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 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 is high-risk,[2] wherein ≥1 ED-based intervention is recommended.[3]
- Parents are critical in supporting youth, such as through lethal means restriction and treatment access.[4]
- But are distressed/overwhelmed,[5] with low confidence in engaging in suicidal prevention.[6]

Goal: Develop text-based intervention for parents that will help them not only support their adolescent (adolescent-focused component) but also improve their own wellness (parent-focused component). For the latter, develop a just-in-time-adaptive-intervention (JITAI) to address time-varying nature[7] of parents' stress. 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. Examine whether, on average, there is a proximal effect of augmenting with *P-F text* on proximal parent stress and affect. Throughout, the former and the latter are the primary proximal outcome and secondary proximal outcome, respectively.

RQ 2. Determine whether the proximal effect of augmenting with *P-F text* on proximal parent stress and affect varies over time.

RQ 3. Explore whether the proximal effect of augmenting with *P-F text* on proximal parent stress and affect is moderated by prior parent stress and affect.

RQ 4. Investigate whether, on average, there is an association between parent stress at decision point t and the distal outcome of parental self-efficacy at week 12 (study end).

Note: 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.

IV. Study Design

A. Study Participants and Overall Study Time Frame

A sample of 120 pairs of parents and suicidal adolescents aged 13-17 years were enrolled in the trial. Participants were recruited from Psychiatry Emergency Services at Michigan Medicine between November 2021 to June 2022. Among these dyads, 41 ***parents*** were entered in a micro-randomized trial

after the initial randomization (see CONSORT diagram in Primary Reference). Of these 41 parents, 1 participant withdrew on Day 1 of the study and, as such, did not have a consecutive prior randomization assignment and subsequent proximal outcome measurement. 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) post discharge of the teen from the emergency department.

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 at 11am and in the evening at 8pm with a fixed randomization probability of 0.5 to either augment *Adolescent-Focused (A-F) Text* with *Parent-Focused (P-F) Text* or not augment. The micro-randomizations occurred in the study software platform. The welcome message was a pre-requisite for any subsequent randomization to occur. Likewise, 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 ED discharge) when the welcome message was sent by the platform
  Note: All baseline assessments were completed by parents at the index ED visit. These assessments included questions on Demographics, Perceived Social Support, Parental Coping Self-Efficacy, and Parental Depression and Anxiety Symptoms.
- '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) between 8-11am and 6-8pm, both treated as continuous (range: 1-5). Distal outcome was parent self-efficacy measured via follow-up surveys at week 2, week 6, and week 12, treated as continuous (sum across 10 items [0-10 scale] with

range: 0-100). EMAs were administered using Qualtrics to parents via a text message with the link to each survey.

Exceptions: To accommodate off-hour work shifts of one parent, the window for morning survey completion were adjusted to be between 6am-11am. Their micro-randomizations remained at 11am and 8pm like all other participants.

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

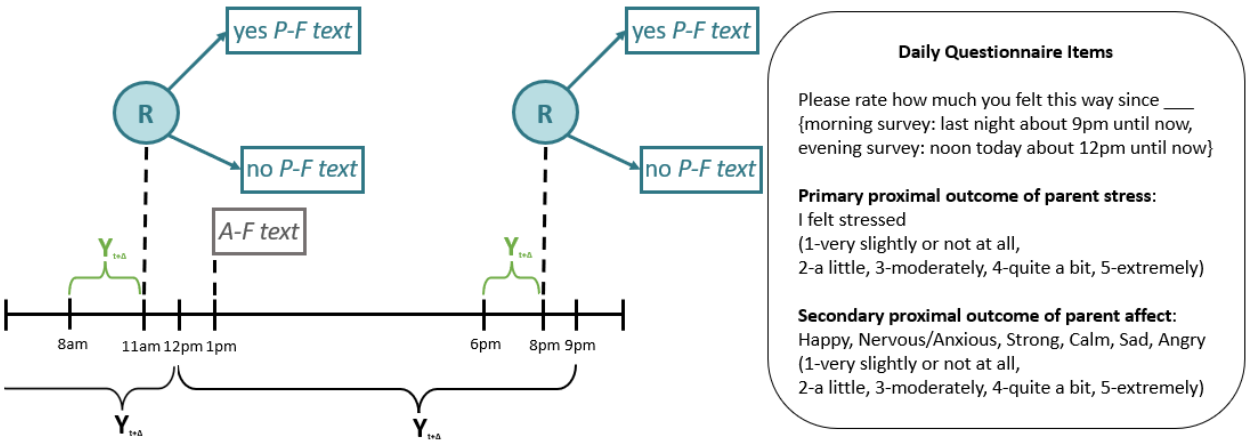

Figure 1. Diagram of MRT portion of trial design

Notes: Assignment of randomization (represented by encircled *R*) to *P-F text* denoted by A_t (i.e., 1/0 at decision point t), on proximal parent stress and affect, i.e., on a proximal outcome denoted by $Y_{t+\Delta_t}$. The intervention components are *Adolescent-Focused (A-F) text* was augmented (or not augmented) with *Parent-Focused (P-F) text.*

