such as their self-efficacy and stress. Exploratory objectives include change in teacher and staff classroom instruction and behavior management after participating in the intervention. Individual participant-level data will be collected directly from teachers and staff who consent to participate in the intervention. A pre-intervention assessment and two post-intervention assessments will be collected. The consent will be administered once, electronically, via REDCap before collecting pre-intervention assessments. All assessments will be administered via REDCap.

Study intervention: A prospective behavioral intervention

Duration of participant's enrollment: Up to 1 year

Duration of study: Up to 2 years

Safety: N/A

[1] Based on the scale there is no pre-intervention validated measurement so only a post-intervention measurement is being used.

4.2 Scientific Rationale for Study Design

School employees will participate in the intervention for up to 1 year. The pre-intervention CARE assessment battery for teachers and staff will be distributed for completion up to one month prior to the CARE teacher and staff resiliency workshop. The post-intervention CARE assessment battery will be distributed for completion at one-week post intervention and two months post-intervention.

Based on clinical experience of the investigators and published data, the one-week post intervention time point provides insight into the immediate uptake of skills and improvement in emotional well-being of participants who have completed a resiliency workshop. The two-month post-intervention time frame aids in the determination of which skills and concepts endured over time.[11]

The resiliency workshop is delivered across one to four days during a one to four-month period to provide teachers and staff the opportunity to practice skills they have learned prior to being introduced to new concepts and techniques. The CARE team follows up with participants via email on a weekly basis to provide reminders of prior practices and context for their use. This approach has been shown to be effective for promoting teacher and staff mental health and well-being in prior iterations of this workshop. Staff will be identified as either non-administrative staff or administrative staff. Non-administrative staff and teachers attend CARE workshops together and do not include administrative staff to promote openness and feedback. Administrative staff attend CARE workshops that are designed to meet the unique needs of principals and administrators. Specifically, at least six studies have investigated effectiveness of CARE on improving classroom learning, general participant well-being, self-efficacy, reduced burnout, improved self-awareness, self-care and compassion, and mindfulness. [6,7,8,12,13,14] Additional work has demonstrated the impact of CARE on teachers' cardiovascular health, including lower heart rate.[6]

4.3 Study Definition of Enrollment

Study enrollment is defined as the participant has provided informed consent and completed the pre-intervention CARE assessment battery measures (see Section 6.1).

4.4 Study Definition of Completion

Study participation is defined as complete after teachers and staff complete the 2-month post-intervention CARE assessment battery.

5 STUDY POPULATION

5.1 Selection of the Study Population

Adults will be screened for participation according to the criteria in Section 5.2.

5.2 Inclusion/Exclusion Criteria

Inclusion Criteria	- Adult participant, defined as an adult (18 years or older) employed by a school working with youth in kindergarten through 12th grade. - Fluent in the English language

Exclusion Criteria	N/A

5.3 Participant Discontinuation/Withdrawal

5.3.1 Participant/Parent Decides to Withdraw Consent

Participants may voluntarily withdraw consent to participate in the study at any time. Participants are not obligated to state the reason for withdrawal. No additional study data will be collected after consent has been withdrawn, however, all data collected prior to consent withdrawal will be maintained in the database.

5.3.2 Handling of Withdrawals

The reasons for withdrawal, or failure to provide a reason, must be documented.

Reasons of withdrawal may include the following:

1. Participants who withdraw consent to participate in the study.
2. Study Investigator/Sponsor decision

6 STUDY PROCEDURES

6.1 Summary of Procedures

Procedure	Enrollment/ Baseline	Intervention	Follow-up
Teacher and staff informed consent	X		
CARE assessments for teachers and staff	X[1]		X[2]
CARE teacher and staff resiliency workshop		X	

[1] Pre-intervention CARE assessment to be distributed for completion up to one month prior to the CARE teacher and staff resiliency workshop (intervention).

[2] Post-intervention CARE assessment to be distributed for completion one week post-intervention and two months post-intervention.

6.2 Enrollment/Baseline

The following data will be obtained at the time of enrollment.

- Adult teacher and staff informed consent
- CARE assessments for teachers and staff, pre-intervention (including collection of demographic variables)
    - To be distributed for completion up to one month prior to the intervention.

6.3 Intervention

The intervention will be a professional development workshop for teachers and staff delivered across one to four days. The CARE intervention aims to help teachers and staff handle the stresses of school-related work by offering tools and resources for reducing stress, preventing burnout, enlivening teaching, and helping students thrive socially, emotionally, and academically. Tools include mindful awareness practices and caring and emotion skills training. Each intervention workshop includes 30 to 35 participants and a facilitator, who is part of the CARE team.[15] The workshops will be held at a location selected by the school, likely on their campus.

