**Registry of Efficacy and Effectiveness Studies**

**Study Title:**
Evaluation of Mobile Messaging on Responsive Caregiving: Bright By Text Study

**Registry ID: 7680.1v1**

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**Version History**

**The first version of this entry was published on August 9, 2021 2:37:33 PM EDT**
Currently viewing this version.

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**Section I: General Study Information**

**PI name:** Elisa Garcia
**PI affiliation:** SRI International

**Co-PI name:** Sarah Gerard
**Co-PI affiliation:** SRI International

**Co-PI name:** Todd Grindal
**Co-PI affiliation:** SRI International

**Co-PI name:** Claire Christensen
**Co-PI affiliation:** SRI International

**Primary Funding Source(s):**
Overdeck Family Foundation
The David and Lucile Packard Foundation

**Award Number(s):**
The David and Lucile Packard Foundation: 2019-69707
Overdeck Family Foundation: Proposal 19-071-653-EDF

**IRB Name:**
SRI International Institutional Review Board

**IRB Approval Date:**
3/16/2020

**IRB Approval Number:**
50274

**Other Registration Name:**
-

**Other Registration Date:**
-

**Other Registration Number:**

-

**Study Start Date:**
5/18/21

**Study End Date:**
2/28/2022

**Intervention Start Date:**
5/18/21

**Timing of entry:**
Prior to collection of outcome data

**Brief Abstract:**
The Mobile Messaging on Responsive Caregiving study will evaluate the impact of two mobile messaging programs intended to improve responsive caregiving, attitudes, knowledge, and confidence of parents of young children. The study's primary goal is to build the evidence base on the use of mobile messaging-based behavioral interventions as a support for parents of young children. To examine the impacts of two mobile messaging programs on parent outcomes, we will conduct one experimental study of mobile messages provided by Bright By Text and one quasi-experimental study of mobile messages provided by Too Small To Fail/Univision. Outcomes will be measured using parent pre- and post- intervention surveys.

This entry describes the experimental study of mobile messages provided by Bright By Text. SRI will recruit up to 500 parents, dependent upon the rate at which parents sign up for the study over a 4-month period. As parents enroll in Bright By Text during the 4-month study recruitment period, Bright By Text will invite those with children in the eligible age range to participate in the study. SRI will screen for eligibility: Participants must have an 18- to 36-month-old child, must not already be enrolled in Bright By Text, and must complete the baseline survey. Upon consenting, all participating parents will take a baseline online survey. Half of the parents who complete the baseline survey will be randomly assigned to a treatment group and half to a waitlist control group. The treatment group will receive typical messages from Bright By Text for 12 weeks. Parents assigned to the control group will receive 3-4 placebo messages during the study, to include reminders that they are participating in a study and nutrition tips. Parents in both groups may opt out of the study at any time, and parents in the treatment group may opt out of receiving messages at any time. We will invite all participants (treatment and control) to complete a second brief survey via mobile phone 12 weeks after they enrolled in the study. Parents assigned to the control group will then be offered the full Bright By Text mobile messaging program, and parents in the treatment group will continue to receive messages as desired.

**Keywords:**
Randomized control trial, RCT, Quantitative, Parenting, Early childhood, Mobile messaging

**Comments:**
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*Section II starts on the next page.*

## Section II: Description of Study

**Type of Intervention:**
Curriculum/Product, Mobile messaging program for parents

**Topic Area of Intervention:**
Early Childhood Education, Education Technology, Parenting

**Number of intervention arms:**
1

**Target school level:**
18-36 months

**Target school type:**
National recruitment

**Location of Implementation:**
United States

**Further description of location:**
Recruitment will be conducted in the United States only and will not be localized to any states or regions. Bright By Text uses both national (e.g., social media) and regional (e.g., local partnerships) approaches to recruit parent users, who may be invited to participate in the study if they sign up for Bright By Text during the recruitment window and meet eligibility criteria.