[1] *A-F text* was delivered every day in the study, regardless of the intervention a participant was randomized to in the morning or evening

[2] In this figure, 11am-12pm and 8pm-9pm are "grace periods", in that participants were permitted (by design of the study) to complete surveys during the grace period, if they could not complete it within the initial block of time they were allocated

[3] Observe that the block of time to complete the survey in the morning is 3-hours long (8am-11am; and 5-hours long from 6am-11am for exception case) while the block of time to complete the survey in the evening is 2-hours long (6pm-8pm). We emphasize that the incongruence in number of hours in the morning and evening was by design.

[4] $Y_{t+\Delta_t}$ in green-colored font denotes the proximal outcome during the intended schedule, whereas $Y_{t+\Delta_t}$ in black-colored font denotes the observed and permitted proximal outcome.

Figure 2 provides examples of the base adolescent-focused mobile text messages and the augmented parent-focused (P-F) texts in this MRT, as well as the categories for the P-F texts.

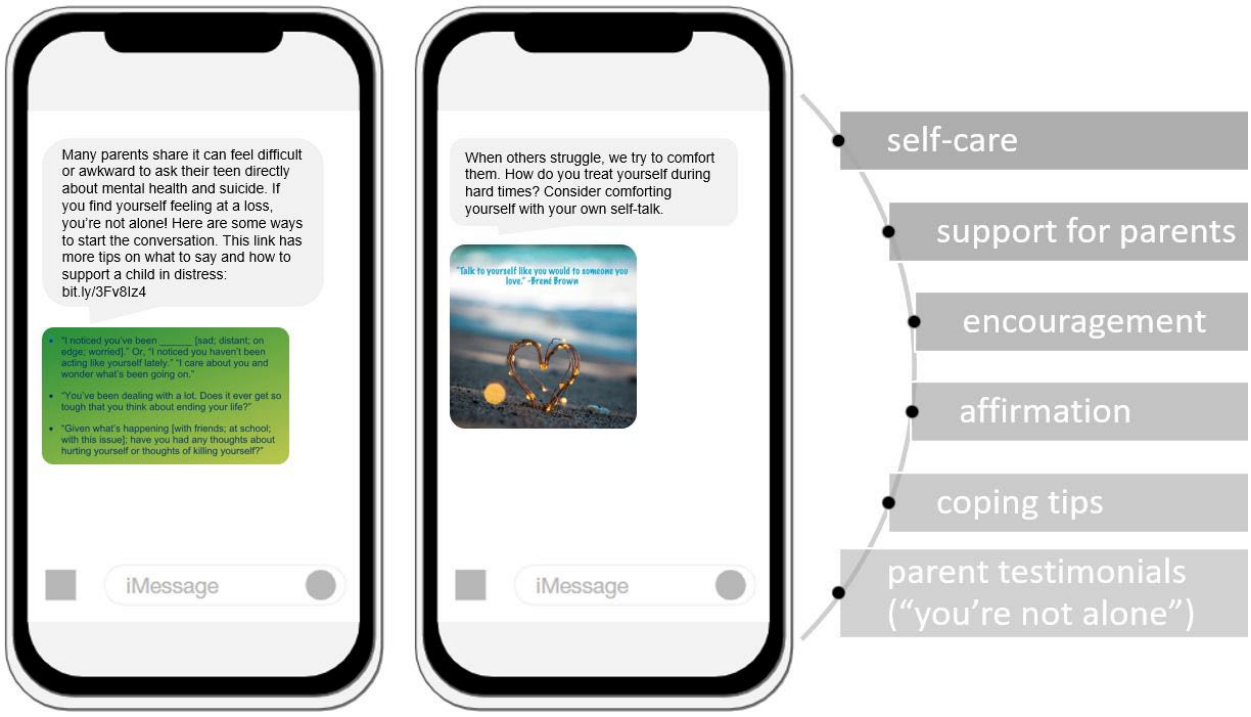

Figure 2. Examples of adolescent-focused (left) and parent-focused (right) support messages. Categories for parent-focused texts (right).

V. Participants Who Requested to Be Withdrawn from the Study

Among the 40 participants in the analytic sample for the MRT, one participant (participant ID 418) requested to be withdrawn on day 40 (out of 42 days) from the study.

