Comprehensive Early Childhood Parenting Supports and Children's Health and Development
NCT04226053
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Columbia University Human Subjects Protocol Data Sheet

General Information

Title: Columbia Study of Mothers and Babies

Protocol: AAAR1340(M00Y10)

Effective Date: 03/14/2025 **Expiration Date:** 03/13/2026

Background

Study Purpose and Rationale:

Study Purpose: Our research project is to launch a small-scale randomized controlled trial (RCT) of an innovative program in New York City called Room to Grow (RtG). RtG's mission is to enrich the lives of babies born into poverty throughout their critical first three years of development. The research-informed program model combines tailored, one-on-one sessions with an expert clinical social worker in-person every three months plus ongoing communication (phone and email), provision of essential baby items including books, toys, clothing, and equipment (retail value of in-kind items over three years averages $10,000), and connections to vital community resources (e.g., housing, entitlements, child care, social services). The goal of RtG's innovative program is to help parents increase the probability that their children will enter school ready to learn and continue on to meet their full potential in education, work, and citizenship. The therapeutic, psychodynamic approach and robust three-year long relationship with families is designed to act as the catalyst for sustainable, long-term change in parenting methods and family system stability. Critically, and in contrast to other programs aimed at improving parenting and child development, RtG believes that providing concrete material assistance enhances the effectiveness of counseling and referrals to low-income families by reducing economic stress and freeing up scarce resources. The program builds on decades of research on the importance of parenting supports for low-income families and their children, the significance of concrete material support and poverty reduction in enhancing children's health and development, and the recognition that the early years are an effective time to provide critical supports that influence long-term outcomes. Numerous programs, such as home-visiting models that provide parenting supports to low-income new mothers have shown promising results (Cates et al., 2016; Peacock et al., 2013). After decades of correlational research establishing relationships between income, poverty, and children's health and development, there is an emerging literature providing convincing causal evidence that income matters for child outcomes (Duncan, Morris, and Rodgrigues, 2011; Chaudry and Wimer, 2016). Both strains of this research build upon additional research that clearly suggests early childhood is a key period of vulnerability where interventions can make a lasting difference in the fortunes of low-income children and their families (Duncan, Magnuson, Kalil, and Ziol-Guest, 2012). Our research will build upon this literature, by testing an intervention that combines *both* parenting supports and meaningful provision of material support - in essence, assessing whether a combined approach can prove potentially more powerful than the sum of its parts.**Research Questions**: Given the topic outlined above, our research will provide answers to a number of important research questions.1) Does random assignment to RtG alleviate parents' experiences of material hardship and financial stress?2) Does random assignment to RtG enhance the quality of parents' home environment and interactions with children?3) Does random assignment to RtG enhance parents' connection to essential community and health services?It should be noted that our project is designed to investigate proximal outcomes. Over the long-term, our team hopes to build upon these proximal outcomes and to eventually follow children through school-age, as well as greatly expand the number of children that are included in the RCT project.

Rationale: **Knowledge Production**: The evaluation of RtG provides the unprecedented opportunity to test the combined value of parenting education with social and material supports. Our project leverages an innovative approach that combines income supports, parenting education and connection to community services to promote the early health and development of young children. Both parenting and income support programs each aim to promote low- and moderate income families' positive health and development, but too often they work in isolation, potentially limiting their ability to reduce disparities in both parents' and children's health and development. RtG's innovative model provides an opportunity to test the combined effect of these services, and provide valuable information to practitioners and policy makers on the synergistic effects of these program components. It also provides a low-cost model compared to existing home-based interventions. The proposed research can facilitate change in the early childhood field by demonstrating preliminary evidence that this innovative model can achieve demonstrable effects on key proximal outcomes over the first year of life and provide a first step towards building the evidence for multipronged approaches to meeting the needs of low-income families. Findings from this study may guide the field towards more integrated approaches that combines material support, connection to resources, and parenting assistance to make real impacts in the health and development of young children. **Culture of Health**: RtG and its evaluation will provide clear contributions to the development of a culture of health and relevant policies in the early childhood space. First, this will be the first RCT that provides a combination of parenting and community supports with *substantial* and empowering provision of material support. Many parenting programs provide some developmentally appropriate books or toys, but it is incredibly rare to provide the retail equivalent of roughly $10,000 in support over the first three years of life. Second, if successful, the project will help inform both income support and parenting programs about the potential virtues of combining aspects of both such programs. This will establish whether a model such as RtG's holds promise for transforming early childhood parenting programs in helping to build a culture of health and for reducing health disparities among children from divergent backgrounds. **Value**: RtG is an organization that believes deeply in the value of evaluation for quality improvement purposes. The organization and its leadership look forward to learning from the evaluation project in order to understand more about what's working well and what could be improved in the program delivery and curriculum. The team at RtG

