

Study Protocol and Statistical Analysis Plan

How Long Should a Behavioral Activation Single-session Intervention be? A Four-armed
Trial Comparing Effectiveness by Intervention Duration

ClinicalTrials.gov ID NCT06313736

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Protocol

Researchers will use the crowdwork platform CloudResearch Connect to recruit and compensate participants. Researchers will pay participants \$0.25 USD for completing the screener and (if eligible) the study information sheet. If participants are eligible, researchers will send them invites through the crowdwork platform to participate in the next parts of the study. Researchers will pay them \$4.00 for completing session 1 of the study and \$1.00 for the 8-week follow-up. Participants are only allowed to complete the study once and cannot participate in the study if they have participated in another study from the research team relating to depression on CloudResearch Connect in the last two months.

Researchers will recruit a sample of 1,100 adults who struggle with depression. To recruit these adults, potential participants will complete a screener and, if eligible, read the study content information and decide whether to participate (2 minutes). Within five days, participants who consent will be invited to complete the first part of the study. In this part, they will first complete a questionnaire of demographics and well-being at baseline (roughly 4 minutes), be randomly allocated to one of four conditions with equal odds of assignment to each condition, complete the SSI to which they were randomized (2-15 minutes) and then complete the post-test measures (roughly 4 minutes) just after the SSI and eight weeks later. Combined across all three study sessions, the study should take roughly 29 minutes. At the end of the study, researchers will offer participants access to a list of free online mental health support resources (shown in supporting documents). At the end of the study, researchers will also offer participants permanent access to all four SSIs.

The research team created the SSIs of different lengths aiming to make the active elements in each SSI as consistent as possible. Thus, even though the 2-minute version contains less content than the 15-minute version, researchers tried to ensure it expresses the same general message and activates similar mechanisms of change. Participants will complete questionnaires asking about their well-being and experiences with the interventions at baseline, post-test, and 8-week follow-up.

All interventions and survey materials are available at <https://osf.io/g846j>.

Statistical Analysis Plan

Main analysis: The main DV is change in depressive symptoms (PHQ-8) from baseline to 8-week follow-up. The main analysis compares change in PHQ-8 score from baseline to 8-week follow-up across experimental conditions. Researchers will use a mixed-effects model predicting depressive symptoms with condition, measurement time point (1 = baseline, 2= 8-week follow-up), and the 2-way interaction between condition and measurement time point as IVs and a participant identifier as a random intercept. Using the “lme4” package in R, these analyses will take the following form:

`lmer(phq8 ~ time*condition + (1|pid))`

Secondary analysis: Researchers will re-run the same analysis as above separately for each secondary outcome collected. Researchers will also duplicate the main analysis but with the following covariates included in the mixed-effects model: gender (multiple choice), age (continuous), ethnicity (categorical), education level (categorical), employment (categorical), and if one completed the study on a phone (binary).

Inference criteria

For all analyses, researchers will use the standard $p < 0.05$ criterion for determining statistical significance. Researchers will use two-tailed tests for each of researchers' analyses.

Data exclusion

Main analyses will be limited to only those participants who 1) were randomized to a condition (i.e., those who consented to participate and completed the baseline measures), 2) did not indicate that they did not participate seriously at the end of the study, and 3) completed the study only once.

Missing data

Based on researchers' previous work on Cloudresearch Connect, researchers do not foresee a great deal of missing data or differential dropout. Although researchers will take efforts to avoid missing data (e.g., a financial incentive for completing the study and reminder emails), it is not necessary to impute missing data before performing a longitudinal mixed-model analysis (Twisk et al., 2013). Participants with missing data at some assessments will be included in the analysis and results will be modeled on the basis of the available data.