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

<u>From here onward, we will only refer to the remaining $(40 \times 84) - (2 \times 2) = 3,356$ decision points.</u>

VI. Issues Relating to the Delivery of Intervention Components

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

- There were rare instances when parents were randomized to *P-F* in either the morning decision point or the evening decision point (or randomized to *P-F* at both decision points) but never received a P-F 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 both phone numbers on 12 June 2022 and the platform unintentionally halted P-F 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 1c).
- **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 1c).

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 participant IDs and decision points impacted according to reason why text message was not delivered

	Participant IDs Impacted	File with Decision Points Impacted	
Reason why text message was not delivered		Decision Points in the Morning	Decision Points in the Evening
(R1) Platform glitch	ID 419	See "list decision points Ib-R1-1.csv"	See "list decision points Ib-R1-2.csv"
(R2) Mobile phone carrier network issue	IDs 366, 368	See "list decision points Ib-R2-1.csv"	See "list decision points Ib-R2-2.csv"
(R3) Unknown/ Cannot be Determined	IDs 325, 396, 397, 420	See "list decision points Ib-R3-1.csv"	See "list decision points Ib-R3-2.csv"

Table 1c. 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 (namely, delayed beyond survey windows by 4.1 to 13 hours; see Table 2c).

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

	Total # Participants Impacted	# Decision Points Impacted		
Reason why EMA was outside of survey window		# 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 participant IDs and decision points where parents completed subsequent EMA outside of survey window

		File with Decision Points Impacted	
Reason why EMA was outside of survey window	Participant IDs Impacted	Decision Points in the Morning	Decision Points in the Evening
(R1) Survey timed out	IDs 337, 396	See "list decision points IIb-R1-1.csv"	None
(R2) Unknown/ Cannot be Determined	IDs 312, 320, 323, 324, 331, 346, 374, 376, 378, 382, 383, 394, 397, 409	See "list decision points IIb-R2-1.csv"	See "list decision points IIb-R2-2.csv"

Table 2c. 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.

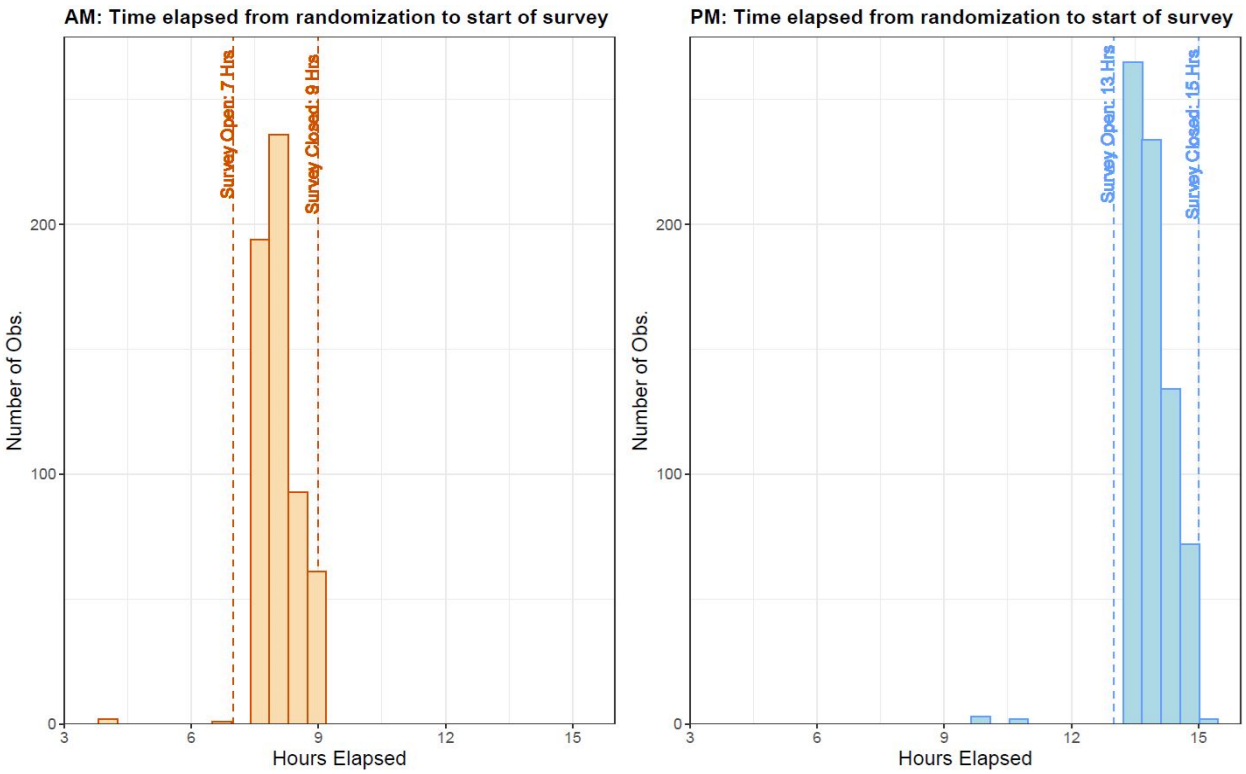

Figure 3. Time elapsed from randomization assignment to proximal outcome over study time period

B. *EMAs Completed Within Grace Period*

Even if the delivery of and completion of EMAs followed the intended schedule, we found this occurred infrequently in that 17 surveys were completed within the one-hour grace period (note that this would have been after micro-randomization, as displayed above in Figures 1A and 1B).

