Pilot MRT: Documentation for Micro-Randomized Trial

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This document details the study design and data processing for Aim 3, which is the pilot 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 served as a learning opportunity for gathering information about challenges with respect to implementing the intended study design, and that this information is critical to inform and overcome such feasibility considerations in the design of a full scale MRT.

II. Brief Background and Motivation

- Suicide is 3rd leading cause of death among youth; 57% increase in youth suicide 2007-18.[1]
- Post-discharge period is high-risk,[2] wherein ≥1 ED-based intervention is recommended.[3]
- Parents are critical in supporting youth, such as through offering support, ensuring lethal means restriction and treatment access.[4]
- Parents may be distressed/overwhelmed,[5] reporting low confidence in engaging in suicidal prevention.[6]

Goal: Develop text-based intervention for parents to help them support their adolescent (adolescent-centered component) as well as improve their own well-being (parent-centered component). For the latter, develop a just-in-time-adaptive-intervention (JITAI) to address time-varying nature[7] of parents' stress and youth functioning. Note that the content in this document pertains to documentation for the analysis of the experimental design of a micro-randomized trial, which is purposed with developing an optimized JITAI.

III. Aims/ Research Questions (RQ) of Pilot Micro-randomized Trial

RQ 1. Explore whether, on average, there is a proximal effect of providing parents with *P-C text* on proximal parent stress (primary outcome) and affect (secondary outcome).

RQ 2. Explore whether the proximal effect of *P-C text* on proximal parent stress and affect varies over time.

RQ 3. Explore whether the proximal effect of *P-C text* on proximal parent stress and affect is moderated by a set of time-varying variables (e.g., teen's well-being at prior observation) and baseline variables (e.g., parent's stress severity assessed at baseline).

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

IV. Study Design

A. Study Participants and Overall Study Time Frame

A sample of 120 pairs of parents and adolescents aged 13-17 years were enrolled in the trial (see Czyz et al. *J Consult Clin Psychol*). Participants were recruited from a Psychiatric Emergency Department (ED)

between November 2021 to June 2022. Among these dyads, 41 ***parents*** were randomized to take part in the micro-randomized portion of the study. Of these 41 parents, 1 participant withdrew on Day 1 of the study and, as such, did not take part in the MRT (did not experience micro-randomizations nor surveys). Hence, ***N=40 parents*** were included in the analytic sample for this MRT.

From here onward, we will focus on the N=40 parents in the MRT analytic sample.

B. The Micro-Randomized Trial (MRT)

After initial randomization, the N=40 parents were followed for 42 days (6 weeks) following enrollment.

a. Intervention Options and Schedule of Micro-randomizations

Figure 1A displays the trial design for this study. Parents were micro-randomized twice daily in the morning and the evening with a fixed randomization probability of 0.5 to either provide *Parent-Centered (P-C) Text* or not. The micro-randomizations occurred in the study platform. The welcome message was provided when participants were enrolled in the study, and the first occurrence of a randomization was one day after the welcome message was sent by the platform.

Definition of 'Day 0' and 'Day 1': In no instance was there ever a parent who was not micro-randomized exactly one day after the welcome message was sent by the platform. Hence, we define:

- 'Day 0': the day (post enrollment) when the welcome message was sent by the platform
  Note: All baseline assessments were completed by parents and adolescents at the index ED visit.
- 'Day 1': the day when the first micro-randomization occurred

From here onward, we use these definitions of 'Day 0' and 'Day 1'.

b. Proximal Outcomes and Schedule of Ecological Momentary Assessments (EMA)

Proximal outcomes were parent stress (primary) and parent affect--negative and positive (secondary), measured via ecological momentary assessments (EMAs) in the morning (prior to the morning randomization) and in the evening (prior to the evening randomization), both treated as continuous (range: 1-5). The window for the morning survey was typically 9-11am whereas the window for the evening survey was typically 6-8pm.

The diagram for the MRT design is shown in Figure 1.