6.4 Follow-up

6.4.1 CARE Assessments for Teachers and Staff

The following data will be distributed for completion one week post-intervention and two months post-intervention.

- CARE assessments for teachers and staff, post-intervention (see Section 6.5.3)

6.5 Evaluation Details

6.5.1 Summary of Evaluations

Applicable informed consent will be documented for all participants. Participants will be asked to complete the pre-intervention CARE assessments online at the time of consent (up to one month before the intervention). The post-intervention CARE assessments will be completed online by participants one week after and two months after the intervention. REDCap will be used to distribute electronic consents and the pre- and post-assessments using a public link sent to the school administrator(s), who will then distribute it to the participating teachers and staff. Participants' email addresses will be collected within the REDCap survey and will be used solely for payment/incentive purposes. No additional assessments will be collected from the participants as part of this study.

Participants will be instructed that all questions are optional. The questionnaire will include the following:

- Demographic variables
- CARE Assessments

6.5.2 Demographic Variables

Participants will be asked a series of questions about their demographics, including their race, ethnicity, gender, school name, school role (administrative staff, non-administrative staff or teacher), and the total number of years they have taught, at current grade level and at current school. We will not share data categorized by role with school districts. We will only share aggregate data grouped by schools with school districts if there are more than 10 participants. If there are fewer than 10 participants at a school, we will group schools together to provide a summary report. If the number of workshop participants for the administrative or non-administrative staff group is less than 10, then these participants will be grouped together and identified as "staff."

6.5.3 CARE Assessments

The CARE assessments are a battery of reliable and validated surveys that aim to collect teachers' and staff's self-reported self-efficacy, burnout, anxiety, depression, and stress.

The following assessments will be completed before and after the behavioral intervention:

- CARE Assessment Battery:
    a. Teachers' Sense of Efficacy Scale;
    b. Maslach Burnout Inventory;
    c. Symptoms of anxiety Generalized Anxiety Disorder 7 (GAD7);
    d. Symptoms of depression – Patient Health Questionnaire 8 (PHQ-8);
    e. Perceived Stress Scale (PSS)
    f. Experiences with the CARE for Professional Development Program (post-test only)

6.6 Participant Compensation

Participants will receive a $25.00 electronic Amazon gift card after completing each of the CARE assessments at baseline, one-week post-intervention, and two months post-intervention during afterschool hours. The CARE assessment battery is anticipated to take approximately 45 minutes to complete. The maximum compensation amount per participant is $75, and a maximum of three payments will be distributed to participants. The payment amount is based on the 2022-2023 annual salaries for North Carolina teachers.[16] Participants' names and email addresses will be shared with Amazon, Inc. so they can send participants the $25 electronic gift card to their email address. A third-party vendor, Amazon, Inc., will be used to distribute payments.

7 ASSESSMENT OF SAFETY

No safety will be recorded as part of this study.

8 STUDY TERMINATION

This study may be terminated at any time by NICHD or the study principal investigators. Reasons for termination may include but are not limited to, if in their judgment, no further benefits are to be achieved from the study. If the study is terminated, notifications will be made to the IRB of record and study participants, in accordance with all applicable regulations governing the study and site/investigator.

9 STATISTICAL CONSIDERATIONS

9.1 Study Endpoints

9.1.1 Primary Endpoints

Primary Objective: Examine the impact of a teacher resilience program on mental health and well-being outcomes of K-12 teachers and staff (administrative and non-administrative).

Primary Endpoint: Change in CARE assessment scores after the intervention compared to before.

- Teacher cohort 1: Change in raw CARE assessment scores (Teachers' Sense of Efficacy Scale; Maslach Burnout Inventory; Symptoms of anxiety Generalized Anxiety Disorder 7 (GAD7); Symptoms of depression - Patient Health Questionnaire 8 (PHQ-8); Perceived Stress Scale (PSS))
- Staff-non administrative cohort 2: Change in raw CARE assessment scores (Teachers' Sense of Efficacy Scale; Maslach Burnout Inventory; Symptoms of anxiety Generalized Anxiety Disorder 7 (GAD7); Symptoms of depression - Patient Health Questionnaire 8 (PHQ-8); Perceived Stress Scale (PSS))
- Staff administrative cohort 3: Change in raw CARE assessment scores (Teachers' Sense of Efficacy Scale; Maslach Burnout Inventory; Symptoms of anxiety Generalized Anxiety Disorder 7 (GAD7); Symptoms of depression - Patient Health Questionnaire 8 (PHQ-8); Perceived Stress Scale (PSS))

9.1.2 Exploratory Endpoints

Exploratory Objective: Examine teacher and staff (administrative and non-administrative) classroom instruction and behavior management.

