Document Title: Statistical Analysis Plan

Study Title: Violence Intervention and Prevention (VIP) Corps to Reduce Maternal Injuries and Deaths Due to Violence

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Statistical Analysis Plan for the project "Creating VIP Corps to Reduce Maternal Deaths"

The goal of this randomized controlled trial is to compare violence intervention and prevention corps (VIP Corps) against the attention control training.

Study population

Undergraduate and professional students training for helping professions in which they may encounter pregnant and postpartum people.

Intervention group

VIP Corps Training

Control group

Attention Control Training

Randomization

Participants are randomized to either VIP Corps Training or Attention Control Training in a 1:1 ratio, stratified by College.

Primary Outcomes

1. Change in knowledge of intimate partner violence (IPV), substance use, anxiety and depression
2. Change in attitudes toward pregnant or postpartum people experiencing IPV, substance use, and/or anxiety and depression
3. Change in mortality and morbidity knowledge
4. Change in self-confidence to ask pregnant or postpartum people about IPV, substance use, and anxiety or depression

Description of the Primary Outcomes

Knowledge of intimate partner violence (IPV), substance use, and anxiety and depression is summarized by Big3 myth scale.

Attitudes toward pregnant or postpartum people experiencing intimate partner violence (IPV), substance use, and anxiety or depression. This measure is based on Domestic Violence Myth Acceptance and expanded to substance use and anxiety or depression. 45 items and 3 subscales. Response options: 1-5 indicating ranging from strongly agree to strongly disagree. Lower scores

indicate greater acceptance and increased willingness to address intimate partner violence (IPV), substance use, and anxiety or depression among pregnant or postpartum people.

Knowledge of pregnancy-associated causes of maternal mortality and morbidity is created for this randomized controlled trial (RCT). This is a 17-item scale ranging from 0-35 with higher scores indicating greater (accurate) knowledge.

Violence Against Women Health Care Provider Survey expanded to providers' willingness to ask clients about: a) Intimate partner violence (IPV), b) substance use, and c) anxiety or depression. 41 items querying self-confidence and actions in asking clients about risk factors for maternal morbidity. The response options 1-5 indicate strongly agree to strongly disagree. Higher scores are desired as indicators of greater self-confidence and likelihood of actions with clients.

Secondary outcomes

Change in engaged bystander actions to address IPV, substance use, and mental health issues among pregnant and postpartum people.

Description of Secondary outcomes

New Bystander Action Survey developed for this randomized controlled trial (RCT). There are 20 items that measure the opportunity to take action with clients, friends or family members; actions taken, and perceived impact. There are 6 response options ranging from 0 times to more than 12 times (in the past 6 months). More actions and a higher score are desired as indicators of greater actions to identify risk of maternal morbidity and provide resources to reduce this risk.

Analysis

Participant characteristics will be calculated and compared between the intervention and control groups (see the shell for Table 1 below). Categorical variables will be summarized by frequencies and percentage values, continuous variables will be summarized by sample means and standard deviations. If the sample means and standard deviations are not sufficient to summarize the distributions of continuous variables, sample quantiles will also be calculations (minimum, median, maximum, etc.). Study outcomes will be compared between the groups as shown in Table 2.

Fisher exact tests and Wilcoxon Mann-Whitney tests will be used for comparing the groups. If the groups are different in some characteristics, which may happen by chance, inverse probability weighting will be used to balance the groups, and the IPW analyses will be applied for all planned analytic methods.

Before and after intervention changes in the continuous primary and secondary outcomes will be compared between the intervention groups using the analysis of covariance approach, where changes will be compared between the groups controlling for the baseline (pre-intervention) value of an outcome.

Alternative methods: (1) if the analysis of covariance does not apply due to model assumptions violation, median regression with the two explanatory variables (intervention indicator and pre-intervention value) will be used instead. (2) Another alternative is to categorize our outcome into a binary variable.

Changes in proportions of binary outcome variables will be compared between the groups using generalized estimating equations (GEE) with logit link function. Alternatively, in the case of lack of convergence of the GEE model, we will limit the comparison to discordant pairs only and compare the proportions of improved outcomes between the intervention groups.

All the above primary and secondary analyses will be conducted on intention to treat basis. See the shell for Table 3 (Model 1). On secondary basis we will compare the primary and secondary outcomes by study arm within subgroups defined by training completion status. See the shell for Table 4 (Model 1).

Missing data will be excluded from the main comparisons. However, we will explore the possibility and the use of multiple imputations for the primary and secondary outcomes. If multiple imputations are used, the standard errors will be adjusted as described in Little and Rubin's "Statistical Analysis with missing data" (Wiley, 2002).

