NCT03721276

Title of Research Project: Project EQuIP: Empowering Queer Identities in Psychotherapy

SAP Date 10.7.2019

Statistical Analysis Plan

Feasibility and Acceptability

Feasibility was assessed in terms of treatment attendance. Acceptability was assessed in terms of responses to the quantitative exit survey that all participants completed at 6-month follow-up and the qualitative exit interview conducted with 20 randomly selected participants after 6-month follow-up. Qualitative exit interviews were transcribed verbatim, and the third and eighth authors served as coders and double-coded all transcripts. Thematic analysis was used to identify patterns of responses, and emergent codes were categorized into larger themes (Braun & Clarke, 2006).

Intervention Efficacy

We assessed intervention efficacy using an intent-to-treat analysis including all eligible cases (n = 60). First, to determine randomization effectiveness, differences in baseline demographic characteristics were assessed between the immediate intervention (n = 30) and waitlist control (n = 30) conditions using t tests for continuous measures and chi-square tests for categorical measures. Income and gender identity differed between conditions (p < .05), with the waitlist control group reporting higher income and having a larger proportion of cisgender women; thus, we included income and gender identity as covariates in subsequent analyses.

Dependent variables were assessed for normality using skewness and kurtosis thresholds of ± 2 (Field, 2013; George & Mallery, 2010). Suicidality and internalized stigma were found to be non-normal; we therefore log-transformed these variables for further statistical tests (reassessment of skewness and kurtosis after transformation showed normal distribution).

In a first set of analyses, we used linear mixed models with maximum likelihood estimation and a compound symmetry covariance structure (selected based on fit criteria, i.e., lowest Akaike information criterion [AIC]) to test the Condition x Time interaction for all intervention outcomes including mental and behavioral health (e.g., depression), minority stress processes (e.g., rejection sensitivity), and universal risk processes (e.g., emotion regulation). To do so, we limited the data to baseline (time = 0) and 3 months postbaseline assessment (time = 1) and examined the Condition x Time interaction effect of receiving immediate EQuIP (condition = 1) versus receiving the 3-month waitlist (condition = 0). Thus, the estimate of interest compared preintervention to immediate postwaitlist outcomes in the immediate intervention group to prewaitlist and immediate postwaitlist outcomes in the waitlist control group. Effect sizes (d) for linear mixed models were calculated as mean pre–post change in the immediate intervention group to the mean pre–post change in the waitlist control group, divided by the pooled baseline standard deviation (Morris, 2008).

In a second set of analyses, we examined the clinical significance of observed changes in those mental health outcome measures that possess established clinical cutoffs (i.e., CES-D, ODSIS, OASIS). To do so, we used generalized linear mixed models with a logit link and binomial distribution to examine the Condition x Time interaction effect predicting the odds of meeting or

exceeding the clinical cutoff among participants receiving immediate EQuIP (condition = 1) versus those receiving the 3-month waitlist (condition = 0). For interpretability, we report proportions of participants meeting or exceeding clinical cutoff by condition and time.

In a third set of analyses, we conducted a pooled analysis whereby data from all participants were pooled to examine change in outcome from immediate preintervention to postintervention using paired t tests (i.e., baseline to 3 months postbaseline for the immediate intervention group and 3-months postbaseline to 6-months postbaseline for the waitlist control group). Pooled analyses are useful in waitlist-controlled studies (where all participants ultimately receive treatment) to assess the pre–post effect of the intervention in a larger sample than the condition x time analyses allow. One participant assigned to the waitlist control group did not complete 3-month or 6-month assessments and was dropped from the pooled analysis (n = 59). Effect sizes (d) for pooled analyses were calculated as $\frac{2t}{\sqrt{df}}$.

Finally, we assessed the longer-term persistence of observed intervention effects by limiting analyses to immediate 3-months postbaseline (time = 1) and 6-months postbaseline (time = 2) among participants in the immediate intervention condition (condition = 1), the only participants to have completed assessments 3-months after receiving the intervention. Specifically, we examined the significance of changes between time points for all outcomes, including mental and behavioral health (e.g., depression), minority stress processes (e.g., rejection sensitivity), and universal processes (e.g., emotion regulation). Results were evaluated at p < .05.

References

Braun, V., & Clarke, V. (2006). Using thematic analysis in psychology. *Qualitative Research in Psychology*, *3*(2), 77-101.

Field, A. (2013). Discovering statistics using IBM SPSS statistics. SAGE.

George, D., & Mallery, P. (2010). SPSS for Windows step by step. A simple study guide and reference (10. Baskı). *GEN, Boston, MA: Pearson Education, Inc.*

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