Title: Evaluating and Predicting Response to a Single Session Intervention for Self-Dislike

Date: 9-4-2019

NCT: Not yet assigned

Unique Protocol ID: IRB2019-00312

Evaluating and Predicting Response to a Single Session Intervention for Self-Dislike

Data Collection Status

No data has been collected already for this study.

What's the main question being asked or hypothesis being tested in this study?

Whether a single session online intervention for self-dislike decreases:
1. Fear of self-compassion from immediate pre to immediate post intervention
2. Self-hatred immediate pre to 1 month post-intervention
3. Individual depression symptoms (including suicidality) immediate pre to 1 month post-intervention

more than a placebo online single session intervention encouraging the disclosure of feelings in college students.

We will also explicitly test whether the following variables are predictors of the effect of the self-dislike treatment on self-hatred of at least the smallest variance predicted of interest:
4. Pre intervention self-hatred score
5. Screening positive for clinical depression based on self-report
6. Immediate pre to post-intervention reduction in fear of self-compassion

7. We will also assess whether any of the variance shared between the treatment and changes in individual depression symptoms immediately pre Intervention to 1 month post-intervention is statistically mediated by change in self-hatred from immediate pre intervention to 1 month post intervention

Describe the key dependent variable(s) specifying how they will be measured.

The fear of self-compassion will be assessed by averaging the items of the fear of self-compassion scale by Gilbert et. al., 2011. Note that the PDF contains other fears around compassion, but we will only administer the 15-item version of the fear of self-compassion.

http://self-compassion.org/wp-content/uploads/publications/fears-of-compassion-1.pdf

Self-hatred will be measured by averaging the seven items of the Self-Hate scale by Turnell et. al., 2019

https://www.sciencedirect.com/science/article/pii/S0165032718313144?via%3Dihub

Depression symptoms will be assessed by the scores on the individual items of the IDAS-II Dysphoria Subscale and the suicidality item only from the PHQ-9

https://journals.sagepub.com/doi/full/10.1177/1073191112449857

https://onlinelibrary.wiley.com/doi/full/10.1046/j.1525-1497.2001.016009606.x

How many and which conditions will participants be assigned to? (optional)

2 conditions, each participant will only be randomly assigned to one:

A single Session Intervention for Self-Dislike
A single Session Intervention for Feelings Disclosure

This assignment will be conducted in a double masked manner (participants will be masked to whether they received active treatment and investigators will be masked to which condition the participant is randomized to as the randomization occurs automatically within the survey).

Specify exactly which analyses you will conduct to examine the main question/hypothesis. (optional)

For all sum/average score scales/variables included in all analyses, we will run a parallel analysis using the psych R package using the default arguments of fa.parallel. If the items of the scale do not load onto one factor at both time points, as indicated by the parallel analysis, we will conduct a principal components analysis on all scale items using prcomp in R, extract the first factor, and use this first factor score in place of the sum/average score in all primary analyses.

1. We will first test if the assumptions necessary to interpret a multiple linear regression are met. If not, we will apply the following corrective practices so that the regression is interpretable. We will document any of these changes when we report our results.

If assumptions are not met, we intend to predict the outcome variable (e.g., immediate post intervention fear of self-compassion) with the corresponding baseline variable (e.g., pre intervention fear of self-compassion) in a random forest. Residuals calculated from this model will be robust to assumptions from the linear model and will then be entered as the outcome variable whenever there is an outcome variable discussed below.

If the assumptions for interpreting a regression are met, we will enter pre-intervention fear of self-compassion as a covariate and treatment condition as the predictor of post-intervention fear of self-compassion in a multiple linear regression. We will consider a p value of less than .05 for the treatment coefficient in favor of the self-dislike intervention a significant effect of the self-dislike treatment on change in fear of self-compassion. We will also cross-validate the result using 10 folds with the ‘validate’ function from the ‘beset’ package in R to estimate how well this estimate will predict results in out of sample data (i.e., percentage of variance explained) using default settings for the ‘validate’ function.

2. We will follow the same procedures for hypothesis 1 but replacing “fear of self-compassion” with “self-hatred.”

3. We will first create residualized individual depression symptoms by predicting the 1 month post intervention value of the symptom (e.g., 1 month post-intervention sadness) with the pre intervention version of the same symptom (e.g., immediate pre-intervention sadness). If any of the residuals are non-normally distributed we will correct this with the random forests procedure described in the analytic plan for hypothesis 1. We will then conduct t-tests for each symptom (11 total, 10 from IDAS-Dysphoria, 1 Suicidality item from the PHQ-9) and Holm-Bonferroni correct each test for multiple comparisons.