has purposefully created a culture that uses data to inform decision-making and looks forward to understanding the full scope of results from the RCT. RtG is currently developing plans for expansion over the next five years as part of a formal strategic planning process. The organization hopes to eventually serve double or more the number of families in each city where it operates, New York and Boston. Findings to date from internal evaluations are extremely encouraging. However, programs without evidence of effectiveness from an RCT are unlikely to be able to expand within the community or to be funded by private or public health and social service agencies. At the same time, it is often challenging for new programs that straddle multiple service domains - especially small innovative programs like RtG that don't easily fit within the strictures of larger grant RFPs - to obtain funding for projects dedicated to evaluating program effectiveness. Our belief is that this project will allow us to circumvent this catch-22 that is so common to the field. It is our hope that other foundations and government agencies (or private donors) will be excited to build upon support from the Robert Wood Johnson Foundation and that we will be able to extend the initial momentum generated by this project over time.

Study Design:

Study Design: As noted above, our study will consist of a small-scale RCT of RtG in New York City (RtG also has a Boston site that will not be currently part of the study). Late-term pregnant mothers are typically referred to RtG from outside service providers, most of which are hospital staff across New York City and a few non-profits. These referrals are submitted to Room to Grow staff through paper or online forms with basic information. From these referral forms, select directory information is entered into a Google document that is shared with Drs. Duch, Wimer, and their staff: client's first and last name, due date, referral date, phone number and email, age bracket of over or under 18, and referral agency. No other information, including any health-related information, is passed on to Columbia staff. Columbia staff then initiate contact with referred clients—after a client agrees to study participation and schedules their baseline survey appointment they are randomized by Columbia staff to either the treatment or control group. If a client refuses study participation the client is not randomized by Columbia staff and the referral is passed back to Room to Grow, where the referral is randomly assigned to either be in or out of the program; this process ensures that all referrals undergo randomization regardless of their decision to participate in the study.

Additional funding has allowed for the expansion of recruitment size; the current goal is to recruit 160 treatment group subjects and 160 control group subjects Treatment and control group subjects will both be given an incentive of $50.00 in cash for their participation in the survey, and control group subjects will also be given a gift basket filled with approximately $75.00-$100 worth of developmentally-appropriate gifts for their impending child (items are purchased from Amazon, and prices vary depending on when items are purchased). Approximately, four business days after the in-home visit, Columbia staff will let control group participants know that they were not selected for the Room to Grow Program; subjects in the treatment group will receive follow-up from Room to Grow. Experienced interviewers will conduct the interviews in either English or Spanish. Subjects will be enrolled in the "Columbia Moms and Babies Study" and follow-up permission and information will be collected during the baseline visit (i.e., subjects will be asked for best modes of future contact and have the opportunity to provide friends' and family members' contacts, email addresses, etc.). Additionally, to inform understanding of program operations and potential outcomes, 9 RtG program graduates will be invited to participate in Focus Groups; 20 RCT participants will be randomly selected and invited to participate in qualitative interviews; the three clinicians at Room to Grow will be invited to participate in qualitative interviews. An in-person visit will be completed with enrolled subjects that have completed the 42M phone survey, once the subject's focal child is at least 3 ½ years old. At the end of the 42M survey, study participants are informed of an opportunity to participate in the in-person visit conducted by the Columbia study team at the School of Social Work. We will also offer study participants the option to have the in-person visit take place in their home. New York City residents will be eligible for the visit. We will also have a handful of subjects who no longer live in NYC during the in-person visit phone contact. If any one of these subjects are living outside of NYC & are within reasonable traveling distance to/from Columbia University's School of Social Work or Nash Building, they too will be eligible for the visit.

