

Statistical Analysis Plan

"Empowerment Self-Defense Training for the Prevention of Victimization of Transgender Women"

ID: R21MD014807

NCT04934189

1/18/2023

Statistical Design and Power

This R21 will use a non-experimental pilot study of 3 groups of 16 transgender women to assess preliminary feasibility and acceptability. A fully powered randomized controlled trial is neither practical nor advisable in this R21. The decision to use a single group, non-randomized design, rather than a randomized controlled trial (RCT), is best considered in light of critiques regarding the use of pilot RCTs to guide decision-making about whether to pursue larger-scale RCTs.⁷⁴⁻⁷⁶ The central point of these critiques is that because of their small size, pilot RCTs provide imprecise data on effect sizes, which can lead to both Type I and Type II errors. As a result, subsequent RCTs that are based on pilot RCTs may be underpowered (e.g., if pilot RCT suggests an artificially large effect size for the treatment [Type I error]) or not pursued (e.g., if pilot RCT suggests an artificially small effect size [Type II error]) even if the treatment could actually have been effective.⁷⁵ On the other hand, pilot trials do provide valuable information on the feasibility of study procedures, including recruitment, retention, implementation of the intervention, and data management. As the key objectives of this R21 are to develop the ESD self-defense training tailored for TW (Aim 1) and to assess its preliminary feasibility and acceptability (Aim 2), we will maximize the amount of useful information that can be gained about study feasibility and treatment efficacy in order to guide a future RCT of the new tailored violence prevention curriculum.

Data Management. Following the CONSORT statement,⁸² we will track how many participants: (a) are told about the study; (b) are screened for the study; (c) do and do not meet inclusion criteria; (d) are invited to participate; and (e) actually enroll. Pre-inclusion attrition rates may reveal potential enrollment bias. To explore how differential refusal may affect generalizability of findings, we will also record the reasons for exclusion from and refusal to participate in the study. As recommended by the IOM Report,⁸³ we will model the effects of dropout patterns as data not missing at random using Bayesian analysis utilizing a pattern-mixture modeling approach. We will consider scale transformations, such as log, to decrease the effect of outliers.

Feasibility Analyses. The primary target outcomes of Aim 2 will be completion of the pilot study at the target recruitment total ($n = 48$), with $< 25\%$ dropout from assessments (Table 1. Research Plan). Secondary target outcomes related to assessment procedures, acceptability of the intervention, and laboratory and data management are detailed in Table 1 of the Research Plan. Successful completion of the pilot trial, including meeting or exceeding these benchmarks for success, will support the feasibility and acceptability of recruiting participants into a future RCT of the tailored ESD intervention using similar procedures and a similar population.

Power Analyses. Preliminary efficacy of the tailored ESD violence prevention intervention will be evaluated as an exploratory aim via administration of the battery of validated questionnaires assessing 1) behavior change variables (i.e., use of resistance tactics, self-protective behavior, and assertive relational communication); 2) psychological variables hypothesized to mediate the effects of the intervention on behavior (i.e., resistance self-efficacy, attributions of self-blame, rape myth acceptance, gender minority risk and resilience factors); and 3) reductions in rates of exposure to victimization) at baseline, post-intervention, and at the 3- and 6-month follow-up assessments.

Given its modest size and aims, this pilot is not powered to detect reductions in victimization exposure. Nonetheless, we will conduct exploratory analyses to evaluate potential trends that may emerge for the effects of treatment on behavior change, violence risk and resilience variables, and victimization.

A power analysis was performed using the R package WebPower for a representative variable for each these three outcomes categories. Sample size can be derived based on effect size (f) and power ($1-\beta$). Here $f=\sigma_m/\sigma$, Cohen (1988, p. 275), σ_m is the standard deviation of population means and σ the standard deviation within the populations. Even though Cohen (1988) provides general magnitudes for small effect size: $f = 0.1$, medium effect size: $f = 0.25$, large effect size: $f = 0.5$, he argues that these guidelines are to be used when there is insufficient prior knowledge and “may not be reasonably descriptive in any specific area.” The preliminary efficacy results derived from the proposed pilot trial will further inform our estimate of an effect size

of clinical interest for these outcomes. This information will be used to plan for a sufficiently powered confirmatory trial (e.g., R01).

1. Behavior Change Variable: use of self-protective behavior

Test procedure: paired two-sample *t*-test, one-sided, $\alpha = 0.05$, $s_d = 8$

Power calculation: GPower

	Power			
Effect Size (ES)	0.8	0.85	0.9	0.95
1	398	462	550	694
1.5	178	206	245	310
2	101	117	139	175
2.5	65	75	90	113
3	46	53	63	79

2. Attitudinal Mediator Variable: self-efficacy

Test procedure: paired two-sample *t*-test, one-sided, $\alpha = 0.05$, $s_d = 8$

Power calculation: GPower

	Power			
Effect Size (ES)	0.8	0.85	0.9	0.95
1	398	462	550	694
1.5	178	206	245	310
2	101	117	139	175
2.5	65	75	90	113
3	46	53	63	79

3. Reductions in Exposure to Victimization Variable: sexual victimization reduction

Test procedure: chi-square test for independence, two-sided, $df = 2$, $\alpha = 0.05$

Power calculation: R package powerAnalysis

	Power			
Effect Size (ES)	0.8	0.85	0.9	0.95
0.1	964	1093	1266	1545
0.2	241	274	317	387
0.3	108	122	141	172
0.4	61	69	80	97
0.5	39	44	51	62

Inferential analyses. We will use repeated measures one-way ANOVA to test if the tailored ESD curriculum has statistically significant effect on measures of behavioral and psychological/attitudinal change. If a significant effect is detected, we will use Tukey's pairwise-comparison procedure to compare all treatment means, with a 95% family confidence coefficient. To assess changes in exposure to victimization, we collapse into three levels: (a) no history of victimization; (b) moderate victimization; (c) severe victimization. For this categorical data, a chi-square test of independence will be performed to compare post-treatment vs. pre-treatment, 3-month FU vs. pre-treatment, and 6-month FU vs. pre-treatment respectively to assess the preliminary efficacy of the program, with a family-wise type I error controlled at 0.05 using Bonferroni procedure.