**Brief Description of Intervention Condition:**
The treatment group will receive typical messages from Bright By Text for 12 weeks. Parents in both groups may opt out of the study at any time, and parents in the treatment group may opt out of receiving messages at any time.

**Brief Description of Comparison Condition:**
Parents assigned to the control group will receive 3-4 placebo messages during the study, to include reminders that they are participating in a study and nutrition tips. Parents in both groups may opt out of the study at any time. We will invite all participants (treatment and control) to complete a second brief survey via mobile phone 12 weeks after they enrolled in the study. Parents assigned to the control group will then be offered the full Bright By Text mobile messaging program.

**Comparison condition:**
Other

**Comments:**
Participants in the control group will receive delayed treatment after collection of outcome measures.

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## Section III: Research Questions

**Confirmatory research questions:**

**Question 1:**
Does providing 12 weeks of access to the Bright By Text mobile messaging program improve responsive caregiving among parents of children ages 18 to 36 months, as compared to business as usual?

**Question 2:**
Does providing 12 weeks of access to the Bright By Text mobile messaging program improve parenting attitudes among parents of children ages 18 to 36 months, as compared to business as usual?

**Question 3:**
Does providing 12 weeks of access to the Bright By Text mobile messaging program improve parenting knowledge among parents of children ages 18 to 36 months, as compared to business as usual?

**Question 4:**
Does providing 12 weeks of access to the Bright By Text mobile messaging program improve confidence in parenting among parents of children ages 18 to 36 months, as compared to business as usual?

**Exploratory research questions:**
**Question 1:**
How does the impact of providing 12 weeks of access to the Bright By Text mobile messaging program on responsive caregiving among parents of children ages 18 to 36 months vary by demographic variables?

**Question 2:**
How does the impact of providing 12 weeks of access to the Bright By Text mobile messaging program on parenting attitudes among parents of children ages 18 to 36 months vary by demographic variables?

**Question 3:**
How does the impact of providing 12 weeks of access to the Bright By Text mobile messaging program on parenting knowledge among parents of children ages 18 to 36 months vary by demographic variables?

**Question 4:**
How does the impact of providing 12 weeks of access to the Bright By Text mobile messaging program on confidence in parenting among parents of children ages 18 to 36 months vary by demographic variables?

**Question 5:**
Does providing 12 weeks of access to the Bright By Text mobile messaging program improve parent-reported child vocabulary among children ages 18 to 36 months, as compared to business as usual?

**Comments:**
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## Section IV-A: Study Design (Selection)

**Study Design:**
Randomized Trial (RT)

**Comments:**
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## Section IV-B: Study Design (Input)

***Study Design: Input***

**Unit of random assignment of intervention:**
Parent

**Assignment within sites or blocks:**
No

**Probability of assignment to treatment:**
.50

**Unit outcome data measured:**
Parent

**Intermediate clusters between unit of random assignment and unit of measurement:**
No

**Comments:**
Upon consenting, all participating parents will take a baseline online survey. Half of the parents who complete the baseline survey will be randomly assigned to a treatment group and half to a waitlist control group.

***Design Classification***

**Based on the responses above, this study has been classified as:**
RT: 1-level

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## Section V: Sample Characteristics

**Approximate number of outcome data units (Parent) in the comparision condition:** 250

**Approximate number of outcome data units (Parent) in the intervention condition:** 250

**Were there certain outcome data units (Parent) that were targeted for the study?**
Yes - We will target parents who sign up to receive Bright By Text mobile messages and that have a child ages 18 – 36 months.

**Were there certain outcome data units (Parent) that were excluded from the study?**
Yes - Our sample will include only parents who meet these criteria: (1) Parents must register a phone number to receive Bright By Text messages at the time of study enrollment. They must not have previously been enrolled in Bright by Text. (2) Parents must have a child who is 18 to 36 months old. (3) Only one parent per household is eligible to participate. (4) Parents must complete the baseline survey to participate.