The ANCOVA for continuous outcomes and GEE-based for binary outcomes confirmatory analysis will be extended as needed to adjust for covariates: multiple regression models will extend ANCOVA model, median and GEE regressions will include additional covariates. Additional covariates will be added to the model in two separate sets as described in Tables 3 and 4.

Sensitivity analysis will employ the linear mixed model analyses and doubly robust models where the regression models proposed for the primary and secondary outcomes will be reweighted by the inverse probability of completing the training (among completers) and by the inverse probability of not completing the training (among the non-completers). Then, the doubly robust estimator of the VIP treatment effect will be calculated with its uncertainty quantified by bootstrap resampling.

Power calculations

The effect size of 0.243 standard deviations is detected with POWER=0.8 at ALPHA= 0.05 if 267 participants are enrolled in each group. For binary outcomes Cohen's h=0.171 will be detected. Cohen's h=0.171 corresponds to p1=0.20 and p2=0.273, or p1=0.30 and p2=0.382.

Table 1. Student characteristics by Study Arm

Variable	Randomization Assignment (N=534) Intervention (N=267)	Attention Control (N=267)	P
Participant Characteristics			
Age, years			
Unknown			
Gender Identity			
Cisgender Female			
Cisgender Male			
TGD			
Race			
Asian			
Black/AA			
White			
Other			
Unknown			
Ethnicity			
Hispanic/Latino			
Non-Hispanic			
Other			
Unknown			
Kentucky Resident			
Yes			
No			
Unknown			
Student in Health College			
Yes			
No			
Unknown			
Anticipated Graduation Year			
2023			
2024			
2025			
2026			
2027			
Unknown			
Interacts with Patients			
Professionally			
Yes			
No			
Unknown			
Month of Pre-Training Survey			
Jan-Apr			
May-Aug			
Sep-Dec			

Categorical variables are summarized by counts and percent values, continuous by sample means and standard deviations

Table 2. Construct Distribution Pre-Training by Group

		Control Group n =		Intervention Group n =		
Construct	**Item**	**n**	**Mean (SD)**	**n**	**Mean (SD)**	**p-value**
Attitudes about Inquiry	ASK1					
	ASK2					
	ASK3					
	AVERAGE					
Opinions about IPV, SU, and MH	ASK4					
	ASK5					
	ASK6					
	AVERAGE					
Self-Confidence to Address IPV, SU, and MH	SC1					
	SC2					
	SC3					
	SC4					
	SC5					
	SC6					
	AVERAGE					
Big 3 Myths	DVMAS3					
	DVMAS4					
	DVMAS5					
	DVMAS6					
	DVMAS8					
	DVMAS9					
	DVMAS10					
	DVMAS11					
	AVERAGE					
Feelings about Professional Role	DVMAS12					
	DVMAS13					
	DVMAS14					
	AVERAGE					
Preparedness to Inquire	DVMAS15					
	DVMAS16					
	DVMAS17					
	AVERAGE					

*Satterthwaite method used to calculate p-value because of unequal variances. All other t-tests assume equal variances.

AVERAGE is calculated such that if someone is missing or more, but less than half, of the components, their average value is the average of their available components of the construct. Individuals missing greater than or equal to 50% of the components have their value of the construct set to missing.

Table 3. Primary Analyses – Assessment of Intervention vs. Control Group on Change in **Average** of Construct Components from Pre- to Post-Training (If missing ≥1 component of construct, construct is calculated as average of available components)

	Model 1[a]			Model 2[b]			Model 3[c]		
Construct	**n**	**β [95% CI]**	**p-value**	**n**	**β [95% CI]**	**p-value**	**n**	**β [95% CI]**	**p-value**
Opinions about IPV, SU, and MH									
Attitudes about Inquiry									
Self-Confidence to Address IPV, SU, and MH									
Big 3 Myths									
Feelings about Professional Role									
Preparedness to Inquire									

a Model 1 is adjusted for baseline values of the construct being assessed
b Model 2 is adjusted for baseline values of the construct being assessed, College, and whether participant professionally interacts with pregnant or postpartum people.
c Model 3 is adjusted for baseline values of the construct being assessed, College, whether participant professionally interacts with pregnant or postpartum people, wave, and whether participant completed training.