Data: Our project will rely almost entirely on primary, proximal data. As noted above, after randomization, both treatment and control group subjects will engage in an in-home interview with experienced Columbia staff. These surveys will be approximately 45 minutes in length and subjects are paid $50.00 for their time. Critically, expected baby due dates will be collected for both groups, in order to plan for timing of subsequent follow-up(s). Subjects will be contacted following the birth of their child with general congratulations and a few months later via mail or other methods to inquire if any changes have occurred to their contact information and to remind them that Columbia staff will be calling them when their baby is around ten months old to schedule a follow-up survey. 10.5, 25, and 42-month follow-up surveys will be conducted via phone (and potentially online for some subjects) by the Columbia Population Research Center's experienced survey research team. The in-person visit will include a brief assessment of the receptive vocabulary (ROWPVT-4) of the child, an assessment of the child's executive function skills, a follow-up survey, and assessments of parenting. In addition, we will request the parent's consent for administrative record linkage to information from the NYC Department of Education (e.g. test scores, grade level). The three types of data collected - repeated survey data, administrative records, and in-person visit based assessments - will be combined into a single dataset for analysis.

Statistical Procedures:

Measures: We plan to conduct a baseline assessment late in the third trimester of pregnancy (weeks 28-34) as an in-person home visit and a follow up survey over the phone when the baby is ten months, twenty-five, and forty-two months old. Our measures fall within five main categories: 1) Demographics; 2) Financial security; 3) Maternal mental health and stress; 4) Parenting quality, and 5) Child Outcomes.

1) Demographics: ¨We will measure a standard set of demographic variables at baseline, including age, a full household roster (age, gender, and relationship to respondent for all members of the household), education, employment, race/ethnicity, immigration status, and a global measure of total household income.

2) Financial security: We will collect detailed measures of financial stress and material hardship.Financial stress measures will be adapted from the Fragile Families and Child Wellbeing Study, while material hardship measures will be adapted from the Survey of Income and Program Participation, the Fragile Families study, and the Robin Hood Poverty Tracker. Hardship measures will include indicators of food insecurity, housing hardship, utility hardship, medical hardship, and general financial hardship (e.g., running out of money between pay cycles). We also plan to develop new measures of frequency and intensity of hardships in order to capture gradations beyond simple yes/no measures that are standard in the literature.

3) Maternal mental health and stress: We will measure maternal depression and stress both atbaseline and follow-up with identical measures.

The Parenting Stress Index Short Form (PSI) PSI was developed based on the theory that total parental stress is a function of child and parent characteristics, as well as situational variables. The short form contains 36 items in three main domains: parental distress, parentchild dysfunctional interaction, and difficult child. The total parenting stress score describes the overall level of parenting stress that an individual is experiencing. Internal consistency (Cronbach's alpha) for the PSI (Short-Form) ranges form 0.80-0.91 and test-retest reliabilities from 0.68-0.85. In the 10 month survey we will only include the attachment subscale.

The Perceived Stress Scale (PSS) is a widely used instrument for measuring the perception of general stress. This 14-item scale measures how stressful or uncontrollable participants find their lives. Respondents rate the frequency of their feelings and thoughts related to events and situations that occurred in the last month. Reliability alphas are between 0.84 and 0.86, with test-retest reliability at 0.95 (Cohen, Kamarck, & Mermelstein, 1983).

The Center for Epidemiological Studies-Depression (CES-D), is a 20-item measure that asks caregivers to rate how often over the past week they experienced symptoms associated with depression, such as restless sleep, poor appetite, and feeling lonely. Response options range from 0 to 3 for each item (0 = Rarely or None of the Time, 1 = Some or Little of the Time, 2 = Moderately or Much of the time, 3 = Most or Almost All the Time). Scores range from 0 to 60, with high scores indicating greater depressive symptoms. The CES-D has shown good sensitivity and specificity and high internal consistency (Lewinsohn, Seeley, Roberts, & Allen, 1997; Radloff in 1977). We will use a shorter version (12 item) that has been used in previous studies showing good reliability.

4) Parenting Quality: We will measure the quality of the home environment, parent-child attachment,positive discipline practices, parental attitudes towards parenting, family routines, parenting confidence/efficacy and quality.

