

Pilot MRT: Main and Sensitivity Analyses

Lauren Zimmermann, Jamie Yap, Ewa Czyz

This document provides information on the main and sensitivity analyses performing for Aim 3, which is the micro-randomized trial (MRT) portion of the pilot study titled: *Developing text-based support for parents of adolescents after an emergency department visit*.

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I. Preface

We wish to remind the reader that, as a pilot study, this initial development of the proposed just-in-time adaptive intervention to deliver support for parents of suicidal adolescents served as a learning opportunity for gathering information about challenges with respect to implementing the intended study design. This information is critical to inform and overcome such feasibility considerations in the design of a full scale MRT.

As detailed in the documentation file titled *1. Pilot MRT Master Documentation*, the analytic sample for this pilot MRT entailed 40 parents of suicidal adolescents that were micro-randomized twice per day for the 6-week or 42-day (84 decision points per participant) study. Likewise, the sample size referred to throughout this document of $N=3,354$ participant-decision points arises from having $(39 \text{ parents} \times 84 \text{ decision points}) + (1 \text{ parent who withdrew on day } 40 \times 80 \text{ decision points}) - (1 \text{ parent} \times 2 \text{ decision points with delayed EMA completions discarded})$, across the MRT analytic sample of 40 parents.

Throughout the materials in this repository, we denote the intervention components of the adolescent-focused and parent-focused support mobile texts in italics as follows: *A-F text* and *P-F text*, respectively.

II. Research Question (RQ) 1 Analysis

As detailed in Section III of *1. Pilot MRT Master Documentation*, RQ 1 of this pilot MRT was to examine the effect of augmenting (vs. not augmenting) with a parent-focused (P-F) text intervention on proximal parent stress and affect. We perform the generalization of regression, by using and adapting the R code made available by Boruvka and colleagues (1) that accommodates a continuous outcome. Below is the estimating equation under consideration.

$$\mathbb{P}_N \left\{ \sum_{t=1}^T (Y_{t+\Delta_t} - B_t' \alpha - (A_t - p_t) Z_t' \beta)^2 \right\}$$

N=40 parents, T=84 decision times

where A_t is treatment at decision time t that is centered, $p_t = P[A_t = 1]$ denotes the known theoretical randomization probabilities, and $Y_{t+\Delta_t}$ represents a proximal outcome at time $t + \Delta_t$. B_t and Z_t are design matrices, with the former comprising time of day and day in study and the latter comprising a vector of ones representing a linear time trend. β is the causal excursion effect of interest with $\hat{\beta}$ being the estimator that minimizes the estimating equation, and α is the nuisance parameter. And \mathbb{P}_N denotes the average over participant-decision times in the sample.

The analytic sample was complete cases with respect to non-missing values in each proximal outcome. Because the proximal outcomes corresponded to separate items within the EMAs, participants may have responded to one item and not another. In turn, degree of missing values varies slightly between the considered proximal outcomes. For the primary proximal outcome of parent stress, the total number of participants was 40 parents and the total number of decision points was 2,245 participant-decision points with complete records included in RQ 1 analysis. The remaining observations are enumerated for the secondary proximal outcome of affect in **Figure 10**.