After this correction, any p-values less than .05 will be taken to mean there was a significant treatment effect on the symptom. We will then cross-validate, or test the potential out-of-sample performance (i.e., percentage of variance explained), all models where there was a significant effect of treatment using the using default settings for the ‘validate’ function in the ‘beset’ R package.

4-6. We will first subset this analysis to contain only participants who were randomized to the self-dislike intervention. We will then conduct an elastic net analysis using the default settings in the ‘beset’ package in R with the following predictor variables:

Gender (male, female, non-binary), gender minority status (non-binary gender identification or not), age, race/ethnicity, racial/ethnic minority status (endorsing being white/caucasian vs. not), sexual minority status (endorsing being heterosexaul vs. not), first year in undergraduate or not status, full vs. part time enrollment in college, self-reported GPA, being a member of a student club/organization or not, English first language or not, living in campus residence hall vs. not, international student or not, relationship status (not currently in a relationship, in a relationship but not living together, in a relationship and living together, engaged, married), have children or not, recent transfer (past 12 months) student or not, pre intervention fear of self-compassion, pre intervention drinking to cope, pre intervention social anxiety, screening positive for depression based on PHQ-9 vs. not, self-reported understanding of the intervention, self-reported effort put into the intervention credibility of intervention, self-reported interestingness of intervention, how logical the intervention seemed, how confident they would be in recommending intervention materials to those who were struggling, perceived relevance of intervention to college students, self-reported increased confidence in ability to handle emotional difficulties due to the intervention, pre intervention self-hatred, residualized change in fear of self-compassion pre to immediate post intervention, and residualized change in verbally expressed emotion-sadness pre to immediate post intervention.

We will then assess how much potential of out sample variance all of these variables combined predict in how well people responded to the intervention indexed by residualized change in self-hatred pre to 1 month post intervention.

We will then compare these potential out of sample variances predicted to the smallest variance predicted of interest, which will be calculated this way:

Following procedures outlined in this paper (https://psyarxiv.com/syp5a/ as of August 23, 2019, version 2) we will ask this question at one month follow-up:

Compared to when you took this survey about 1 month ago, how would you rate the extent of your self-dislike today?

Much less self-dislike
A little less self-dislike
The same self-dislike
A little more self-dislike
A lot more self-dislike

Our analyses will then follow their procedures for the global transition method to determine the smallest effect size of interest (d_z which accounts for correlation between measures across time)

We will then convert this d effect size to an R^2 effect size via the compute.es package in R (to convert from d to r) and then squaring that number to arrive at an R^2 metric for the smallest variance predicted of interest.

We can then use the 'importance' argument in the R package beset to identify how much each candidate predictor contributes toward the model R^2 and evaluate if the R^2 contributed toward the model is above, the same as, or below the smallest variance predicted of interest (Predictors will be standardized prior to the analysis to ensure comparability across predictors).

We would consider self-hatred, screening positive for depression, and/or change in fear of self-compassion as important predictors if their individual contributions to the R^2 of the model were the same as or greater than the smallest variance predicted of interest.

7. We will fit a Mixed Graphical Model network using the MGM package in R with the standard presets (including hyperparameters) with the following variables:

Treatment Condition (Self-Dislike or Feelings Disclosure Placebo), residualized change in all individual symptoms of the IDAS II as calculated in analysis 3, and change in self-hatred as calculated in analysis 2.

We will then descriptively evaluate whether the treatment directly connects to change in self-hatred within this network and which/how many changes in individual symptoms are indirectly connected to the effects of treatment via change in self-hatred.

However, if a mixed graphical modeling package in R that can conduct Bayesian hypothesis testing in a network context exists when the analyses are conducted (none are presently known to these authors) we will instead conduct a Bayesian hypothesis testing network to determine the Bayes Factors for:

- An effect size of at least d = 0.20 for the edge connecting treatment to change in self-hatred
- Effect sizes of at least d = 0.24 for the edges connecting change in self-hatred to change in each individual depression symptom
- Effect sizes of at least d = 0.24 for the edges connecting treatment to change in each individual depression symptom

We will consider Bayes Factors greater than 3 evidence for the alternative hypothesis (effects at least as large as those in the previous paragraph) and Bayes Factors ⅓ or lower evidence for the null hypothesis (effects smaller than those in the previous paragraph). Bayes Factors between ⅓ and 3 with be considered inconclusive evidence.