Positive discipline practices, attitudes toward parenting, family routines and parenting efficacy will be assessed with survey items from the Early Childhood Longitudinal StudiesBirth Cohort (ECLS-B) nine-month survey. ECLS-B is a prospective cohort of approximately 11,000 children born in 2001 in the United States and followed up every 1 to 1.5 year from birth (Wave 1, averaged nine months) through Kindergarten (Wave 4, averaged 60 months). The dataset includes information on children's cognitive, social, emotional and physical development across multiple settings collected from children, their parents, and education providers (Snow, 2007).

We have created our own questions to measure **knowledge of child milestones.** These questions have been adapted from the New York Zero to Three milestones checklist. https://www.zerotothree.org/resources/103-9-12-months-your-baby-s-development.

The Parenting Sense of Competence Scale (PSOC; Gibaud-Wallston & Wandersman, 1978). The PSOC measures parental competence on two dimensions: Satisfaction and Efficacy. It is a 17item Likert-scale questionnaire (on a 6 point scale ranging from strongly agree [1] to strongly disagree [6]), with nine questions under Satisfaction and seven under Efficacy. Satisfaction section examines the parents' anxiety, motivation and frustration, while the Efficacy section looks at the parents' competence, capability levels, and problem-solving abilities in their parental role. Internal consistency is excellent with Crohnbach's alpha ranging from 0.75 to 0.88 for the Efficacy scale in two samples of mothers with preschool children. (Johnston and Mash, 1989; Lovejoy et al., 1997).

The **StimQ** (Dryer, 2013) is a measure of cognitive stimulation in the home. The StimQ consists of four subscales: Availability of Learning Materials, Reading, Parental Involvement in Developmental Advance, and Parental Verbal Responsivity. Forms are available in Spanish and require 15 to 20 minutes to administer and two to three minutes to score. Internal consistency is excellent with Crohnbach's alpha ranging from 0.88 to 0.93. Test-Retest reliability is also excellent, with an intraclass correlation coefficient of 0.93. The correlation between the StimQ-T and the gold standard, the IT-HOME inventory was 0.55, with $p<0.001$.

We will use the **Attachment subscale of the Parenting Stress Index (PSI)** to assess parents' sense of closeness with the child and his or her ability to observe and effectively respond to the child's needs. Internal consistency for the Parent Domain of the PSI ranges from 0.75 to 0.87.

The **Confusion, Hubbub, and Order Scale (CHAOS**; Matheny, Washs, Ludwig, & Philips, 1995)) is a questionnaire filled out by parents that is designed to assess the level of confusion and disorganization in the child's home environment. The statements are scored using a 4-point scoring system. The questionnaire consists of 15 statements, to each of which a parent or caregiver assigns a number between 1 and 4 that correspond to the following: 1 = Very much like your own home; 2 = Somewhat like your own home; 3 = A little bit like your own home; 4 = Not at all like your own home. Two items (6 and 10) from the CHAOS scale are included in the survey.

At the in-person visit, the 3 Bag Task is used to measure parent supportiveness and parent detachment.

a) **Parent Supportiveness**: The 3-bag task utilizes a semi-structured play protocol in which the parent-child dyad is instructed to play with the toys in each of three bags in a predetermined sequence (see Fuligni & Brooks-Gunn, 2013). The semi-structured play interactions are videotaped and the parent-child behaviors scored in accordance with the 3-bag task coding scales used in the NICHD Study of Early Child Care (NICHD Early Child Care Research Network, 1999; Brady-Smith et al, 2000). The parent supportiveness scale is a composite of maternal sensitivity, positive affect, and the extent to which the parent provides cognitive stimulation while interacting with their child. The coding scales included measures of both child and maternal behavior. Each scale score ranges from 1 to 7 points to indicate the prevalence and intensity of the observed domain. Scoring considers both the quantity of behavioral indicators observed and the quality or intensity of the behaviors. A score of 1 represents virtually no evidence of the particular behavior, and score of 7 indicates very high levels of the behavior.

