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

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Study Protocol

The second year of "A Trauma-Informed Approach for Positive Youth Development for Montana Students" will continue in the same format as winter 2020, but with 35 participants in an experimental group, along with 20 students in a control group within the same school and enrolled in classes by the same physical education teacher. District leaders wish to hold the study during the Jan-March 2021 window, as this timeframe has shown a historical spike in inappropriate student behaviors and absenteeism. Twice weekly 45-minute sessions during the 8-week intervention period will occur within two physical education classes in order to draw enough participants to gauge statistical significance with resulting data; a third physical education class with the same teacher will serve as the control group for the study, therefore creating 3 gym class clusters, which will allow for computer-generated randomization. Instead of individuals being randomly assigned, gym class clusters of individuals will by randomly allocated to intervention groups. Control group participants will also be offered 8 weeks of yoga after the study concludes.

Student incentives for at least a 75% attendance record in the experimental group include receiving a Fitbit Inspire HR for the study to track their physical health data and students will retain these to encourage healthy exercise and sleep patterns following the study. Teacher incentives for completion of surveys include classroom supply money (funneled through school administration). Gift cards will be provided to parents/guardians who complete the surveys about their child; these will be disseminated by school officials for parents to pick up at the high school, or they may be mailed by the PI on request. Control group participants will also each receive Fitbit Inspire HR upon completion of all pre- and post-survey measures as an incentive.

Data will be collected in a way to best protect student privacy and confidentiality; all surveys will request that participants self-identify through a confidential code provided by the PI, and all reflective journals will be labeled with this code as well. Cortisol tubes will also be labeled with this unique code. The PI will maintain the code key in an encrypted computer file, which can only be unlocked with an access code that is known only by the PI; this computer will be kept in a locked office at all times, and all data will be securely destroyed (either by computer deletion or secure shredding) no later than one year after the conclusion of the study.

The intervention might bring up strong emotions for the participants; so too might the administration of the ACE survey during preliminary data collection. 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. 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). Additional resources for outside assistance will be shared with participants; these resources, along with processes for reporting and responding to adverse outcomes, can be found in the study's Human Subjects form and on student assent and parent consent forms.

Participants in this feasibility study may have reductions in severity of depression and/or anxiety as well as improvements in overall behavioral health and well-being. 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). Benefits also include vital data to inform other potential interventions.

Aim 1: Pilot test a trauma-informed yoga intervention for 15-18 year-old male and female high school students.

To prepare for pilot study year 2, feedback has been gathered from the school district, teachers, and students via focus groups and email communications to assess the burden from the various assessment instruments and participation in the pilot. Assessment measures listed below comport with this feedback. Retention and satisfaction of participants, as measured by survey instrumentation from year 1 has indicated the need for an ongoing partnership with the school district and an expansion to additional high school physical education classes (8-week intervention, n=35). During year 2, the study will compare results between the experimental group and a new 20-participant control group, which will be located within the same school setting. The intervention's effectiveness for youth mental and physical health will be assessed with: surveys measuring depressive and anxiety symptomology; and a wearable fitness tracker (added in year 2) with cortisol testing to measure physiological changes (e.g., resting heart rate and sleep cycle patterns).

Aim 2: We will implement a limited feasibility study of partial online yoga delivery via Zoom within the context of the pilot study's physical education classes to explore scalability to rural communities without access to yoga instructors as well as provide a contingency for COVID-19 school closures.

One session will be held during the PE class period with the yoga instructor teaching remotely to the entire class; another will be held outside of the regular school day with participants attending synchronously from home at a time to be determined by surveying participants' preferences and availability; both sessions will have a 75% participation rate goal. Qualitative feedback will be gathered from both the yoga instructor and participants on their remote experiences. Remote delivery will also be provided for the control group following the conclusion of the study.

Aim 3: Evaluate the study's school-community-academic partnership at the conclusion of the program using a mixed methods survey. The results will be compared using paired *t* tests with data from the same survey, collected at the end of year 1. The CAB will meet monthly to determine program adjustments. Survey administration and data analysis will occur in summer 2021. The PI will share results with the CAB to determine areas for program refinement and assess need for study continuation with a year 3 expansion.

Sources of Materials. Assessment measures will include the following:

Description of Measure	Source (if applicable)	Timeline for Dissemination	Cronbach's Alpha/Validity & Reliability
Center for Youth Wellness ACE-Q Self-Reporting Screener for Teens	Burke-Harris & Renschler, 2015	Pre-intervention (in order to determine ACE scores of participants)	Longitudinal testing currently underway to measure content and construct validity/reliability
Generalized Anxiety Disorder Scale (GAD-7)	Spitzer et al., 2006	Pre- and post-intervention	Cronbach's alpha: .79-.91 Reliability = .85