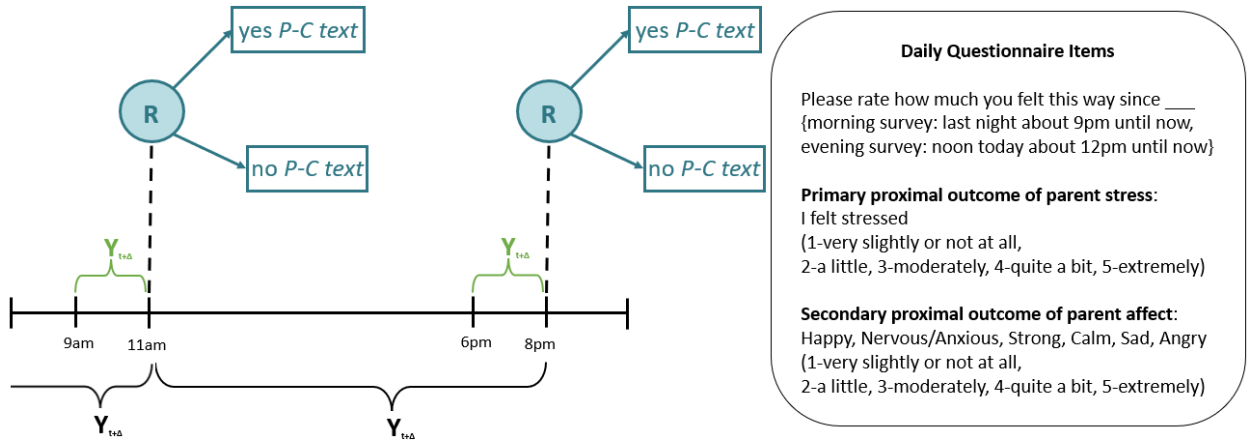

Figure 1. Diagram of MRT portion of trial design

Notes: Assignment of randomization (represented by encircled *R*) to *Parent-Centered (P-C) text* is further denoted by A_t (i.e., 1/0 at decision time t) and proximal outcomes of parent stress and affect are denoted by $Y_{t+\Delta_t}$. The MRT involves providing vs. not providing *P-C text.*

[1] $Y_{t+\Delta_t}$ in green-colored font denotes the time during which the proximal outcome was measured in the daily questionnaire window, whereas $Y_{t+\Delta_t}$ in black-colored font reflects the look-back of the observed proximal outcome.

V. Participants Who Requested to Be Withdrawn from the Study

Among the 40 participants in the analytic sample for the MRT, one participant requested to stop receiving texts on day 40 (out of 42 days) from the study.

- **Main Analysis**: We do not include this participant's observations on Days 41 and 42 in any analyses; for this participant, only observations between Days 1 to 40, inclusive, are included in all analysis.

From here onward, we will only refer to the remaining $(39\ parents \times 42\ days \times 2\ times\ per\ day) + (1\ parent \times 40\ days \times 2\ times\ per\ day) = 3,356$ decision points.

VI. Issues Relating to the Delivery of Intervention Components

In rare instances, P-C text messages sent by the software were not received by parents. For example:

- There were rare instances when parents were randomized to *P-C* in either the morning decision point or the evening decision point (or randomized to *P-C* at both decision points) but, to our

knowledge, did not receive a P-C text message in at least one decision point for that day. In these instances, parents received one text message less than the total number of text messages they were supposed to receive for that day.

There are three reasons:

(R1) ***Platform Glitch***: There was a platform glitch on June 13 to June 14, 2022, wherein a parent sent a "STOP" indication to stop texts on 12 June 2022 and the platform unintentionally halted P-C text messages for another participant during this time.

(R2) ***Mobile Phone Carrier Network Issue***: There was a network issue that resulted in failed messages on select participant-days.

(R3) ***Unknown/Cannot be Determined***: There were platform malfunctions, due to an unknown cause, which resulted in the undelivered texts in rare participant-days.

Table 1a displays the number of participants and decision points impacted by this issue. As we can see, 18 out of 3,356 (or 0.5%) decision points were impacted.