b) **Parent Detachment**: The 3-bag task utilizes a semi-structured play protocol in which the parent-child dyad is instructed to play with the toys in each of three bags in a predetermined sequence (see Fuligni & Brooks-Gunn, 2013). The semi-structured play interactions are videotaped and the parent-child behaviors scored in accordance with the 3-bag task coding scales used in the NICHD Study of Early Child Care (NICHD Early Child Care Research Network, 1999; Brady-Smith et al, 2000). The parent detachment scale measures the parent's awareness of, attention to, and engagement with the child. Detachment can take the form of being consistently inattentive, being inconsistently attentive, and/or interacting with the child in a perfunctory or indifferent manner. Each scale score ranges from 1 to 7 points to indicate the prevalence and intensity of the observed domain. Scoring considers both the quantity of behavioral indicators observed and the quality or intensity of the behaviors. A score of 1 represents very low detachment, and score of 7 indicates very high detachment

5) Child outcomes: We will ask parents to report on children's developmental milestones using survey items from ECLS-B. at the 10-month and 25-month survey. The in-person visit instruments will assess the child's executive functioning (including working memory span, attention-shifting, and inhibitory motor control) and receptive language skills.

Receptive Language Skills:

ROWPVT: The test offers a quick and reliable measure of an individual's understanding of English-speaking vocabulary, which is assessed by asking the individual to point to named objects, actions, and concepts pictured in illustrations. The ROWPVT is a standardized language assessment based on a mean of 100 and a standard deviation of 15. Scores of 85-115 are considered to be within the average range of functioning. Scores above 115 are considered above average and scores below 85 are considered below average. Scores from this measure indicate that a child's receptive vocabulary is above average, below average, or equivalent to their same age peers.

ROWPVT: Spanish-Bilingual Edition (ROWPVT: Spanish-Bilingual Edition) is as standardized specific language assessment based on a mean of 100 and a standard deviation of 15. The assessment was norm referenced on typically developing individuals who are proficient in both Spanish and English. The examinee has the option to respond in English or Spanish and instructions are provided in both languages. The purpose of this assessment is to evaluate an individual's overall Receptive vocabulary (i.e. what he/she comprehends) skills when given the opportunity to utilize both languages. The examinee is presented with a picture scene, the examiner then verbally presents a word and the examinee must then point to the picture that corresponds with the word. This is a standardized language assessment based on a mean of 100 and a standard deviation of 15. Scores of 85-115 are considered to be within the average range of functioning. Scores above 115 are considered above average and scores below 85 are considered below average. Scores from this measure indicate that a child's receptive vocabulary is above average, below average, or equivalent to their same age peers.

Working Memory Span (EF-Touch: Houses game)

This task measures working memory and is based on work from Kane & Engle, 2003. Working memory involves holding information in short-term storage and attending to one item while overcoming interference from the other. In this task, children are presented with pictures of houses with animals and colors in them. The child is asked to name the type of animal and color in each of the houses and then, after a short delay, the house is presented again - but this time the house is empty. The child is asked to recall only one piece of information (e.g., either the color or the animal that was in the house). The task requires children to perform the operation of naming and holding in mind two pieces of information simultaneously and to activate one while overcoming interference occurring from the other. The task becomes more difficult as the number of houses increases. In the pretest phase, it is established that children can name both the colors and the animals in the task. Children then receive three 1-house trial, three 2-house trials, and three 3-house trials. There are 18 items. The score on this activity is a proportion from 0 to 1, zero indicating no items correct and 1 indicating all items were correct.

Attention-Shifting Performance (EF-Touch: Something's the Same game)

This task measures attention shifting and requires children to use flexible thinking. It was adapted from the Flexible Item Selection Task developed by Jacques and Zelazo (2001). For the initial trials in the task, children are presented with two pictures (animals, flowers, etc.) that are similar along a single dimension of color, shape, or size. Initially, the child is explicitly told how two of the pictures are the same in some way. Then, the child is then presented with a third picture alongside the original two and asked to state how the new picture is similar to one of the original pictures (e.g., if the first two pictures were similar along the dimension of shape, the third card would be similar to one of the first two along the dimension of color or size). This task requires the child to shift his/her attention from the initial dimension of similarity to a new dimension of similarity. In the most difficult items all of the pictures are presented at once and children are prompted to identify both dimensions of similarity. There are 30 items. The score on this activity is a proportion from 0 to 1, zero indicating no items correct and 1 indicating all items **were correct.**

