Guardians Receiving Information through Navigators (GRIN)
Statistical analysis plan
NCT05511935
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GRIN Phase I feasibility study
Statistical design and power

Number of subjects

We will enroll 60 participants per group, for a total of 120 participants.

Power estimate and effect size

We computed power for multiple regression based on the designated outcomes, a single measure of treatment exposure, dosage of the exposure, and demographics modeled as control measures.[1] Table 1 shows the results of simulation models for continuous outcomes, which varied the values of R^2 for the multivariate regression, the treatment measure's contribution to R^2, and the total number of predictors in the model.[2]

We estimated power at .80, assuming each outcome measure will have the same range of explained variance, and produced a range of sample sizes under the following conditions:

- The probability of the outcome (target achieved) for the treated under the null hypothesis (p_1) and under the alternative hypothesis (p_2), with $p_1 + p_2 = 1$. Three pairs of probabilities will be used, with the constraint that $p_1 < p_2$.
- R^2 other than X, that is, the proportion of variance explained by predictors other than the treatment (the same values set for multiple linear regression were used).
- The distribution and π parameter of the treatment variable: binomial and the parameter 0.5 (same probability of being a case or a control).

Because varying the number of predictors had little influence on the simulation, we used six predictors with multiple linear regression. As Table 2 shows, increasing the effect size reduces the required sample size. Power for dichotomous outcomes using multivariate logistic regression required slightly larger sample sizes. Therefore, with a medium R^2 value (.30) and contribution of treatment <.30, the estimated sample size for power = 0.80 is 36 (range 23-59). Our planned sample size of 60 participants per condition will give us adequate power and allow for attrition.

Table 1. Power estimates for continuous outcomes

R^2	Contribution of treatment to R^2	Estimated effect size	Estimated sample size for power = 0.80	Range of est. sample size for power = 0.60-0.95
0.30	0.02	0.071	112	74-184
0.30	0.05	0.200	42	28-68
0.30	0.10	0.500	19	14-29
0.40	0.02	0.053	152	96-249
0.40	0.05	0.143	58	37-94
0.40	0.10	0.333	27	18-42
0.50	0.02	0.042	191	120-314
0.50	0.05	0.111	73	47-119
0.50	0.10	0.250	34	23-55

Statistical methods for outcome measures

A repeated measures ANOVA of pre- to posttest scores by condition will assess program effects. Multiple linear regression with continuous outcomes and logistic regression with dichotomous outcomes will also assess program effects. The regression models will use forward inclusion to enter (in order) pretest scores, additional baseline and demographic controls and specified interaction terms, and then model program effects on the four designated outcomes (knowledge, attitudes and beliefs, self-efficacy, and intentions).

Works Cited

[1]Faul, F., Erdfelder, E., Buchner, A., & Lang, A.-G. (2009). Statistical power analyses using G*Power 3.1: Tests for correlation and regression analyses. *Behavioral Research Methods, 41*, 1149–1160.

[2]Hertzog, M. A. (2008). Considerations in determining sample size for pilot studies. *Research in Nursing & Health, 31*, 180-191.