A Trauma-Informed Approach for Positive Youth Development for Montana Students

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Clinical Trial #: NCT04234425

Study Protocol

Initial efforts for relationship building with a school system have already begun; the PI recently concluded a pilot yoga study in March of 2019 at Park High School, and school and district leadership have expressed a keen interest in continuing this type of intervention for students. For example, in the coming academic year, the school would like to implement this proposed research study, focusing on increasing the number of student participants while gathering additional data for continuous program improvement. Todd Wester, district administrator with Park County schools, has also expressed a desire in continuing this research and eventually expanding it to other schools in the district in collaboration with the PI.

In the September 2019, the PI will facilitate a focus group discussion of both male and female high school students at Park High School to gauge student interest in the project and determine best approaches to promote recruitment and retention in the project (particularly with male students). These focus groups will be facilitated through the "Principal Advisory" lunchtime program with the high school principal and PI. Following the focus group discussions, high school participant recruitment will begin with school administrator recommendation for inclusion in the project, and those students will be offered slots in the program first; to allow for maximum recruitment and retention, the intervention will take begin in late Fall 2019 between athletic seasons/events. 30-minute sessions will take place twice weekly during the physical education class during the 8-week intervention period. After students have been given an option for inclusion, the program will accept any additional voluntary participation by students within the school, and program recruitment will conclude by the end of 2019. Participation will be voluntary and will be indicated by student signature of the assent form; parent consent will also be required for student participation in this 8-week study. The 30 students to be enrolled in the program will provide written informed consent regarding the scope and details of the study and procedures for participating in the study. The consent form and assent form will include information about participants' rights to end participation at any time during the study.

Incentives for teacher completion of surveys include classroom supply money for teacher completion of surveys (funneled through school administration).

It is possible that the intervention may bring up strong emotions for the participants; so too might the administration of the ACE survey which will be part of the preliminary data collection (more below). To mitigate this potential, the PI will caution students that this may occur and emphasize the importance of self-care and knowing one's own limits with the intervention. Immediate referrals regarding suicidality, self-harm, depressive thoughts, etc. will be directed to the school nurse. If needed, referrals for additional, outside treatment will be provided as determined by school officials and/or requested by the participant and/or the participant's legal guardian(s). It will also be explained to participants that this study is not designed to be a clinical/psychological intervention but rather an academic intervention, so students that need additional mental health supports will be referred to appropriate outside agencies.

Additional resources for outside assistance will be shared with participants and participant parents/guardians on the assent/consent forms, listing the following avenues for additional help:

- Talking with someone who you can trust
- Calling 911, your doctor or other healthcare provider
- Going to an Emergency Room
- Calling 1-800-273-TALK (8255) to talk with a crisis worker for free
- Texting 741741 to text with a counselor for free

Visiting NowMattersNow.org to learn skills for dealing with thoughts of suicide

Methods

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Aim 1: Foster a partnership with a rural southwestern Montana school and test the feasibility of implementing a trauma-informed yoga intervention.

For this pilot study, feedback will be gathered from the school district, teachers, and students from the focus group via conversations and/or email communications to determine the level of burden from the various assessment instruments and participation in the pilot; plans and identified needs for this study are ongoing with the school district and the PI. Retention and satisfaction of participants, as measured by survey instrumentation) from year one will indicate the feasibility of an ongoing partnership with the school district, determine possible expansion to the middle school in year two, and will assess both students' and teachers' perception of value of the intervention. Because this is a feasibility study, no control group will be utilized, and the focus of the project will be to examine pre and post survey results and cortisol levels.

Aim 2: Collect preliminary data for the intervention (surveys, interviews and cortisol levels) to assess effectiveness of the intervention to improve youth mental and physical health (e.g., behavioral, social, emotional, and physical functioning).

Sources of Materials. Assessment measures will include the: 1) Adapted ACE Self-Reporting Screener (which will only be given pre-intervention to determine ACE scores of participants) 2) "Toolkit" of validated survey measures to assess academic, social, and emotional functioning of adolescents across multiple domains; 3) Teacher Perceptions of Student Wellness Pre- and Post-Surveys, 4) Cortisol levels before, during, and after the intervention period, 5) Collection of reflective journals from the group participants, and 6) Collection of secondary behavioral and academic data (grade averages in reading and math, attendance, and office referrals).

The "toolkit" of validated student pre and post surveys includes the following measures:

To assess academic functioning:

- Engagement (Simons-Morton & Crump, 2002)

- Class Absences and School Misbehavior (adapted from Kessler, 2001)

To assess emotional and social functioning:

- Depressive Symptoms (SMFQ) (Adrian Angold & Elizabeth J. Costerllo, 1987)
- Generalized Anxiety Disorder 7-item (GAD-7) scale (Spitzer et al., 2006)
- Loneliness (Hughes et al., 2004)
- Difficulties in Emotion Regulation Scale (Neumann et al., 2010)

Teacher Perceptions of Student Wellness Surveys (rated on a Likert Scale of 1-5) include questions before and after program implementation relating to academic, emotional, and social functioning as well. Examples of survey questions include items assessing individual students, such as whether they are "in control of their behavior (e.g., less reactive)," "can concentrate on work," and "can deal appropriately with stress and anxiety (e.g., during test-taking or similar events)." Teachers will be given an incentive of $25 in classroom supply money (funneled through school administration) for the completion of each pre and post survey for each of the student participants.