Table 4. Secondary Analyses – Assessment of Study Condition and Training Completion Status on Change in **Average** of Construct Components from Pre- to Post-Training (If missing ≥1 component of construct, construct is calculated as average of available components)

		Model 1[b]		Model 2[c]		Model 3[d]	
Construct	**Group[a]**	**β [95% CI]**	**p-value**	**β [95% CI]**	**p-value**	**β [95% CI]**	**p-value**
Opinions about IPV, SU, and MH	Training Incomplete						
	Training Complete						
Attitudes about Inquiry	Training Incomplete						
	Training Complete						
Self-Confidence to Address IPV, SU, and MH	Training Incomplete						
	Training Complete						
Big 3 Myths	Training Incomplete						
	Training Complete						
Feelings about Professional Role	Training Incomplete						
	Training Complete						
Preparedness to Inquire	Training Incomplete						
	Training Complete						

There were XX participants in the attention-control arm and XX participants in the intervention arm who did not complete training. There were YY participants in the attention-control arm and YY participants in the intervention arm who completed training.

a Reference is attention-control group with specified training completion status.

b Model 1 is adjusted for baseline values of the construct being assessed

c Model 2 is adjusted for baseline values of the construct being assessed, College, and whether participant professionally interacts with pregnant or postpartum people.

c Model 3 is adjusted for baseline values of the construct being assessed, College, whether participant professionally interacts with pregnant or postpartum people, wave, and whether participant completed training.

Supplemental Table 1. Description of Items

Construct	Item Name	Description
Attitudes about Inquiry	ASK1	Because a pregnant or postpartum person might be offended or stop seeing me, I am hesitant to ask about their experiences of partner violence.
	ASK2	Because a pregnant or postpartum person might be offended or stop seeing me, I am hesitant to ask about their experiences of substance use.
	ASK3	Because a pregnant or postpartum person might be offended or stop seeing me, I am hesitant to ask about their experiences of depression or anxiety.
Opinions about IPV, SU, and MH	ASK4	Just from their behavior, I can recognize that a pregnant or postpartum person is experiencing partner violence.
	ASK5	Just from their behavior, I can recognize that a pregnant or postpartum person is experiencing substance use.
	ASK6	Just from their behavior, I can recognize that a pregnant or postpartum person is experiencing depression or anxiety.
Self-Confidence to Address IPV, SU, and MH	SC1	I am comfortable caring for pregnant or postpartum people experiencing partner violence.
	SC2	I am comfortable caring for pregnant or postpartum people experiencing a substance use disorder.
	SC3	I am comfortable caring for pregnant or postpartum people experiencing depression or anxiety.
	SC4	I feel confident in my ability to care for and support pregnant or postpartum people disclosing partner violence.
	SC5	I feel confident in my ability to care for and support pregnant or postpartum people disclosing a substance use disorder.
	SC6	I feel confident in my ability to care for and support pregnant or postpartum people disclosing depression or anxiety.
Big 3 Myths	DVMAS3	Making a partner jealous is asking for violence.
	DVMAS4	Most partner violence involves mutual violence between the partners.
	DVMAS5	I hate to say it, but if a pregnant or postpartum person stays with a violent partner they basically deserve what they get.
	DVMAS6	People who continue to use drugs or other substances after they are pregnant, care little about themselves and their fetus.
	DVMAS8	Pregnant or postpartum people who have anxiety, depression or suicidal thoughts should not have other children.
	DVMAS9	I would find it difficult to be empathic, concerned or helpful for a pregnant or postpartum person who stays with their abusive partner.
	DVMAS10	I would find it difficult to be empathic, concerned or helpful for a pregnant or postpartum person who continues to use substances

	DVMAS11	I would find it difficult to be empathic, concerned or helpful for a pregnant or postpartum person who remains depressed, suicidal, or anxious.
Feelings about Professional Role	DVMAS12	It is my role as a helping professional to advocate for a pregnant or postpartum person who uses substances or has a substance use disorder.
	DVMAS13	It is my role as a helping professional to advocate for a pregnant or postpartum person who experiences partner violence.
	DVMAS14	It is my role as a helping professional to advocate for a pregnant or postpartum person who is depressed or has anxiety.
Preparedness to Inquire	DVMAS15	I know how to respond to a pregnant or postpartum person who denies obvious signs of their partner's violence toward them.
	DVMAS16	I know how to respond to a pregnant or postpartum person who denies obvious signs of their use of substances.
	DVMAS17	I know how to respond to a pregnant or postpartum person who denies obvious signs of their depression, anxiety or another mental illness.
N/A	DVMAS2	When a partner is violent toward a pregnant or postpartum person it is because they lost control of their temper.
Responses to all items are provided on a 5-point Likert scale where 1=Strongly Agree, 2=Agree, 3=Neutral, 4=Disagree, and 5=Strongly Disagree		