Statistical analysis plan

Identifying the active elements of a digital single-session intervention targeting depression: a factorial experiment

ClinicalTrials.gov ID: **NCT06322849**

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Arms and Interventions: details

We will conduct an 8-arm factorial trial to determine the main and interaction effects of the candidate components. The 8 conditions are provided in Table 1.

	Breathing	Psychoeducation	Testimonials + Saying is believing exercises	Action plan
Condition 1	Yes	No	No	No
Condition 2	Yes	No	No	Yes
Condition 3	Yes	No	Yes	No
Condition 4	Yes	No	Yes	Yes
Condition 5	Yes	Yes	No	No
Condition 6	Yes	Yes	No	Yes
Condition 7	Yes	Yes	Yes	No
Condition 8	Yes	Yes	Yes	Yes

Table 1

Breathing – This component will present a triangle breathing video for 2 minutes and will be present in all 8 conditions.

Psychoeducation – This component provides information on how taking action can help improve our mood and different types of actions participants can take to improve their mood.

Testimonials + Saying is believing exercises – Participants are shown examples of how other individuals have taken action to improve their mood. The participant is also asked to provide advice to another simulated individual who is stuck in a *negative mood spiral*.

Action plan – The participant is walked through to plan the details of a positive action that they want to take to improve their mood.

Randomization

Participants will be randomized to one of the 8 conditions with equal probability using Qualtrics's internal randomizer.

Data collection and sample size

Data collection procedures

We will recruit participants through the CloudResearch Connect platform. All potential participants will be paid $0.25 for completing a 2-minute screener of depressive symptoms to determine their eligibility for the study. Eligible participants will be paid $3.00 for completing the first part containing the baseline questionnaires, 1 of the 8 conditions, and immediate post-intervention questionnaires (18 minutes). They will be compensated $1.00 for completing the 2-week follow-up (5 minutes), and $1.00 for completing the 8-minute follow-up (5 minutes). Payment will be delivered online through CloudResearch Connect.

Sample size

We will recruit 880 participants with 110 participants in each group.

Sample size rationale

We aimed to detect a main effect of Cohen's d = 0.15 for the candidate components (we considered d=0.15 as the minimum acceptable effect size for a candidate component to be independently useful). We calculated the sample size using the MOST package in R, which performs power calculations using simulated data.

Stopping rule

We will stop the trial when we have reached the required number of participants.

Analysis plan

Demographic data

We will report demographic variables as percentages of the total number of participants.

Effects of candidate components and common factors

We will run 3 separate multiple regressions with the PHQ-8 score at immediate post-intervention, 2-week follow-up, and 8-week follow-up as the dependent variable and baseline PHQ-8 and the effect-coded candidate components as the predictors (Collins et al., 2014). We will use the *stats* package in R to run the regression.

lm(8-week PHQ-8 ~ baseline PHQ-8 + (mainEffectPsychoeducation + mainEffectSIBT + mainEffectActionPlan)^3)

SIBT = Saying is believing + Testimonials

As an exploratory analysis, we will repeat the above multiple regression and include credibility rating and expectancy rating at immediate post-intervention as predictors.

lm(8-week PHQ-8 ~ baseline PHQ-8 + (mainEffectPsychoeducation + mainEffectSIBT + mainEffectActionPlan)^3 + credibility rating + expectancy rating)

We will run another exploratory analysis with 8-week PHQ-8 as the dependent variable and baseline PHQ-8 and effect-coded candidate components as predictors, and we will include all the demographic variables as co-variates.

lm(8-week PHQ-8 ~ baseline PHQ-8 + (mainEffectPsychoeducation + mainEffectSIBT + mainEffectActionPlan)^3 + gender + age + ethnicity + sexual orientation + educationLevel + employment + MacArthurScaleofSubjectiveSocialStatus + programCompletiondevice)

We will also run 4 separate multiple regressions with measures of hopelessness (BHS-4), autonomy, relatedness, and competence (BMPN) as dependent variables and the effect-coded candidate components as predictor variables.

The regression coefficients will provide the main and interaction effects of the candidate components (Kugler et al., 2018).

Mediation effects of autonomy, relatedness, and competence

To evaluate the mediation effects of autonomy, relatedness, and competence, we will use the joint significance test (MacKinnon et al., 2002). It is a causal steps approach to evaluate mediation effects. It tests two null hypotheses: the effect of the mediator on the dependent variable is 0 (*b* pathway), and the effect of the independent variable on the mediator is 0 (*a* pathway). If the effects of both the *b* and *a* pathway are significantly different from 0, it is considered evidence for mediation (Strayhorn et al., 2022). We will separately evaluate whether autonomy, relatedness, and competence:

1. at immediate post-intervention mediates the PHQ-8 scores at 2-week and 8-week follow-up
2. at 2-week follow-up mediates the PHQ-8 score at 8-week follow-up.

Inference criteria

To determine statistical significance of the candidate components, we will use $\alpha = 0.10$ to reduce the risk of ruling out potentially active ingredients (Watkins et al., 2023).

For all other analyses, we will use $\alpha = 0.05$. We will use two-tailed tests for all analyses.

Data exclusion

We will exclude participant data if they:

1. dropped out before being randomized to one of the 8 conditions
2. indicate that they did not participate seriously in the study
3. complete the study more than once. In such cases, if possible, we will use data from the first submitted survey.

Missing data

We will take efforts to avoid missing data (e.g., a financial incentive for completing the study and reminder emails). Participants with missing data at will be included in the analysis and missing data will be imputed using the multiple imputation method. We will use the mice package in R for multiple imputation.

Exploratory analysis

Additionally, we will run exploratory analyses using data generated from this study. However, we are not pre-registering these exploratory tests at this time.

References

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