Exploratory Endpoint: Teacher and staff (administrative and non-administrative) perceptions of changes in classroom instruction and behavior management after professional development (post-test only).

- Teacher cohort 1: Change in raw perceived changes in classroom instruction and behavior management after professional development
- Staff non-administrative cohort 2: Change in raw perceived changes in classroom instruction and behavior management after professional development
- Staff administrative cohort 3: Change in raw perceived changes in classroom instruction and behavior management after professional development

9.2 Analysis Population

All participants enrolled to the study who completed the intervention will be included in the analysis population used for primary and exploratory objectives.

The number of participants who either completed the study or discontinued early from the study will be summarized using a CONSORT diagram. Demographic and characteristics at study baseline (1 week prior to intervention) will be summarized.

9.2.1 Per-protocol Population

For the primary endpoint, participants must have completed the pre and post-CARE assessment to be included in the per-protocol (PP) population.

For the exploratory endpoint, participants must have completed the post-CARE assessment, to be included in the per-protocol (PP) population.

9.3 Analysis Plan

Summary statistics of the schools and staff in the three cohorts (teacher, staff administrative and staff non-administrative) will be presented using data collected during pre- and post-CARE assessment. We will not share data categorized by role with school districts. We will only share aggregate data grouped by schools with school districts if there are more than 10 participants. If there are fewer than 10 participants at a school, we will group schools together to provide a summary report. If the number of workshop participants for the administrative or non-administrative staff group is less than 10, then these participants will be grouped together and identified as “staff.” Under these circumstances, there will be two cohorts instead of three. Means/medians with standard deviations (and interquartile ranges) will be tabulated.

Descriptive statistics (i.e. number of observations, mean, standard deviation, median and interquartile range) will be presented for continuous variables (e.g. as age, weight, etc.). Other descriptive statistics such as counts, proportions, and/or percentages will be presented to summarize discrete variables (such as race, sex, etc.). All descriptive analyses will be presented by appropriate stratification group and overall as specified under each analysis section.

The analysis and PP populations will be used for the primary and exploratory analyses, unless otherwise specified. A detailed description of statistical methods for all analyses will be prepared and presented in the statistical analysis plan prior to data lock for final analyses.

9.3.1 Primary Analysis

For the first primary endpoint for the teacher, staff administrative and staff non-administrative cohorts (change in CARE assessment scores after professional development intervention compared to before), the overall proportions will be reported and the change from pre- to post- will be presented in graphical form (bar chart).

95% confidence intervals for raw change in pre-post assessment scores for each assessment will be computed using a non-parametric bootstrap.

9.3.2 Exploratory Analysis

For the exploratory endpoint for the teacher and staff cohorts (teacher, staff administrative and staff non-administrative perceptions of changes in classroom instruction and behavior management after professional development), descriptive statistics will be reported and raw mean change from pre- to post- will be presented in graphical form (bar chart).

9.4 Sample Size Considerations

No formal sample size calculation was completed for this study. This study will enroll as many adults as possible during the study period, up to 1,000 total participants.

10 FUTURE USE OF STUDY RECORDS

The research data collected in this study, and provided to the sponsor, will be kept indefinitely.

Information about this study, including study results, will be published without further permission from the participant as detailed in the informed consent form. Participants will not be identified in any publications or presentations made about the study.

After the study is completed, information about the study, including study data, may be provided to the National Institutes of Health (NIH). Identifiable data will be kept at the DCRI and the DCRI will not share these data with the NIH. With NIH approval, the data submitted may be used by other researchers for future research. The study data submitted will be de-identified, meaning it will not include any information that can identify the participant. The study team may also share the de-identified study data with other researchers. When the participant's de-identified study data are provided to other researchers for the purposes of future research, it will be done without obtaining additional permission.

11 SOURCE DOCUMENTS AND ACCESS TO SOURCE DATA/DOCUMENTS

All data collected in this study will be entered by the participant directly into REDCap.

