A Trauma-Informed Intervention for Positive Youth Development and Teacher Wellness in Rural Montana

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Clinical Trial # NCT05085392

Statistical Design and Power

Study design

This study is a non-randomized, Phase I clinical trial. Participants will be high school students and teachers in southwest Montana. In the first year, 30 teachers from the same school district will be recruited to participate in a virtually -delivered trauma-informed yoga intervention (heart rate variability data will be gathered from a group of high school students to assess utility for the measure in year 2). In the second year, we will expand the intervention to high school students in Livingston city and rural Park County schools, recruiting 30 students in each area to participate in a synchronous, virtually-delivered, trauma-informed yoga intervention during their health enhancement classes. In addition, 30 teachers from the rural Park County schools will be recruited to participate in the same virtually-delivered, trauma-informed yoga intervention offered to Livingston teachers concurrently.

In each year, participant assessments (surveys, salivary cortisol, and heart rate variability(HRV)) will be administered prior to intervention and immediately after the intervention at 6 weeks. Follow-up assessments will be conducted in the fall semester following each intervention to measure persistence of the treatment. Thus, Livingston teachers may have up to six time points of data collection, while Park County students and teachers and Livingston students will have up to three. In addition, salivary cortisol and HRV will be collected at the midpoint of the intervention (3 weeks) each year. Measures collected are detailed in Table 1.

Table 1. Measures recorded for students and teachers, with collection timeline and validity measures.

Description of Measure	Source (if applicable)	Timeline for Collection	Cronbach's Alpha/Validity & Reliability
Center for Youth Wellness ACE-Q Self-Reporting Screener for Teens (Adolescents Only)	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) (Adolescents and Teachers)	Spitzer et al., 2006	Pre- and post-intervention	Cronbach's alpha: .79-.91 Reliability = .85 Validity = 73.3%
Patient Health Questionnaire for Depressive Symptomology (PHQ-A for adolescents, PHQ-9 for Teachers)	Johnson, 2002	Pre- and post-intervention	Chronbach's alpha = .835 Reliability = .875 Validity = 89.5%
Connor-Davidson Resilience Scale (CD-RISC) (Adolescents and Teachers)	Connor & Davidson, 2003	Pre- and post-intervention	Chronbach's alpha = .94 Reliability = .96
Columbia Suicidality Screener (C-SSRS) (Adolescents Only)	Greist et al., 2014	Pre- and post-intervention	Cronbach's alpha: .81-.95 Reliability = .97 Validity = 99%
Professional Quality of Life Index (Pro-QOL)	Hudnall Stamm, 2009	Pre- and post-intervention	Cronbach's alpha: .90 Reliability = .80-.90

(Teachers Only)			
Teachers' Sense of Self-Efficacy (Short Form) (Teachers Only)	Tschannen-Moran & Woolfolk-Hoy, 2001	Pre- and post-intervention	Cronbach's alpha: .90 Reliability = .74
Cortisol salivary assays (Adolescents and Teachers)	Salimetrics Laboratories	Pre (beginning of week 1)-, mid- (week 3) and post-intervention (end of week 6)	Mean accuracy of salivary cortisol testing > 90%
Heart rate variability data (Adolescents and Teachers)	HeartMath Institute	Pre- (1 week prior to intervention to establish a baseline), mid- (week 3) and post-intervention (at conclusion of week 6)	Pearson correlation between electrocardiogram (ECG) and ear clip pulse plethysmograph (PPG) device (Em Wave Pro Plus) mean resting baseline = .997*, p <0.01; RMSSD Pearson correlation = .958*, p < 0.01
Collection of secondary data, including attendance and academic data (MAPS benchmark/progress monitoring standardized assessment scores, attendance, and office referrals) (Adolescents Only)	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

Power considerations

This is an early-phase trial, the results of which will be used to inform full power analyses for future clinical trials. We do not expect to be powered to detect small intervention effects. However, as a preliminary assessment of power, we consider the power of a paired t-test comparing pre- and post- intervention scores on the various response measures, including survey scales, cortisol, and HRV. We compute power in terms of Cohen's d, a standardized effect size measure that describes the impact of the intervention in terms of the number of standard deviations that the effect is equivalent to (so an effect of 5 points on a scale with SD 20 would have a Cohen's d of 0.25). On this scale, an effect size of 0.2 is typically considered "small", 0.5 "moderate", and 0.75 "large". This may not align with clinically meaningful differences in outcome measures, however.

For comparisons within intervention groups in their first (and sometimes only) year of intervention, we expect to have 30 participants in each group (Livingston students, Livingston teachers, rural students, rural teachers). Assuming a Type I error rate of $\alpha = 0.05$, we achieve 80% power to detect a Cohen's d of 0.53, and 90% power to detect a Cohen's d of 0.61. Thus, the study is adequately powered to detect moderate-to-large effects of the intervention. The study design will allow us to estimate the magnitude of effects, intra-class correlations by school and classroom, and the variability of intervention impacts—all the inputs needed to perform a formal power analysis for a future Phase III trial. Full power curves for n = 30 and n = 15 participants are given in Figure 1.