Decision:

- **Main Analysis:** We will retain all impacted decision points in all analyses (7+11+1,671+1,667 = 3,356 decision points; see Table 1b).
- **Sensitivity Analysis:** We will perform the following sensitivity analysis: restrict the dataset to exclude all impacted decision points (7+11 = 18 decision points; see Table 1b).

Table 1a. A summary of the number of participants and number of decision points impacted according to reason why text message was not delivered

	Total # Participants Impacted	# Decision Points Impacted		
Reason why text message was not delivered		# Decision Points in the Morning	# Decision Points in the Evening	Total # Decision Points
(R1) Platform glitch	1	1	1	2
(R2) Mobile phone carrier network issue	2	0	2	2

(R3) Unknown/ Cannot be Determined	4	6	8	14

Table 1b. A summary of the total number of participants and decision points included in main analysis and sensitivity analysis.

Impacted by (R1), (R2), **or** (R3)			**Not** impacted by (R1), (R2), **and** (R3)			
Total # Participant IDs Impacted	# Decision points in the morning	# Decision points in the evening	Total # Participant IDs Not Impacted	# Decision points in the morning	# Decision points in the evening	Grand Total # Decision Points
7	7	11	33	1,671	1,667	3,356

VII. Issues Relating to Delivery of Ecological Momentary Assessments (EMA)

A. EMAs Completed Outside of Intended Schedule

In rare instances, the delivery and completion of EMA did not follow the intended schedule. Although the bulk of EMA completions were within scheduled survey time windows for the morning and evening, a few were submitted later than expected by parents.

There are two reasons:

(R1) ***Survey Timed Out***: Parents may have forgotten to click submit on the surveys and returned to the browser at a later time to submit.

(R2) ***Unknown/Cannot be Determined***: There were platform malfunctions, due to an unknown cause, which may have enabled participants to access surveys after the close of the window.

Table 2a displays the number of participants and decision points impacted by this issue. As displayed, 29 out of 3,356 (or 1%) decision points were impacted.

Decision:

- **Main Analysis**: Of these 29, we will discard 6 EMA completions because they were substantially outside of the time window and conflicting with the study design.

Table 2a. A summary of the number of participants and number of decision points where parents completed subsequent EMA outside of survey window

Reason why EMA was outside of survey window	Total # Participants Impacted	# Decision Points Impacted		
		# Decision Points in the Morning	# Decision Points in the Evening	Total # Decision Points
(R1) Survey timed out	2	3	0	3
(R2) Unknown/ Cannot be Determined	14	17	9	26

Table 2b. A summary of the total number of participants and decision points impacted and included in main analysis and sensitivity analysis.

Impacted by (R1) **or** (R2)			**Not** impacted by (R1) **and** (R2)				
Total # Participant IDs Impacted	# Decision points in the morning	# Decision points in the evening	Total # Participant IDs Not Impacted	# Decision points in the morning	# Decision points in the evening	Total # Decision Points	Grand Total # Included Decision Points
16	20	9	24	1,658	1,669	3,356	3,354

Figure 3 shows the distribution of time elapsed from randomization to EMA completion, after addressing these instances where the EMA completion was delayed past the survey time window.