We will also preliminarily interpret statistical mediation from treatment to change in an individual symptom via change in self-hatred if there is:

- Evidence for the alternative hypothesis for the edge connecting treatment to change in self-hatred
- Evidence for the alternative hypothesis for the edge connecting change in self-hatred to the change in the individual symptom
- Any level of evidence for the edge connecting treatment to change in the individual symptom

Outliers and Exclusions. Describe exactly how outliers will be defined and handled, and your precise rule(s) for excluding observations. (optional)

We will exclude participants 3 SDs above/below the mean completion time for the study or exit the study prior to randomization for our listed analyses.

We will also test whether there's any association between how quickly participants are responding to questions and the variability in their responses. If there is a response time frame (i.e., a series of questions that require answers where timing is measured) where there is a linear relationship between response time and response variability, we may exclude those participants, as response time and response variability should be uncorrelated and a linear association can indicate random responding. This time frame can be identified visually on a graph, and sensitivity tests can be conducted to determine if slight variations on the visual interpretation affect substantive results.

We will exclude participants who respond with either copy/pasted responses from text earlier in the intervention (e.g. Copy and pasting only text from a previous testimonial slide) to any of free response questions.

We will exclude for primary analyses (but may run sensitivity analyses including them) any participants who provide responses of 5 words or fewer to writing prompts that ask for at least 1 sentence or more.

These exclusions are based on previous single session intervention research conducted online

(see: http://www.jessicaschleider.com/uploads/2/1/8/4/21847128/schleider_weisz_2018_-_in_press_jccap.pdf)

How many observations will be collected or what will determine the sample size? No need to justify decision, but be precise about exactly how the number will be determined. (optional)

We will be recruiting all undergraduate students from a public university (~17,000 undergraduate students) in coordination with Student Affairs at that University. Our final sample size will depend on consent rate in the approximately 2-4 weeks following an initial recruitment e-mail sent out by Student Affairs at the University.

The decision of how long the baseline survey will be available following the initial e-mail from Student Affairs (between approximately 2 and 4 weeks) will be made by coordinating with Student Affairs to assure the survey isn't competing with potential participation in other surveys administered by the University. The investigators will not look at the full data during the data collection process and the decision about the timing of the survey window will not be data dependent. (The project coordinator or other research assistants will download the data necessary to send out follow-up online surveys during data collection, but none of this data is an included variable in any pre-registered hypotheses).

The sample size will also vary based on technical issues and/or the exclusions explicitly laid out in the exclusions section of the pre-registration.

Other. Anything else you would like to pre-register? (e.g., secondary analyses, variables collected for exploratory purposes, unusual analyses planned?) (optional)

Exploratory analyses:

We may test the effectiveness of the intervention in reducing social anxiety disorder symptoms and drinking to cope.

We may also test whether the Feelings Disclosure intervention increases willingness to disclose sadness at least as much, if not more than the Self-Dislike Intervention. We will measure The Measure of Verbally Expressed Emotion, Sadness subscale pre and post intervention. We will first test if the assumptions necessary to interpret a multiple linear regression are met. If not, we

will apply the following corrective practices so that the regression is interpretable as in the primary analyses. We will document any of these changes when we report our results.

If assumptions are not met, we intend to predict the outcome variable (immediate post intervention willingness to disclose sadness) with the corresponding baseline variable (pre intervention willingness to disclose sadness) in a random forest. Residuals calculated from this model will be robust to assumptions from the linear model and will then be entered as the outcome variable whenever there is an outcome variable discussed below.

If the assumptions for interpreting a regression are met, pre intervention scores will be entered as covariates and treatment condition will be entered as the main predictor of post-intervention in multiple linear regressions. We will consider a p value of less than .05 for the treatment coefficient in favor of the feelings disclosure intervention a significant effect of treatment on change in willingness to disclose feelings. If yes, this indicates the feelings disclosure intervention could be a “positive control” with known effects, an even stronger comparison condition than a traditional placebo.

We may also use this data set for other, separate secondary analyses such as (but not limited to) creating an attitude network for fear of self-compassion, assessing which level of the self-hate scale corresponds to certain scores on the PHQ-9 and the IDAS-Dysphoria subscale, assessing the correspondence between the BDI self-dislike item and the self-hate scale, and assessing whether self-hate predicts drinking to cope above and beyond scores on the IDAS-Dysphoria scale using cross-validated linear models.