Table 4a 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 4a. 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. Tables 4b and 4c 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 participant IDs and decision points where parents sent in a two or more EMA completions.

Description	Participant IDs Impacted	File with Decision Points Impacted	
		Decision Points in the Morning	Decision Points in the Evening
(D1) First duplicate survey complete	ID 306, 309, 312, 321, 323, 329, 331, 337, 356, 361, 362, 369, 374, 376, 378, 382, 383, 394, 396, 399, 407, 409, 411, 420, 423	See "list decision points IVb-D1-1.csv"	See "list decision points IVb-D1-2.csv"
(D2) First duplicate survey not complete, retain second duplicate survey instead	IDs 324 [1], 395 [2], 397 [3], 398 [4]	See "list decision points IVb-D2-1.csv"	See "list decision points IVb-D2-2.csv"

Notes:
[1] This was blanks for 1st record and partial complete for 2nd record.
[2] This was blanks for 1st record and fully complete for 2nd record.
[3] This was partial complete for 1st record and fully complete for 2nd record.
[4] This was partial complete for 1st record and blanks for 2nd record.

Table 4c. 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.

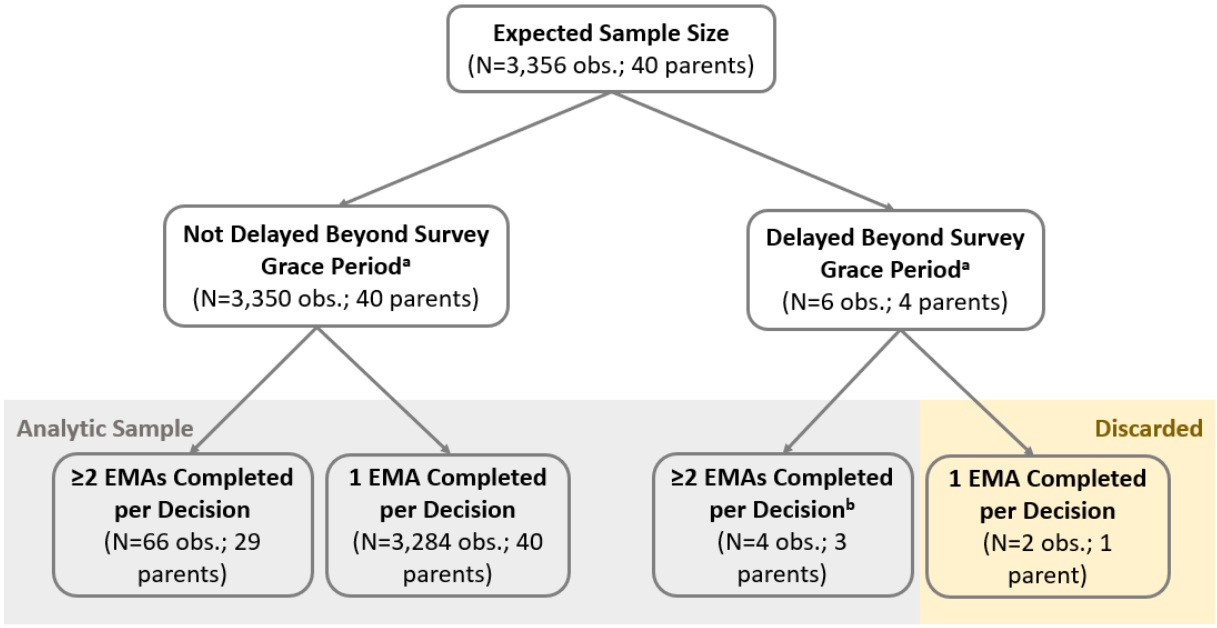

Figure 4. Decision points remaining after excluding due to EMAs completed substantially outside of intended schedule. Notes: (a) there was a one-hour grace period for each survey window, and (b) in the case of a delayed EMA completion beyond the survey grace period, if there was a second duplicate survey within the time window, we retained the second duplicate survey.

VIII. References

1. SC Curtin, M Heron, CDC, NCHS Data Brief, No. 352 (2019)

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