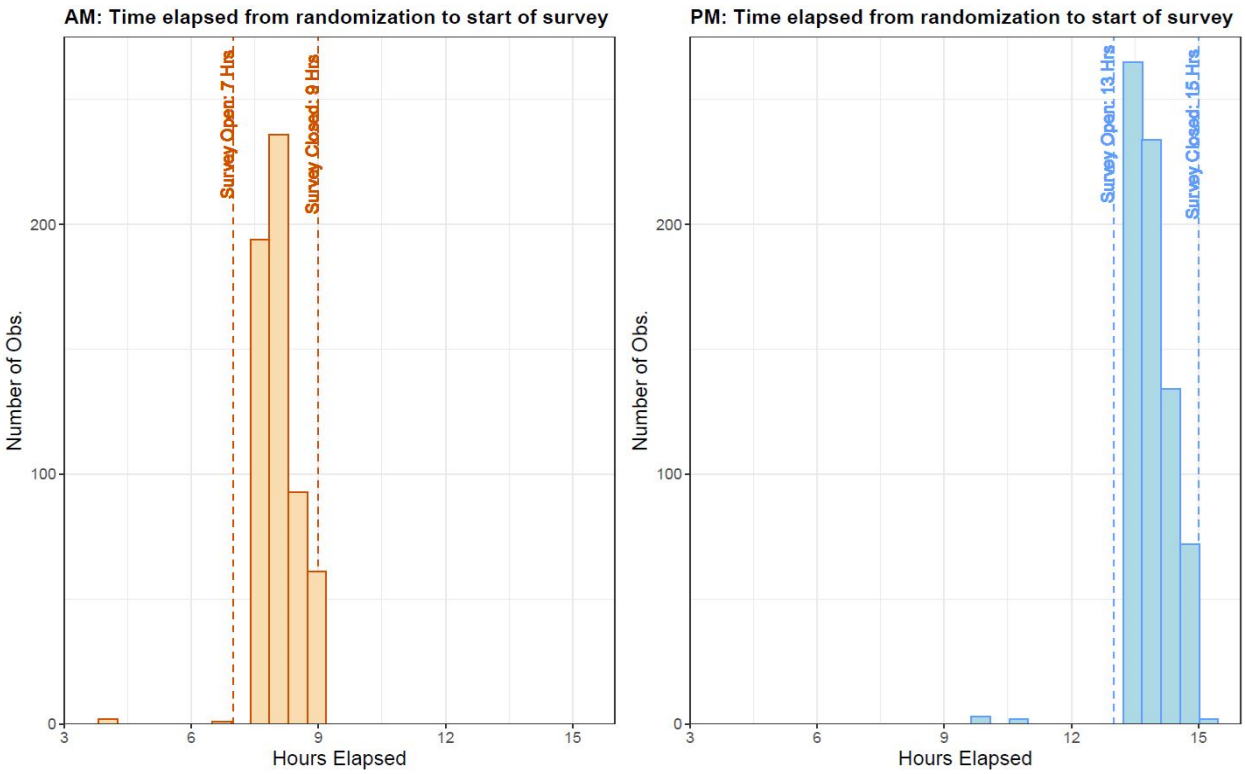

Figure 3. Time elapsed from randomization assignment to proximal outcome over study time period

B. *EMAs Completed Within 1-hour Grace Period*

There were 17 surveys that were completed within the 1-hour grace period.

Table 3a summarizes the number of participants and decision points where this is the case. As displayed, 17 out of 3,356 (or 0.2%) decision points were encompassed.

Table 3a. A summary of the total number of participants and decision points impacted and included in main analysis and sensitivity analysis

Impacted by (D1) **or** (D2)			**Not** impacted by (D1) **and** (D2)			
Total # Participant IDs Impacted	# Decision points in the morning	# Decision points in the evening	Total # Participant IDs Not Impacted	# Decision points in the morning	# Decision points in the evening	Grand Total # Decision Points
11	10	7	29	1,668	1,671	3,356

C. Two or More EMAs Completed per Decision

For select EMA completions, there were multiple submissions (generally two and up to three), in that parents submitted two (or three, in rare instances) survey responses within one survey window.

Table 4a displays the number of participants and decision points impacted by this issue. As demonstrated, 70 out of 3,356 (or 2.1%) decision points were impacted in the context of the MRT study arm. Although this was widespread in that 75% of participants were impacted, the percentage of decision points (2.1%) it impacted was small.

Decision:

- **Main Analysis**: We will keep the first survey submission when fully complete (i.e., all items in the questionnaire were filled out by the parent). That is, there were four instances that were exceptions where the first recorded submission was not fully complete and we will retain the second recorded submission instead. Table 4b detail these four instances.
- **Sensitivity Analysis**: We will perform the following sensitivity analysis: keep the second survey submission (instead of the first) for impacted decision points where there was a duplicate EMA completion.