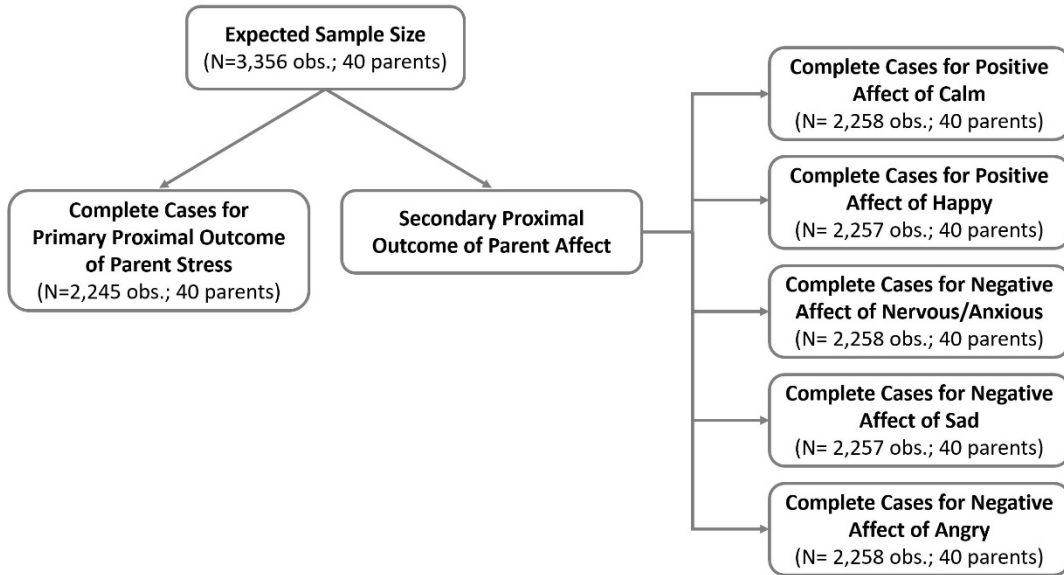


Figure 10. CONSORT diagram displaying the analytic sample for each proximal outcome. Note that observations (obs.) reflect decision points, that is instances where participants (parents of suicidal adolescents) were micro-randomized within the days in the study time period.

a. Additional Sensitivity Analyses

Table 1. Framework for assessing micro-randomization considerations.

	Including Day 28 (N= 2,245 participant-decision points, 40 parents)	Excluding Day 28 (N= 2,192 participant-decision points, 40 parents)
Apply $p_t = 0.5$	$\hat{\beta}_{A_c=A-0.5}(95\% CI)$	$\hat{\beta}_{A_c=A-0.5,noDay28}(95\% CI)$
Apply empirical $\hat{p}_t =$ {0.455 (95% CI: 0.438, 0.472) with day 28, 0.462 (95% CI: 0.445, 0.480) without day 28}	$\hat{\beta}_{A_c=A-0.455}(95\% CI)$	$\hat{\beta}_{A_c=A-0.455,noDay28}(95\% CI)$

Sensitivity Analysis 1. Restrict to not include day 28, where there was an apparent software glitch.

Table 1 column 3 reflects this approach.

Sensitivity Analysis 2. Apply the observed randomization probability of 0.455, instead of the constant randomization 0.50. **Table 1** row 2 reflects this approach.

Sensitivity Analysis 3. (a) Set missing values in the proximal outcome to be a low value and (b) set missing values to in the proximal outcome to be a high value (i.e., 1 and 5, respectively).

III. Research Questions 2 and 3 Analyses

As mentioned in Section III of *1. Pilot MRT Master Documentation*, the RQ 2 and RQ 3 herein were to determine if the effect of the parent-focused (P-F) text varies over time and to explore moderators, respectively. To examine a possible time trend, we first included the main effect of time. Next, an interaction term between time and the intervention assignment was included. Third, we examined whether a higher-order trend of time was present by including the main effect of time and a quadratic time. Consistent with the RQ 1 analysis, we included observations with non-missing values in the proximal outcome.

With respect to effect moderation, we explored a list of candidate moderators, as hypothesized by the implementation scientists, for the effect of augmentation with P-F on subsequent proximal parent stress and proximal parent affect, respectively.

Figure 11 and **Figure 12** show the self-reported stress of parents over the course of the study. In both plots, parent stress visually appears to be decreasing in a linear manner over the study time period. We examined similar plots for the secondary proximal outcomes of positive affect and negative affect; congruently, the time trends were linearly increasing and decreasing, respectively.

