Official Title: Information Visualizations to Facilitate Patient-provider Communication in HIV Care: Info Viz HIV

Statistical Analysis Plan
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Statistical analysis plan

Sample size estimation was based on the recommendation of having 35-40 participants to pilot test instruments, thereby estimating the associated treatment effects.[1-3] To account for 20% attrition (2% over the average rate in health behavior change trials to account for difficulties in retention associated with this population),[4-6] 50 participants were recruited. Adults (≥ 18 years of age), living with HIV, with a detectable viral load (≥ 40 copies/mL) on their most recent laboratory test, who were planning to receive care at the Clinic during the study period, were eligible to participate.

We first characterized the study sample using descriptive statistics. Means and standard deviation and frequency analysis were performed on baseline demographic characteristics. Next, descriptive statistics of all outcome measures were performed, stratified by time point (baseline, 3-, 6-, and 9-months). Means and standard deviations were then computed for outcomes that roughly follow normal distribution and median and interquartile range were computed for skewed variables. So as not to inflate type II error, statistical analyses were only conducted for a subset of outcome variables, selected based on our theoretical model. The variables analyzed were: HIV-related knowledge, self-efficacy to manage HIV, CD4 count, viral load, current health status, and engagement with clinicians. Descriptive statistics of the remaining outcome variables were calculated.

To determine appropriate tests of association, tests for normality were conducted on all variables. If they were skewed, we log transformed variables to determine if skewness improved. The variables that met normality assumptions were then analyzed using general linear regression and those that were heavily skewed were analyzed using Wilcoxon signed-rank tests.

General linear regression with generalized estimation equations (GEE) with robust standard errors were conducted with the following continuous dependent variables: HIV-related knowledge, self-efficacy to manage HIV, CD4 count, and viral load measured at each time point. GEE was used to account for the clustering effect of repeated measures. This analysis allowed us to estimate how scores on outcome measures changed from baseline to follow up visits (at 3-, 6-, and 9-months). Independent variables included in each regression model were if participants were new patients at the time of enrollment and time (baseline, 3-, 6-, and 9-months). If participants were new to the clinic was represented by a dichotomous yes/no variable where “yes” indicated a participant had been attending the clinic for less than 3 months at the time of enrollment, as that is the time it takes to see changes as a result of ART treatment.[7,8] The only variable where log transformation improved normality was viral load, so log transformed viral load was used in that regression model. Histograms of the residuals from final regressions were evaluated again for normality following tests to verify the normality assumptions were met.

Wilcoxon signed-rank non-parametric tests of association were used to compare the outcome measures current health status and engagement with clinician at baseline with those obtained at the follow up time points as initial analyses demonstrated these variables did not meet normality assumptions. This analysis enabled us to establish if the changes seen at different time points in the longitudinal study were statistically significantly different than those obtained at baseline.

Because this is a preliminary pilot test with a small sample size, we wanted to detect any interesting findings, we did not adjust for multiple comparisons in the regression models. In the applied sciences, it is considered appropriate to not adjust for multiple comparisons when the tests are planned, especially when there are only a few tests.[9-11] However, we did use the conservative Bonferroni correction adjustment for multiple comparisons for the Wilcoxon Signed-Rank tests when assessing the outcome measures current health status and engagement with clinician, as we ran each test three times to compare scores on baseline assessments to those at 3-, 6-, and 9-month follow up visits.[12] Therefore, the Wilcoxon signed-rank tests were considered significant if $p \leq 0.05/3 = .017$.

REFERENCES

1. Hertzog MA. Considerations in determining sample size for pilot studies. *Research in nursing & health.* 2008;31(2):180-191.
2. Lancaster GA, Dodd S, Williamson PR. Design and analysis of pilot studies: recommendations for good practice. *J Eval Clin Pract.* 2004;10(2):307-312.
3. Browne RH. On the use of a pilot sample for sample size determination. *Statistics in medicine.* 1995;14(17):1933-1940.
4. Crutzen R, Viechtbauer W, Spigt M, Kotz D. Differential attrition in health behaviour change trials: a systematic review and meta-analysis. *Psychology & health.* 2015;30(1):122-134.
5. Brinkhof MW, Pujades-Rodriguez M, Egger M. Mortality of patients lost to follow-up in antiretroviral treatment programmes in resource-limited settings: systematic review and meta-analysis. *PLoS One.* 2009;4(6):e5790.
6. Bowman AS, Mehta M, Lerebours Nadal L, Halpern M, Nicholas SW, Amesty S. Strengthening the HIV Care Continuum in the Dominican Republic: Application of a Triadic Implementation Framework to Meet the UNAIDS 90-90-90 Treatment Goal. *AIDS Patient Care STDS.* 2017;31(10):407-412.
7. Cohen MS, Chen YQ, McCauley M, et al. Prevention of HIV-1 infection with early antiretroviral therapy. *New England journal of medicine.* 2011;365(6):493-505.
8. Toren KG, Buskin SE, Dombrowski JC, Cassels SL, Golden MR. Time from HIV diagnosis to viral load suppression: 2007–2013. *Sexually transmitted diseases.* 2016;43(1):34.
9. Thompson B. *Planned versus unplanned and orthogonal versus nonorthogonal contrasts: The neo-classical perspective.* ERIC Clearinghouse; 1990.
10. Anderson NH. *Empirical direction in design and analysis.* Psychology Press; 2001.
11. Armstrong RA. When to use the B onferroni correction. *Ophthalmic and Physiological Optics.* 2014;34(5):502-508.
12. Weisstein EW. Bonferroni correction. *https://mathworld wolfram com/.* 2004.