12 QUALITY CONTROL AND QUALITY ASSURANCE

The principal investigator will ensure that all study personnel are appropriately trained and applicable documentations are maintained. The DCRI will implement quality control procedures beginning with the data entry system and generate data quality control checks that will be run on the database.

13 ETHICS/PROTECTION OF HUMAN PARTICIPANTS

13.1 Informed Consent Process

Informed consent procedures, as applicable per Section 13.2, are initiated prior to an individual agreeing to participate in the study and continuing throughout the individual's study participation. The ABC Science Collaborative is providing this professional development workshop as a service that participating schools offer to all teachers and staff. Those that want to participate in pre- and post-intervention assessments will be consented prior to doing so. Participation in the intervention and assessment completion is optional. Risks and possible benefits of participation in this study will be provided to the participants, as appropriate, prior to consenting via REDCap. The study team will distribute the public REDCap eConsent link to school administrator(s) who will then distribute the link to the participating teachers and staff. Administrators, school teachers, and staff will not have access to data submitted via REDCap, nor will they know who completed the surveys.

Consent forms with detailed descriptions of the study procedures, risks, and potential benefits will be approved by the IRB. Consent forms will be provided to the participant electronically to read and note any questions. The consent must be completed prior to performing any study-specific procedures, unless documentation of written consent is waived by the local IRB.

Participants will at least be given overnight to consider whether or not they would like to participate. The consent and the opportunity to complete the pre-intervention CARE assessment will be provided up to one month prior to the intervention.

DCRI will not take part in the consent process, as the consent will be integrated into REDCap. The informed consent forms indicate that participation is completely optional, participants may withdraw at any time, and participants are not obligated to state the reason for withdrawal. If information emerges about new potential risks related to participating in this study or if procedures are modified, the consent forms will be updated to reflect those potential risks, and the participants currently active in the study will be re-consented with the updated consents. If the consent forms are changed for any other reason and the local IRB requires re-consenting of active participants, participants will be asked to review and complete the new consent forms electronically.

A copy of the executed informed consent documents will be provided to participants for their records.

13.2 Documentation of Permission, and Consent

Permission, and consent must be documented using forms and processes determined by the Duke University Health System (DUHS) IRB and the IRB of record, if different.

Prior to enrollment of participants into this study, the protocol, the applicable informed consent template, and any materials or advertisements presented to participants will be reviewed and approved by the DUHS IRB.

Should amendments to the protocol and consent documents be required, the amendments will be written by the sponsor and approved by the DUHS IRB.

Recruitment efforts approved by the IRB prior to participants consenting may be used; however, before any protocol-specific procedures are performed, informed consent or waiver of informed consent must be obtained. The informed consent process will be conducted and the form fully executed before participants undergo any study-specific procedures.

13.3 Confidentiality and Privacy

Participant confidentiality and privacy is strictly held in trust by the participating investigators, their staff, and the sponsor(s) and their agents. Therefore, the study protocol, documentation, data, and all other information generated will be held in strict confidence. No information concerning the study or the data will be released to any unauthorized third party without prior written approval of the sponsor.

Data entered into REDCap will contain personal identifiers, including names, email addresses, and physical addresses. Participant names will be collected for the purpose of consent and payment. Participant email addresses, and physical addresses will be collected for the purpose of payment. Participants' names and email addresses will be shared with Amazon, Inc so they can send participants the $25 electronic gift card. Participants will be informed that they may choose not to share their physical address, and email address and still complete the questionnaires. If they choose not to share their physical address, and email address, they can still participate, but they cannot be paid for completing each of the questionnaires. Payment

information is restricted to a few DCRI team members, and access to this information is restricted by the assigned REDCap role. This study is direct to participant, and no sites will have access to data.

REDCap will assign a unique ID to each participant rather than using a name. Participants will also be asked to select the name of the school where they work and identify whether they are administrative staff, non-administrative staff, or a teacher from a dropdown menu within REDCap. We will not share data categorized by role with school districts. We will only share aggregate data grouped by schools with school districts if there are more than 10 participants. If there are fewer than 10 participants at a school, we will group schools together to provide a summary report. If the number of workshop participants for the administrative or non-administrative staff group is less than 10, then these participants will be grouped together and identified as “staff.”

REDCap will be used to distribute consents, and the pre- and post-assessments using a public link sent to the school administrator(s) who will then distribute it to the participating teachers and staff. The school administrator will not know who did or did not complete the assessments.