**Comments:**
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## Section VI: Outcomes (Input)

### Confirmatory question 1: Outcome Measure 1

**Outcome domain:** Other Outcome Domain - Responsive caregiving
**Minimum detectable effect size:** .18 to .24
**Outcome measure:** Responsive caregiving: Serve and Return Interaction Scale
**Scale of outcome measure:** Ordinal
**Normed or state test:** No
**Test-retest reliability:** N/A
**Internal consistency:** N/A

**Inter-rater reliability:** N/A

**Same outcome measure in treatment and comparison groups:** Yes

**Confirmatory question 1: Outcome Measure 2**

**Outcome domain:** Other Outcome Domain - Responsive caregiving

**Minimum detectable effect size:** .18 to .24

**Outcome measure:** Responsive caregiving: Positive affect scale

**Scale of outcome measure:** Ordinal

**Normed or state test:** No

**Test-retest reliability:** N/A

**Internal consistency:** N/A

**Inter-rater reliability:** N/A

**Same outcome measure in treatment and comparison groups:** Yes

**Confirmatory question 1: Outcome Measure 3**

**Outcome domain:** Other Outcome Domain - Responsive caregiving

**Minimum detectable effect size:** .18 to .24

**Outcome measure:** Responsive caregiving: Frequency of reading items

**Scale of outcome measure:** Continuous

**Normed or state test:** No

**Test-retest reliability:** N/A

**Internal consistency:** N/A

**Inter-rater reliability:** N/A

**Same outcome measure in treatment and comparison groups:** Yes

**Confirmatory question 1: Outcome Measure 4**

**Outcome domain:** Other Outcome Domain - Responsive caregiving

**Minimum detectable effect size:** .18 to .24

**Outcome measure:** Responsive caregiving: Rich language environment scale

**Scale of outcome measure:** Ordinal

**Normed or state test:** No

**Test-retest reliability:** N/A

**Internal consistency:** N/A

**Inter-rater reliability:** N/A

**Same outcome measure in treatment and comparison groups:** Yes

**Confirmatory question 2: Outcome Measure 1**

**Outcome domain:** Other Outcome Domain - Attitudes toward parenting

**Minimum detectable effect size:** .18 to .24

**Outcome measure:** Parenting attitudes item

**Scale of outcome measure:** Ordinal

**Normed or state test:** No

**Test-retest reliability:** N/A

**Internal consistency:** N/A

**Inter-rater reliability:** N/A

**Same outcome measure in treatment and comparison groups:** Yes

**Confirmatory question 3: Outcome Measure 1**

**Outcome domain:** Other Outcome Domain - Parenting knowledge scale
**Minimum detectable effect size:** .18 to .24
**Outcome measure:** Parenting knowledge scale
**Scale of outcome measure:** Ordinal
**Normed or state test:** No
**Test-retest reliability:** N/A
**Internal consistency:** N/A
**Inter-rater reliability:** N/A
**Same outcome measure in treatment and comparison groups:** Yes

**Confirmatory question 4: Outcome Measure 1**
**Outcome domain:** Other Outcome Domain - Confidence in parenting
**Minimum detectable effect size:** .18 to .24
**Outcome measure:** Parenting confidence scale
**Scale of outcome measure:** Ordinal
**Normed or state test:** No
**Test-retest reliability:** N/A
**Internal consistency:** N/A
**Inter-rater reliability:** N/A
**Same outcome measure in treatment and comparison groups:** Yes

**Confirmatory question 4: Outcome Measure 2**
**Outcome domain:** Other Outcome Domain - Confidence in parenting
**Minimum detectable effect size:** .18 to .24
**Outcome measure:** Parent self-efficacy scale
**Scale of outcome measure:** Ordinal
**Normed or state test:** No
**Test-retest reliability:** N/A
**Internal consistency:** N/A
**Inter-rater reliability:** N/A
**Same outcome measure in treatment and comparison groups:** Yes

**Comments:**
The responsive caregiving: serve and return interaction scale is researcher-developed, based on items developed by Fisher et al., (2016). It includes 4 vignette-based items measured on a Likert scale.

