**Empowering Anxious Parents to Manage Child Avoidance Behaviors: A Randomized Trial of a Single-Session Intervention Targeting Parent Accommodation (Project BRAVE)**

Hypotheses, Aims, and Analytic Plan
August 31, 2020

**Study Timeline**
Recruitment is projected to begin in July 2020 and extend through approximately June 2021.

**NOTE:** This analytic plan was developed prior to the study's lead authors (Jenna Sung, Emma Mumper) downloading, seeing, or using any of the data collected as part of this trial. Similarly, other exploratory analysis will be pre-registered at a later date under the same conditions.

**Study Aims and Hypotheses**

The primary goals of the study will be as follows:

1. Examine the SSI's (ORR+Project BRAVE) direct effects on parental accommodation, relative to an information-only control (ORR+delayed SSI) at two weeks follow-up.
2. To assess whether parents' perceive their ability to help their child manage distress as *improved* immediately following the completion of the active SSI (ORR+Project BRAVE), compared to an information-only control (ORR+delayed SSI).
3. Evaluate the SSI's acceptability, per self-report ratings.
4. To assess whether parents' distress tolerance improves in the active SSI (ORR+Project BRAVE) condition versus the information-only control (ORR+delayed SSI) group at two weeks follow-up.

Hypotheses associated with each of these primary aims will be as follows:

1. Parental accommodation of child anxiety will decrease significantly more among parents assigned to the ORR+Project BRAVE group, relative to parents assigned to the ORR+waitlist group from baseline to 2-week follow-up
2. Relative to parents who receive ORR, parents who receive Project BRAVE will be more likely to perceive increases in their preparedness to cope with their child's distress from before to after completing their baseline session.
3. Participants assigned to the Intervention Group will find Project BRAVE to be acceptable, indicated by a mean score of > 3 (out of 5) across Program Feedback Scale items (completed by parents assigned to the intervention group at immediate post-intervention).
4. Parents' self-reported distress tolerance will decrease significantly more among parents in the ORR+Project BRAVE group relative to those ORR+waitlist group from baseline to 2-week follow-up

**Sample Size Justification**

Using G*Power 3.1, sample sizes needed to detect group differences in the primary outcome (changes in accommodation from baseline to follow-up) between the BRAVE group and the Control group of small (.2), medium (.5), and large effects (.8) based on an F test, linear multiple

regression with $\alpha = .05$ and power = 0.80 were 395, 55, and 25, respectively for the primary outcome (hypothesis 1). The target sample of 300 (150 per SSI condition accounting for attrition) reflects power to detect a small to medium effect as observed by previous SSI trials.

**Analytic Plan**

To address *hypothesis 1*, a multiple linear regression with intervention condition (1=ORR+Project Brave; 0=ORR+waitlist control) and baseline accomodation levels (sum score of the first 9 items of the Family accommodation scale with higher scores indicating higher levels of accommodation) as predictor variables will indicate whether ORR+Project BRAVE, versus ORR+delayed SSI access, led to differential reductions in accommodation behavior from baseline to 2-week follow up. A p-value of <.05 will indicate a significant change in parental accommodation from baseline to 2-week follow up.

To address *hypothesis 2*, we will use the two-sample t-test to determine whether the difference between the ORR+project BRAVE and ORR+delayed SSI access group's mean ratings of the perceived post intervention condition change item is significant. A p-value of <.05 will indicate a significant difference between the two conditions. Descriptive statistics of the scores for both conditions will be reported as well with a mean rating above 3 (out of 5) indicating an overall, subjectively-detectable pre-to-post change.

To address *hypothesis 3*, we will examine mean scores on the Program Feedback Scale from the intervention group only. A score above 3 on any given program feedback scale item will reflect endorsement of that item (e.g. positive feedback/adequate acceptability). Thus, a mean score of 3 or higher (out of 5) across participants in this study will indicate participants found the intervention acceptable.

To address *hypothesis 4*, a multiple linear regression with intervention condition (1=ORR+Project Brave; 0= ORR+waitlist control) and baseline parental distress in the context of child negative affect as predictor variables will indicate whether ORR+Project BRAVE versus ORR+delayed SSI led to greater reductions in parental distress from baseline to 2-week follow up. Parental distress will be indicated by the sum score of the distress tolerance scale. A p-value of <.05 will indicate a significant change in parental distress in the context of child negative affect from baseline to 2-week follow up.

**Testing Assumptions**

To justify the use of linear regression models for the purpose of prediction, we will check the following principle assumptions: 1) linearity and additivity of the relationship between dependent and independent variables, 2) statistical independence of the errors, 3) homoscedasticity of the errors, 4) normality of the error distribution. Nonlinearity will be tested by checking for a symmetric distribution of points on a plot of observed versus predictive values or residual versus predicted values. To check statistical independence of the errors, residual autocorrelations will be plotted to identify values that fall outside the 95% confidence band around zero. Homoscedasticity will be checked by plotting the residuals versus the predicted

values to examine the distribution of residual scores. Finally, normally distributed errors will be checked via normal probability plot to measure skewness and kurtosis.