Inhibitory Motor Control (EF-Touch: Pigs game)

This task measures inhibitory motor control and is a standard go no-go task (Durston, Thomas, Yang, Ulug, Zimmerman, & Casey, 2002). Children are presented with a large green button on the screen that makes a "popping" sound when it is touched. Children are instructed to touch the button every time that they see an animal (the 'go' response) except when that animal is a pig (the 'no-go' response). No-go responses vary in difficulty depending on how many go responses preceded them. In the pretest phase, children are asked to identify all of the animals. During administration items, the task is presented in varying numbers of go trials prior to each no-go trial, including, in standard order, 1-go, 3-go, 3-go, 5-go, 1-go, 5-go, 7-go and 7-go. There are 40 items. The score on this activity is a proportion from 0 to 1, zero indicating no items correct and 1 indicating all items were correct.

Statistical procedures will include comparisons of outcomes between the treatment and control groups. Given the small nature of the sample, and concomitantly limited statistical power that entails, our analyses will focus on understanding patterns of associations across outcomes rather than a strict focus on statistical significance. That said, formal tests of significant differences will still be performed.

Procedures

Study Description

1. Study Purpose and Rationale

This study is funded by the Robert Wood Johnson Foundation, an organization that is committed to the betterment of health and wellbeing among all populations in the US. The purpose of the research is to provide an evidence-based evaluation of the unique Room to Grow model and measure its impacts on the health and wellbeing of disadvantaged mothers and babies.

The Room to Grow model combines both parenting supports and meaningful provision of material support-- the study will objectively assess whether a combined approach can prove potentially more powerful than the sum of its parts.

Our project is designed to investigate proximal outcomes. Over the long-term, our team hopes to build upon these proximal outcomes and to eventually follow children through school-age, as well as greatly expand the number of children that are included in the RCT project.

2. Study Design and Statistical Procedures

Our study will consist of a small-scale RCT of RtG in New York City (RtG also has a Boston site that will not be currently part of the study). Late-term pregnant mothers are typically referred to RtG from outside service providers, most of which are hospital staff across New York City and a few non-profits. From these referral forms, select directory information is entered into a Google document that is shared with Drs. Duch, Wimer, and their staff: client's first and last name, due date, referral date, phone number and email, age bracket of over or under 18, and referral agency. No other information, including any health-related information, is passed on to Columbia staff. Columbia staff then initiate contact with referred clients—after a client agrees to study participation and schedules their baseline survey appointment they are randomized by Columbia staff to either the treatment or control group. If a client refuses study participation the client is not randomized by Columbia staff and the referral is passed back to Room to Grow, where the referral is randomly assigned to either be in our out of the program; this process ensures that all referrals undergo randomization regardless of their decision to participate in the study. The treatment group will consist of mothers that were randomly selected to receive Room to Grow services, which include three years of social and practical support for the mother and baby. Mothers in the control group will not receive Room to Grow services. Room to Grow receives more referrals than they can accommodate at any given time, so the randomization process is a fair and equitable system for assigning mothers program slots. As stated above, a participant's decision to partake in the Columbia Study will not affect their chance of receiving Room to Grow services—mothers who refuse to participate in the study are passed back to Room to Grow, where they are randomly assigned in or out of the program. Room to Grow uses a pre-generated list of slot assignments of either "in" or "out"—when a referral is passed back its consecutive position on the list indicates if the referral is accepted into the program.

Additional funding has allowed for the expansion of recruitment size; we have recruited and enrolled 160 treatment group subjects and 160 control group subjects. Treatment and control group subjects will both be given an incentive of $50.00 in cash for their participation in the 45 minute survey, and control group subjects will also be given a gift tote filled with approximately $75.00-$100 worth of developmentally-appropriate gifts for their impending child (this being the only difference between the treatment and control group consent forms attached to the protocol – the different versions of the consent forms only differ in their description of the compensation offered). Study participants who are selected in the RtG lottery will receive a follow-up call from RtG informing them of their selection, and Columbia staff will call the participants who do not receive a place in the lottery and invite them to remain part of the study approximately four business days after completing the baseline survey.