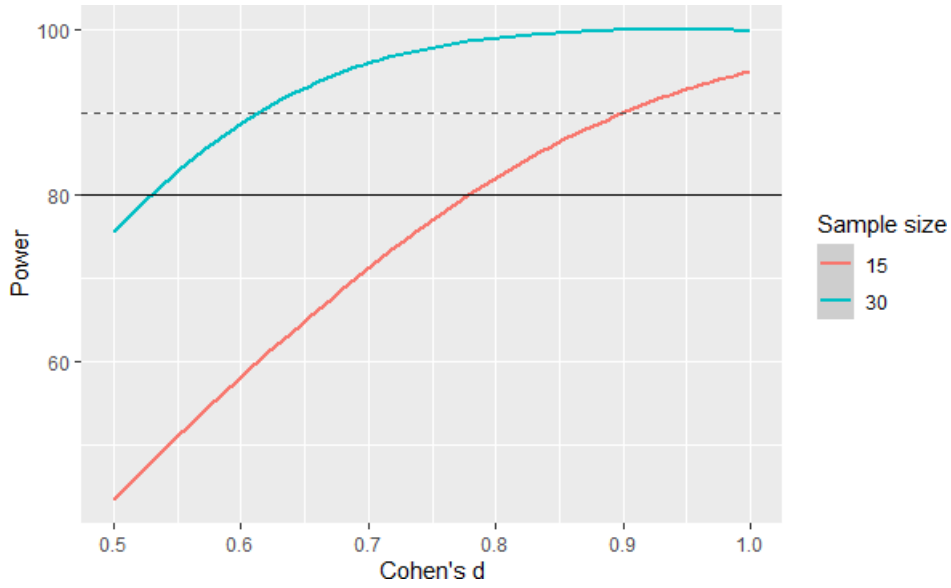

Figure 1. Power curves for sample sizes of 15 and 30. Solid black line indicates 80% power and dashed line indicates 90% power.

Statistical Analysis Plan

For each outcome, we will compute the change in the scale score or biomarker value from baseline to post-intervention (post – pre) and compute unadjusted averages and standard deviations. These computations will be done within participant group (Livingston students, Livingston teachers, rural students, rural teachers).

We will also obtain adjusted estimates using mixed effects linear regression models of post-test score on pre-test score with demographic factors and random effects for school and intervention group nested within school (Laird & Ware 1982). This will allow us to estimate intra-class correlations for intervention group and school, which will be required for sample size estimation in a full efficacy trial.

We propose the following model for the individual response (anxiety, depressive symptoms, etc.), denoted Y_{ijk}, where $i = 1, \ldots, I$ indexes school, $j = 1, \ldots, J$ indexes intervention group (only needed if there are multiple health education classes receiving the intervention in a school), and $k = 1, \ldots, N$ indexes participants within groups.

$$Y_{ijk} = Z_{ijk}\,\theta + X_{ijk}\delta + \alpha_i + \beta_{j(i)} + \varepsilon_{ijk}$$

$$\alpha_i \sim N(0, \tau^2)$$

$$\beta_{j(i)} \sim N(0, \omega^2)$$

$$\varepsilon_{ijk} \sim N(0, \sigma^2)$$

Thus, α_i represents a random effect for school i, with variance τ^2 $\beta_{,j}$ represents a random effect corresponding to group j in school i, with variance ω^2. We model this as a function of Z_{ijk}, the pre-intervention score for participant k in group j in school i, and X_{ijk}, the set of other modeled covariates, centered at their means. This means that the intercept parameter θ gives the expected effect of the program for a student or teacher with "average" demographics and other covariate values after controlling for within-school and within-group correlation. We can use the estimates of the random-effects variances and the residual variance to produce estimates of the intra-class correlations for school and for intervention group.

This is a Linear Mixed Effects (LME) model. As all primary and secondary response variables are continuous and may reasonably be expected to be normally distributed we can implement the model using restricted maximum likelihood (Laird & Ware 1982) using the `lme4` package in **R** (Bates et. al., 2015).

Biomarker analyses. Salivary cortisol and HRV will also be collected mid-intervention. To fully characterize temporal patterns in these outcomes, we will use a different LME model that captures the full trajectory over time. In this case, we propose the following model for the individual response, denoted Y_{ijkt}, where $i = 1,\ldots, I$ indexes school, $j = 1,\ldots, J$ indexes intervention group (only needed if there are multiple health education classes receiving the intervention in a school), $k = 1,\ldots, N$ indexes participants within groups, and $t = 1,\ldots 3$ indexes the time point of the observation.

$$Y_{ijkt} = \theta T_{ijkt} + X_{ijk}\,\delta + \alpha_i + \beta_{j(i)} + \gamma_{k(ij)} + \varepsilon_{ijkt}$$

$$\alpha_i \sim N(0, \tau^2)$$

$$\beta_{j(i)} \sim N(0, \omega^2)$$

$$\gamma_{k(ij)} \sim N(0, \vartheta^2)$$

$$\varepsilon_{ijk} \sim N(0, \sigma^2)$$

Thus, α_i represents a random effect for school i, with variance τ^2, $\beta_{j(i)}$ represents a random effect corresponding to group j in school i, with variance ω^2, and $\gamma_{k(ij)}$ represents a random effect corresponding to student k in group j and school i, with variance ϑ^2. We model this as a function of T_{ijkt}, the time of the t^{th} cortisol or HRV measure for participant k in group j in school i, and X_{ijk}, the set of other baseline covariates included in the model, centered at their means. We can also consider a random slope model with varying slopes for each student over time if model diagnostics suggest this more complex model will be a better fit to the data.

References:

1. Nan M. Laird and James H. Ware (1982) Random-effects models for longitudinal data. *Biometrics* 38:963-974
2. Douglas Bates, Martin Maechler, Ben Bolker, and Steve Walker (2015). Fitting Linear Mixed-Effects Models Using lme4. *Journal of Statistical Software*, 67(1), 1-48