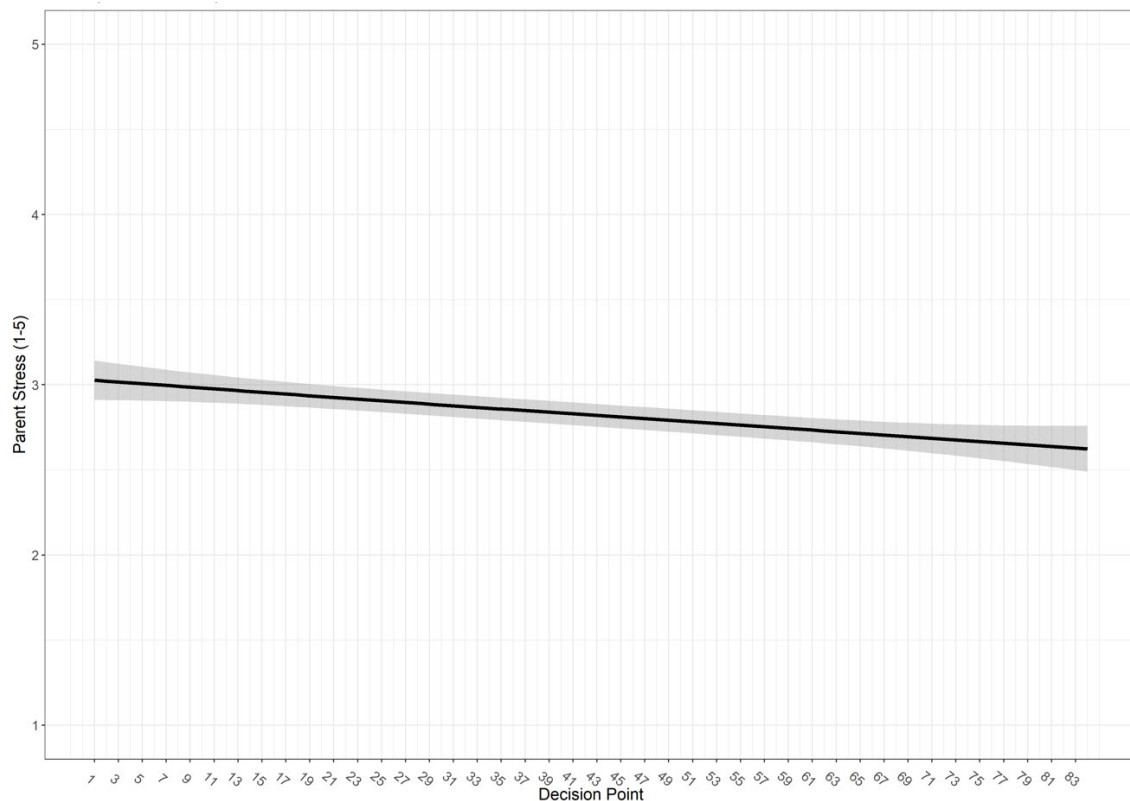


Figure 11. Empirical mean of parent-reported stress at each decision point.

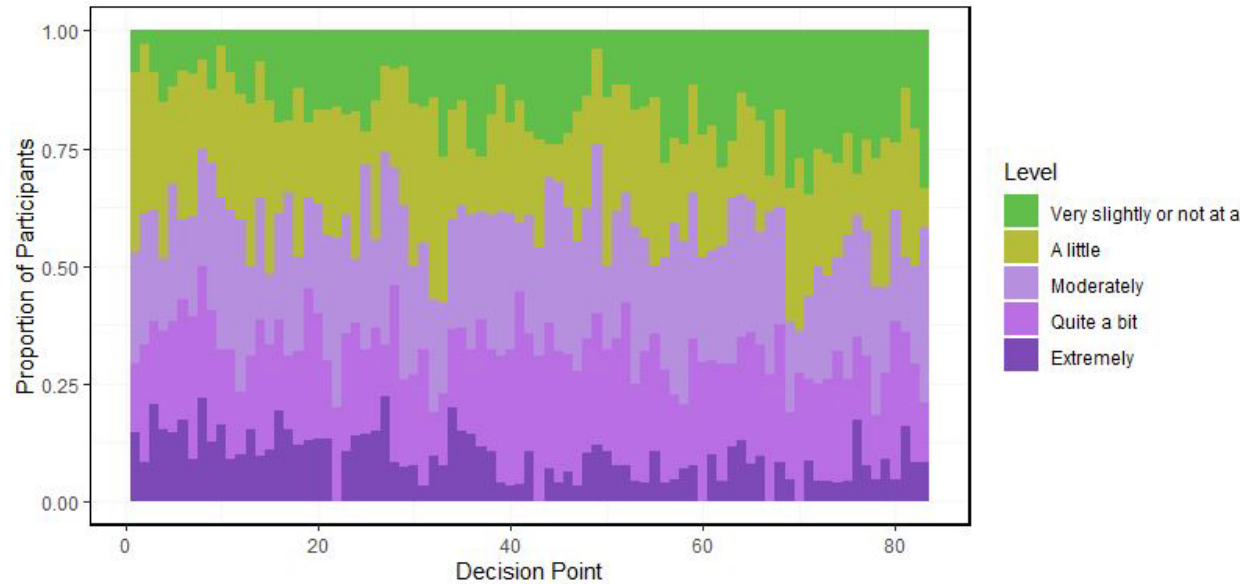


Figure 12. Summary statistics on self-reported stress among parents who completed EMA item at each decision point: empirical proportion of parents reporting each response option are displayed by decision point.

IV. References

1. Boruvka A, Almirall D, K Witkiewitz, Murphy SA. *J Am Stat Assoc.* 2018;113:523, 1112–1121.