The principal investigator will ensure that the use and disclosure of protected health information obtained during a research study complies with the Health Insurance Portability and Accountability Act (HIPAA) Privacy Rule. The rule provides U.S. federal protection for the privacy of protected health information by implementing standards to protect and guard against the misuse of individually identifiable health information of participants participating in clinical trials. Authorization is required from each research participant (i.e., specific permission granted by an individual to a covered entity for the use or disclosure of an individual’s protected health information). A valid authorization must meet the implementation specifications under the HIPAA Privacy Rule. Authorization may be combined in the informed consent document (if approved by the IRB).

The study participant’s contact information will be securely stored for use during the study. At the end of the study, all records will continue to be kept in a secure location for as long a period as dictated by the reviewing IRB, Institutional policies, or sponsor requirements.

Study participant research data, which is for purposes of statistical analysis and scientific reporting, will be transmitted to and stored at the DCRI. Individual participants and their research data will be identified by a unique study identification number. All study data systems used by the DCRI research staff will be secured and password protected.

To further protect the privacy of study participants, this study is covered by a Certificate of Confidentiality (CoC) from the National Institutes of Health. The CoC limits the ability of courts and other agencies from forcing the study team to share participant information or body fluids during a legal or legislative action without the participant’s permission.

14 DATA HANDLING AND RECORD KEEPING

The investigator is obligated to conduct this study in accordance with U.S. Federal Regulation 21 CFR 312.60-68 as specified by applicable state and federal laws, and the International Council for Harmonisation: Good Clinical Practice: Consolidation Guideline.

14.1 Data Handling

Data will be captured using REDCap. All data collected in the context of this study will be stored and evaluated per applicable regulatory requirements and guidance for electronic records.

Data will be stored and evaluated in a manner that protects participant confidentiality in accordance with the legal stipulations applying to confidentiality of data.

14.2 Data Management Responsibilities

The DCRI will be responsible for data management, quality review, analysis, and reporting of the study data.

14.3 Data Capture Methods

Teachers and school staff data will be entered directly into REDCap.

14.4 Types of Data

Data for this study will include demographics and information reflecting the mental health and well-being (self-efficacy, burnout, anxiety, depression, perceived stress) and effectiveness of teachers and staff at the individual level. Participants' personal identifiers will be collected, including names, email addresses, and physical addresses. Participant names will be collected for the purpose of consent and payment. Participant email addresses, and physical addresses will be collected for the purpose of payment.

14.5 Study Records Retention

All records will be retained for at least 5 years after study completion, per Duke Policy.

14.6 Protocol Deviations

A protocol deviation is any noncompliance/unplanned excursion from approved investigational plan (e.g., protocol, MOP), or ICH GCP guidelines. The noncompliance may be on the part of the participant, investigator, or study staff. No protocol deviations will be reported for this study, but indirectly tracked via missing data in the database.

14.7 Data Sharing

Individual-level data, including demographics and responses to the CARE assessments, may be shared with participating NC school districts and collaborators of the ABC Science Collaborative, but will only be shared as aggregate, summary-level data. No raw, individual-level data will be shared. Data may also be shared via publications or presentations.

15 PUBLICATION POLICY

The ABC study will adhere to authorship standards described in the International Committee of Medical Journal Editors' Recommendations for the Conduct, Reporting, Editing, and Publication of Scholarly Work in Medical Journals. Authorship credit should be based on:

- Substantial contributions to conception and design, acquisition of data, or analysis and interpretation of data
- Drafting the article or revising it critically for important intellectual content
- Final approval of the version to be published
- Agreement to be accountable for all aspects of the work in ensuring that questions related to the accuracy or integrity of any part of the work are appropriately investigated and resolved

Additional authorship requirements imposed by individual journals will also be met. Authorship credit will be assigned in an equitable fashion and will be commensurate with participation and effort on the individual manuscript. Committee members will appear as authors on manuscripts based solely on actual contributions to the writing of the manuscript.

All investigators funded by the NIH must submit or have submitted for them to the National Library of Medicine's PubMed Central an electronic version of their final, peer-reviewed manuscripts upon acceptance for publication, to be made publicly available no later than 12 months after the official date of publication. The NIH Public Access Policy ensures the public has access to the published results of NIH-funded research. It requires investigators to submit final peer-reviewed journal manuscripts that arise from NIH funds to the digital archive PubMed Central upon acceptance for publication. Further, the policy stipulates that these papers must be accessible to the public on PubMed Central no later than 12 months after publication.

Refer to:

http://publicaccess.nih.gov/

http://grants.nih.gov/grants/guide/notice-files/NOT-OD-08-033.html

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