**Missing Data**

We will impute any missing data using the expectation-maximization and bootstrapping algorithm implemented with Amelia II in R after running a sensitivity analysis to ensure that data is not missing at random. These imputed datasets allow for more conservative intent-to-treat analyses than listwise deletion or last-observation carried forward. We plan to impute as many datasets as there are percent of missing data for an outcome – rounding up to the next highest percentage (e.g., If 2.4% of data is missing on an outcome, we will create 3 imputed datasets). This process will allow us to retain high power even in the presence of missing data. Cohen's d effect sizes and 95% confidence intervals for analyses will be calculated using t-values for the treatment effects obtained from the analyses with the MOTE package in R.

**False Discovery Rate**

The false discovery rate (FDR) will be applied to identify potential false-positive results. Q-values will be computed for p-values from each mixed effects linear model using an online calculator applying Benjamini and Hochberg's approach Benjamini and Hochberg's approach (1995);www.sdmproject.com/utilities/?show=FDR). Results from tests described above will be considered significant if FDR corrected $q < 0.05$.

**Methodological Details Not Mentioned Elsewhere**

<u>Follow-up Period</u>
We are intending on a 2 week follow-up period from the SSI but will allow up to 5 weeks post-intervention. Participants will be reminded once every two days for 6 days (total of 3 reminders) to complete the post-intervention questionnaires.

<u>Operational Definition of Completion Rates for participants assigned to both conditions</u>

Intervention completion rates for the ORR+ Project BRAVE group will be treated as a categorical (full completers, psychoeducational content completers, personalized-plan completers).

Categorical definitions of completion rates are defined as follows: full completers are all participants who reached the end of the SSI content (slide Q254), psychoeducational completers are all participants who received all of the psychoeducational content of the program (slide Q235), and personalized-plan completers are all participants who completed the step-by-step action plan for responding in a helpful way to their child's anxiety or avoidance (slide Q243)

<u>Excluding Participants From Analysis</u>
Participants will be excluded from analyses *only* if it is apparent from their free responses during the SSI that they are non-english speakers. If a participant completes either the baseline or

follow-up survey more than once, their *more-complete* response will be used in analysis (if responses are equally-complete, their *first* response will be used).

Differential Dropout Rates

We will assess for differential follow-up rates among full completers in each group by using Z-tests of differential proportions where we compare the proportion of people who drop out before completing the follow-up (Y or N) as a function of treatment condition (1 = ORR+Project Brave; 0 = waitlist control).

For participants assigned to the ORR+ delayed SSI access group, a participant must have made it through all baseline measures (i.e., they must reach the final "page" of the baseline questionnaires, or the RCADS, though it is acceptable for the participant to leave the answer blank after seeing it) to be considered a "full completer". For participants assigned to the ORR+Project BRAVE group, a participant must have made it through all of the intervention (i.e. they must reach the final "page" of the intervention) to be considered a full completer.

To be considered a follow-up "completer", a participant must have made it through all of the questionnaires in the follow-up surveys (i.e. they must reach the final "page" of the follow-up questionnaires though it is acceptable for the participant to leave the answer blank after seeing it).

If the p value is greater than .05 we will assume dropout was not dependent on condition assignment and can proceed with interpreting the effects of intervention assignment. If the p value for this test is less than .05 we will conclude that dropout was dependent on condition assignment, and we will take the following steps to improve the interpretability of our results. Unequal dropout between treatment groups can introduce bias in trial results; however, this is not always the case (Bell, Kenward, Fairclough, & Horton, 2013; https://doi.org/10.1136/bmj.e8668). One major concern is that, if data is not missing at random, systematic differences may exist between "dropouts" and "completers" that cannot be corrected for, limiting the interpretability of our results. For example, if more control condition participants experienced a worsening of clinical symptoms and dropped out before completing follow-up measures, this worsening of symptoms would not be captured by completers' data (or by data imputed based on the available completers' data). Thus, should unequal dropout exist between conditions in the present study, we will report the results of our main analyses while highlighting (1) limitations to interpretation, and (2) ways in which this will inform future intervention development.

Further, if unequal dropout is present, we will run a sensitivity analysis to determine a range of possible effect sizes for our outcomes of interest, varying how much "dropout participants" may have changed on each outcome. To establish lower- and upper-end estimates of effect size, we will: (1) calculate residual change for each of our 3 outcomes, (2) identify the 25th and 75th percentile values for residual change in each outcome, (3) run analyses for each outcome where we impute the lower residual change value (25th percentile) for all dropouts/missing data, as well as the higher residual change value (75th percentile) for all dropouts/missing data. This approach explicitly assumes data are not missing at random, providing a more unbiased estimate of the overall treatment effect in the presence of unequal dropout.

Exploratory Moderation Tests

We will also conduct exploratory moderation tests examining various baseline variables as moderators of the SSI's impact on outcome, using the same approaches to missing data and corrections for multiple tests as described elsewhere in the pre-registration