Experienced interviewers will conduct the interviews in either English or Spanish. Subjects will be enrolled in the "Columbia Mothers and Babies Study" and follow-up permission and information will be collected at that point (i.e., subjects will be asked for best modes of future contact and have the opportunity to provide friends' and family members' contacts, email addresses, etc.). Approximately 4 months after the completed baseline interview, subject will be mailed a jotter and a letter with Columbia's contact information so that participants can reach out with updated contact information. Approximately 9-10 months after the baby is born, participants who agreed will be followed up with on the phone and will be asked to participate in a 40 minute survey with a $35 incentive. Due to the transient nature of this study sample, we anticipate that it will be more difficult to reach some subjects than others. For subjects that do not refuse, but who have not completed the follow-up survey after 10 attempts, we will be offer an additional $15 incentive, bringing the total compensation to $50.

Subjects enrolled in the study who consented to future follow-up will again be contacted when their babies are 25 months and invited participate in a 45 minute phone survey with a $40 incentive. In line with procedures from the 10 month follow-up, subjects that do not refuse, but who have not completed the follow-up survey after 10 attempts, will be offered an additional $15 incentive, bringing the total compensation to $55.

Added 12/2/2020

Subjects enrolled in the study who consented to future follow-up at 25M, will again be contacted when their babies are 42 months old. They will be invited to participate in a 55-minute phone survey with a $40 incentive. In line with procedures from the 10-month follow-up and 25 month follow-up, subjects that do not refuse, but who have not completed the follow-up survey after 10 attempts, will be offered an additional $15 incentive, bringing the total phone survey compensation to $55 for these subjects.

Due to the transient nature of this population, we anticipate that a small percentage of subjects will no longer be living with their babies at the 9-10 month or 25-month follow-up. We will make an effort to keep these subjects in the study, as they offer valuable insight into a subset of the population. Subjects will be invited to participate using the same protocol, and the same approved 10M or 25M survey. All subjects will be asked if they are living with their babies. If a subject indicates that they are not living with their baby, the survey version they are administered will omit sections pertaining to child and family routines. Subjects will still be surveyed on sections pertaining to maternal health, hardship and employment. Subjects will still receive full compensation for their participation.

At the time of the 25M follow-up survey, if a subject indicates they are no longer living with their child, we will still invite the subject to complete a slightly shortened version of the 25M survey omitting sections about child and family routines. In addition, we will also ask the subject to voluntarily provide contact information for the new primary caregiver of the child. If contact information is provided, we will attempt to contact the new primary caregiver and invite them to participate in the 25-month PCG follow-up survey. The PCG follow-up survey is similar to the previously approved 25M survey, with an added demographics section from the previously approved Baseline survey. All subjects who complete versions of the 25M follow-up survey will receive an incentive of $40.

Added 4/14/2021

We will follow the same 25M follow-up survey procedures if a subject indicates they are no longer living with their child. If primary caregiver information is unavailable we will ask the subject to voluntarily provide contact information for the primary caregiver to invite them to participate in the 42-month PCG follow-up survey. The PCG follow-up survey is similar to the previously approved 42M survey, with an added demographics section from the previously approved 25month PCG follow-up survey. All subjects who complete versions of the 42M follow-up survey will receive an incentive of $40.

We plan to conduct an in-person baseline assessment (see attached survey instrument) late in the third trimester of pregnancy (weeks 28-34), and conduct phone survey follow-ups at 9-10 months (10M) and 25 months (25M).Our measures fall within five main categories: 1) Demographics; 2) Financial security; 3) Maternal mental health and stress; 4) Parenting quality and, 5) Child Outcomes.

To ensure that all subjects have some access to mental health support, all subjects in the control group receive a flyer with mental health resources in all five boroughs; treatment group subjects receive mental health resources from RtG.

In addition to the survey work described above, our project will include a process evaluation of RtG. This process evaluation will be funded by RtG's evaluation budget, but we believe that it is complementary to the RCT project described here. It is important to understand how RtG delivers services in order to assess program fidelity and dosage. Process data collected during the intervention from treatment families includes timing and duration of visits, the number and nature of touch-points in between routine visits, referrals and accessibility to means-tested benefit programs and community resources, and the scope and achievement rates for short- and long-term goals. This information will document the precise type and amount of service constituted by the intervention, which will be key for future replication or adaptation of the RtG model.