			Validity = 73.3%
Patient Health Questionnaire for Depressive Symptomology for Adolescents (PHQ-A)	Johnson, 2002	Pre- and post-intervention	Chronbach's alpha = .835 Reliability = .875 Validity = 89.5%
Strengths and Difficulties Questionnaire for ages 11-17 (SDQ Self-Report 11-17), Teachers and Parents Report (SDQ-Teacher/Parent Report 11-17)	Goodman, 2005	Pre- and post-intervention	Chronbach's alpha = .86 Reliability and validity vary according to respondent type and age of child self-reporting
Cortisol salivary assays	Salimetrics Laboratories	Pre (beginning of week 1)-, mid- (week 4) and post-intervention (end of week 8)	Mean accuracy of salivary cortisol testing > 90%
Resting heart rate and sleep cycle data (collected from the wearable fitness tracker, Fitbit Inspire HR)	Fitabase Cloud-Based Data Management System	Pre- (1 week prior to intervention to establish a baseline), mid- (week 4) and post-intervention (at conclusion of week 8) (collected through cloud-based data management system, Fitabase)	Heart rate measure = mean margin of error 5.96% and mean agreement of 91% with ECG data Sleep: Cohen's kappa 0.52-0.53 +/- 0.14; per-epoch accuracy of 69%
Collection of secondary data, including attendance and academic data (MAPS benchmark/progress monitoring standardized assessment scores, attendance, and office referrals)	N/A	Office referrals/behavioral data: Collected 8 weeks prior to study and during 8 weeks of intervention for comparison Attendance data: Collected 8 weeks prior to study and during 8 weeks of intervention for comparison MAPS: Pre- and post-intervention	MAPS Data: Pearson correlation coefficients range from .76-.82 in reading and .82-.86 in mathematics Other measures: N/A

Statistical Analysis Plan

Gym class clusters of individuals will by randomly allocated to intervention groups. This approach is necessary because randomization at the individual level is impractical and we strive to avoid contamination between treatment groups. The responses from individuals within a cluster are likely to be more similar than those from different clusters because individuals within a will share a common yoga class experience. This lack of independence introduces complexity to the design and analysis. The degree of similarity, or clustering, will be quantified and reported using the intracluster correlation coefficient (ICC). When the ICC is low, individual observations contribute nearly equally to the analysis. (38). For all participants, baseline surveys (see table above) will be conducted prior to exposure to Yoga (T0). Follow-up surveys will be collected at 8 weeks (T1). Analyses will be conducted using R Version 3.6. Baseline differences between intervention and control group will be examined using independent *t* test or χ^2 test. All data will be analyzed according to treatment assignment. Two strategies will estimate treatment effects: 1) Cluster level analysis using summary measures; and 2) Individual level analysis adjusted for clustering to appropriately account for the nested structure of data and cluster randomization in

estimating. For the first, we will measure mean outcomes by cluster followed by parametric t-tests or non-parametric tests, depending on the distributions of the outcome measures. To account for the variability between gym classes and nested structure of the data, multilevel mixed-effects models will be used for each continuous outcome, with time (T0 & T1) as level 1, students as level 2, and class as level 3. To adjust for baseline pre-treatment values, explanatory variables for each outcome will include grade, gender, prior exposure to yoga at the high school, and survey time point (model 1). To assess the intervention's effect on outcomes, we will use condition (intervention or control) and the interaction between condition and time as predictors (model 2). Effect sizes (ESs) will be calculated as (estimated intervention effect)/√(variance at student level). Interpretation of ES will determine the gains of the intervention versus control group. To calculate power for this cluster randomized trials that compares two means, we used the "clusterPower" package in R (24). Accounting for clustered design effects, 55 participants with variation in cluster sizes, an assumed low intraclass correlation of 0.001, and within-cluster variation of 5 units, this would provide at least 65% power to detect clinically meaningful effects between the treatment and control arm using two-sided tests at alpha=0.05[1]. To maximize test power and precision of estimation considering the few clusters in this study, we will also use wild cluster bootstrap-t procedure it to correct our standard errors (9, 47).

A proxy for improved well-being, secondary academic performance outcomes, will also be analyzed descriptively pre- (during week 1) and post-intervention (at the end of week 8) (see table above).

Physical Health Measures.

Participants enrolled will have their resting heart rate and restorative sleep data tracked and assessed using their Fitbit Inspire HR wristbands. They will be instructed to begin wearing their Fitbit for 1 week prior to starting the intervention to establish baseline data for sleep cycles and resting heart rates; this will also allow the PI to monitor daily data collection to ensure all devices are recording properly and address malfunctions and/or user error prior to the intervention. Once the intervention has begun, the PI will asynchronously and wirelessly connect to their Fitbit data using the Fitabase cloud-based data management platform once weekly to track any changes in duration and quality of restorative sleep and changes in resting heart rate.

Salivary Cortisol Assays.

Students in both the experimental and control groups will be administered cortisol testing at the beginning of weeks 1 and 4 and the conclusion of week 8, each time prior to the yoga session (or at the beginning of their physical education class, if in the control group). Specifically, 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 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 will assess trends and determine usefulness of this measure.

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[1] If we increase **α** to 0.1, we can reduce the probability of a **Type** II **error** and increase our power to 0.86 but we are also more likely to commit a **Type I error** (rejecting a true null hypothesis).

Using deidentified participant codes (with the PI retaining access to the code key system), data will be triangulated through observational data, qualitative remarks in participant journals, pre- and post-survey data, heart rate and sleep cycle data, cortisol analyses, and secondary academic and behavioral data.

Control Group.

Volunteers will participate in a separate physical education class for 8 weeks and will undergo testing as described above, with an opportunity to participate in yoga after T1.