Table 4a. A summary of the number of participants and number of decision points where parents sent in a two or more EMA completions.

	Total # Participants Impacted	# Decision Points Impacted		
Description		# Decision Points in the Morning	# Decision Points in the Evening	Total # Decision Points
(D1) First duplicate survey complete	25	34	32	66
(D2) First duplicate survey not complete, retain second duplicate survey instead	4	3	1	4

Table 4b. A summary of the total number of participants and decision points impacted and included in main analysis and sensitivity analysis

Impacted by (D1) **or** (D2)			**Not** impacted by (D1) **and** (D2)			
Total # Participant IDs Impacted	# Decision points in the morning	# Decision points in the evening	Total # Participant IDs Not Impacted	# Decision points in the morning	# Decision points in the evening	Grand Total # Decision Points
29	37	33	11	1,641	1,645	3,356

Figure 4 enumerates the decision points remaining in analytic sample (N=3,354 obs.; 40 parents) after excluding those (2 obs.) with EMAs delayed past the survey grace period, for which there was no second duplicate survey to retain within the time window.

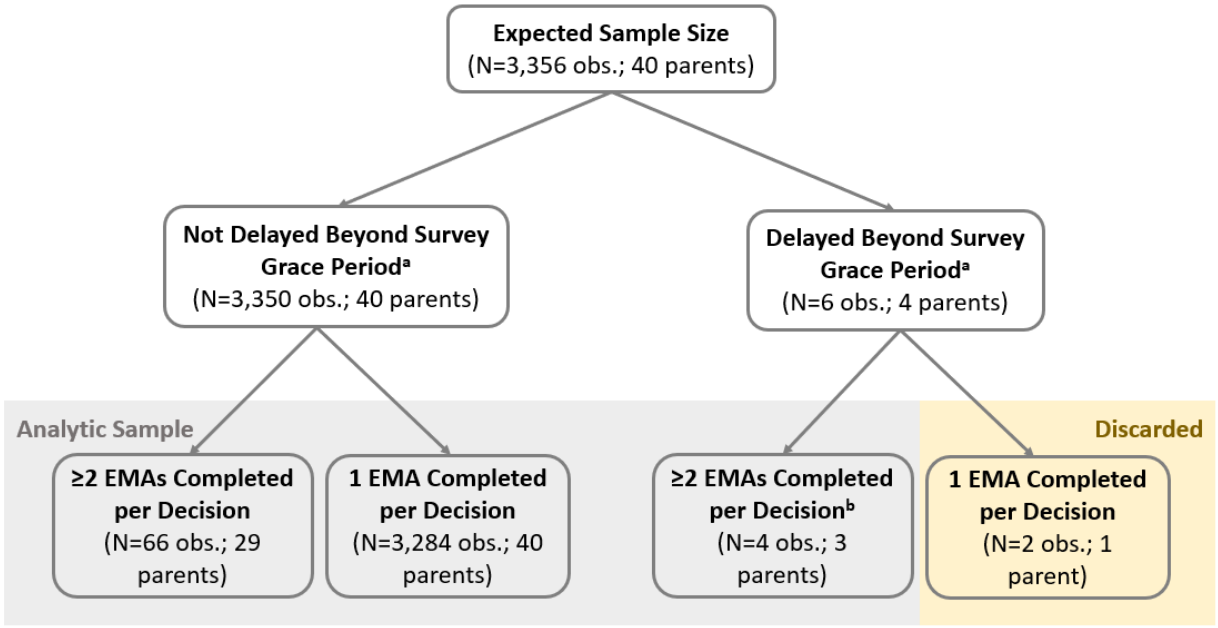

Figure 4. Decision points remaining after excluding due to EMAs completed considerably outside of intended schedule. Notes: (a) there was a brief grace period for each survey window as detailed above, and (b) if there was a second duplicate survey within the time window, we retained the second duplicate survey.

VIII. References

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