To protect student privacy, the ACE screening instrument will only quantify how many adverse events the child has experienced, **not** which ones; quantifying ACE scores will help the researcher triangulate the data to determine program efficacy for students with high, moderate, and low ACE scores. School and district administration will have access to anonymous ACE scores for the purpose of collecting demographic information on the participant population. The remainder of the anonymous data collected will be analyzed and reviewed by the community advisory board; decisions regarding program improvement, future implementation, and modifications will be made by the advisory board as well.

For all participants, the primary behavioral health assessments will utilize descriptive statistics and paired t tests with regards to the validated "toolkit" survey of students to address academic, social, and emotional functioning of adolescents (including measures such as the Generalized Anxiety Disorder Scale and Patient Health Questionnaire for Depressive Symptomology) and a Teacher Perception of Student Wellness Survey to assess changes pre-and post-intervention. Descriptive statistics will be utilized with health outcomes to compare pre-and post-intervention cortisol levels. Any secondary academic outcomes will also be analyzed descriptively pre-and post-intervention, as improvement in academic performance may serve as a proxy for improved well-being (attendance records pre-, during, and post-intervention (absences and times arriving late to school), office referral data prior to, during, and post-intervention, and grade average data based on numerical averages in students' reading and math courses pre- and post-intervention). Baseline data regarding participants' exposure to childhood trauma as measured by the ACE Self-Reporting Screener will be gathered to determine any relationships between individual ACE scores and outcomes from intervention.

To allow all who are interested to participate in the study, the focus of this project will primarily be to determine feasibility of the intervention; therefore, no control group will be utilized, and the focus of the feasibility trial will be to examine pre and post survey results and cortisol levels. Volunteers will participate in the intervention for 8 weeks. During the intervention phase, the participation goal for each student will be to attend 75% or more of the intervention sessions (attendance will be recorded by the yoga instructor).

After students volunteer for program participation, to establish a baseline for participants, students will be given the ACE screening instrument/ toolkit of pre-surveys and then begin the 8-week intervention. Students will be administered cortisol testing at the beginning of weeks 1 and 4 and the conclusion of week 8 during the intervention, each time prior to the yoga session, and they will complete the post surveys at the conclusion of week 8. At each of the three testing periods, students will provide a saliva sample to the school nurse or PI, to be deidentified (using a code key system) before analysis by the CAIRHE Translational Biomarkers Core Lab at MSU. Testing will use the Abcam (ab154996) cortisol in vitro competitive ELISA (Enzyme-Linked Immunosorbent Assay) kit designed for the accurate quantitative measurement of cortisol in saliva (sensitivity 0.12 ng/ml). Deidentified cortisol data will be returned to the PI for re-identification using the code key. Comparisons using paired t tests between pre and post-surveys will be utilized to determine program efficacy, and any changes in cortisol levels throughout the duration of the program will be analyzed to assess any trends and whether this is a useful measure for the next study phase.

Aim 3: Use the preliminary data to modify (as needed) year two of the study for expansion to middle level students and/or increasing the number of high school participants.

This study will utilize descriptive statistics for pre- and post-interventions and analysis of cortisol levels throughout the program to determine the efficacy the intervention.

Statistical Analysis Plan

Quantitative analyses between pre-intervention (T1) and post-intervention (T2) scores will be utilized for participants who completed the measures at both time points using a paired samples t-test or a Wilcoxon signed rank test with continuity correction for non-normal distributions.

Next, analyses of covariance (ANCOVA) following treatment completion will be used to evaluate whether there are significant post-treatment differences in student-reported symptoms between children with low (0-1), moderate (2-3), and high (4+) ACE scores, with pre-intervention student-reported symptoms and attendance rate as the covariate. The outcome measures to be used in these analyses are the GAD-7, PHQ-A, SDQ, and the SDQ subscales. ANCOVA is the clearest and most straightforward analysis to address each of the analytic goals.

Salivary cortisol samples will be deidentified (using a code key system) before analysis by the CAIRHE Translational Biomarkers Core Lab at Montana State University. Testing utilized the Abcam (ab154996) cortisol in vitro competitive ELISA (Enzyme-Linked Immunosorbent Assay) kit designed for the accurate quantitative measurement of cortisol in saliva (sensitivity 0.12 ng/ml). Comparisons using paired t tests between pre and post-surveys will be utilized to determine program efficacy, and any changes in cortisol levels pre and mid-intervention were analyzed to assess any trends and aided in the decision-making process for whether to continue using this measure for the next study phase.