The responsive caregiving: positive affect scale adapts and combines items from existing measures developed by Pianta (1996), Parent & Forehand (2017), and Krysik & Lecroy (2012). It consists of three items measured on a Likert scale.

We will measure frequency of reading and rich language environment with items adapted from the STIM-Q2 Toddler scale (Mendelsohn et al., 2011).

We will measure frequency of reading with two items assessing frequency of reading with the child in days per week and and hours/minutes per day. We will use both items to calculate a weekly reading time estimate.

We will measure rich language environment with two items adapted from the STIM-Q2 Toddler scale. The items measure frequency of shared book reading and labeling with the child. Both use a Likert-type response scale.

The parenting attitudes item was developed by the research team. It is measured on an ordinal Likert scale.

The knowledge about parenting scale was developed by the research team. It consists of four items measured on a Likert scale.

The parenting confidence scale consists of three items adapted from another survey (Silander et al., 2018). Each item is measured on a Likert scale.

The parenting self-efficacy scale consists of one Likert-scale item adapted from Gibaud-Wallston & Wandersman (2001).

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## Section VII: Analysis Plan

**Baseline data collected prior to start of intervention:**
Yes

**Description of baseline data:**
• Child age (months)
• Attitudes toward parenting
• Knowledge about parenting
• Confidence and self-efficacy in parenting
• Caregiver gender
• Child gender
• Child race or ethnicity
• Household income (more or less than $50,0000)
• Caregiver education level
• Whether the child attends center-based care

**Covariates you plan to include in the model:**
-, Caregiver education level, Caregiver gender, Child age (months), Child gender, Child race or ethnicity, Household income (more or less than $50,0000), Pretest (Caregiver attitudes, knowledge, and confidence), Whether the child attends center-based care

**Analytic model:**

$$Y = /beta_0 + /beta_1 TRT + /beta_2 pretest + /beta_3 covars + /varepsilon$$

Our analysis of confirmatory outcomes will use the following ordinary least squares regression model:

Where *Y* represents the outcome of interest;

$\beta_0$ represents the intercept;

$\beta_1$TRT is a dummy variable equal to 1 if the parent was assigned to the treatment group and zero if the participant belongs to the comparison group;

$\beta_2$pretest represents the child's baseline score on the pretest measure (see note);

$\beta_2$covars represents a vector of caregiver, child, and family demographic characteristics (noted

above); and

ε represents the error term.

**Plan to handle cases with missing outcome data:**
Delete cases with missing data for the outcome being analyzed

**Planned multiple comparisons adjustment, confirmatory question 1 (Other Outcome Domain):**
Yes

**Number of planned comparisons to adjust, confirmatory question 1 (Other Outcome Domain):**
4

**Correction for multiple comparisons, confirmatory question 1 (Other Outcome Domain):**
Bonferroni procedure

**Planned multiple comparisons adjustment, confirmatory question 4 :**
Yes

**Number of planned comparisons to adjust, confirmatory question 4 :**
2

**Correction for multiple comparisons, confirmatory question 4 :**
Bonferroni procedure

**Comments:**
We will determine a uniform set of covariates to include in all research questions based on model fit, multicollinearity metrics, and bivariate correlations with the outcome measure ($p < .10$).

We will include a pretest of the respective outcome measure for analyses to predict parenting attitudes (RQ2), knowledge (RQ3), and confidence (RQ4). We will not include a pretest in the model to predict responsive caregiving (RQ1), as no responsive caregiving pretest was administered.

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## Section VIII: Additional Information

**Links:**

No links have been added yet.

**Files:**

File Name: Power Analysis BBT RCT REES Registry.docx

Description: Power analysis for all outcome measures

**Comments:**

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