We will be collecting survey data using the Qualtrics service. This service is widely used in the social sciences, and maintains strict security and privacy standards.

Their security statement is available here: https://www.qualtrics.com/security-statement

And their privacy statement here: https://www.qualtrics.com/privacy-statement

Qualitative Data Gathering

The study will also include a qualitative component including focus groups with up to 9 RtG graduates and qualitative interviews with 20 randomly selected RCT participants (10 control and 10 treatment), and the three RTG clinicians.

We will conduct qualitative interviews with randomly selected study participants after they have completed the 10 month follow-up survey. Columbia research staff will randomly select 10 control group and 10 treatment group participants and invite the subjects to participate in a qualitative sub-study. A qualitative interview guide and revised consent form are attached in the documents section. The qualitative sub-study is intended to provide richer and more nuanced information about the circumstances of mothers and babies living in New York City and the impact that the Room to Grow has on enrolled families. The qualitative interviews will be 45-60 minutes in duration and $40 in cash will be provided to the subjects as compensation. Subjects will be informed that participation in the sub-study is voluntary, and if they are in the treatment group, refusal will not

impact their Room to Grow services. Qualitative interviews will be conducted in the subject's home or an agreed upon location with trained Columbia staff.

We will recruit a maximum of 9 new participants that already graduated from Room to Grow (finalized the three-year program) to gather qualitative information about the impact that RtG had on their children and themselves and how the program could be improved. Because these participants have graduated from RtG it is important to capture their perspective. Graduated participants will be interviewed in focus groups of 4-5 participants. Finally, we will also interview the three clinicians serving families at RtG with the same purpose. All participants will be informed of their rights, including their ability to withdraw at any time and skip any question. Furthermore, current participants and clinicians will be reminded that their answers and participation status will have no bearing on their current Room to Grow services or employment.

IN-PERSON VISIT:

The in-person/home visit will take place either at the study participant's home or on campus. Using the Scheduling Script, staff will either call or email the parent & discuss the in-person visit activities. Staff will encourage or request that the visit be conducted on Columbia campus if the study participant's home (space) is too small or lacks privacy (e.g. the study participant rents a room in someone else's apartment) or if there has been a bedbug infestation within the last 60 days.

IN-PERSON VISIT CONSENT FORM:

The consent form (located on pages 1-3) explains & breaks down the visit into 2 parts:

Part 1: Purpose, procedures, compensation, risks & benefits of the study. The form also explains the ROWPVT-4 and executive function activities for the child, as well as the follow-up survey with the parent.

Part 2 : Explains the videotaping component for the parent & child during the "3-bag" activity. Staff will read this form thoroughly, answer any questions & address any concerns the subject may have.

Note, a separate consent form will be read to the parent before starting the follow-up survey.

CONSENT BOOKLET FOR LINKAGE TO ADMINISTRATIVE DATA:

The consent booklet (located on pages 4-7) outlines the types of administrative data (NYC Department of Education

AND Administration for Children's Services (ACS)/ Child Protective Services (CPS)/ Statewide Central Register of Child Abuse and Maltreatment (SCR) records we hope to link to the survey and in-person visit assessment data. Staff will, either before or after the assessments, review the consent booklet with the parent, and will ask him/her to read over the booklet and decide whether or not to consent for linkage to each type of data.

COMPENSATION Breakdown:

Part 1: Study participants will be offered $20.00 for each activity in part 1: ROWPVT-4, the Executive Function games and the follow-up survey, a total of $60.00 if all three activities in part 1 are completed.

Part 2: An additional $20.00 for the videotaped parent-child interaction. *The videotaped activity is being compensated separately to address concern that some parents may be self-conscious about the videotaping of themselves, and/or their child and prefer not to participate in that portion of the session.

CHILD CARE: As part of our scheduling script we will request that only the subject and the focal child attend the inperson visit to ensure safety guidelines on campus are maintained during the visit. During the call scheduling the visit, staff will inform subjects that only they and the focal child will be allowed in the building for the in-person visit. Exceptions will be made for infant children and other unique circumstances. At their discretion, study staff will be able to offer the subject $40 to help cover the costs of child care if they express difficulty obtaining child care for their other children.

TRAVEL ALLOWANCE: In addition to the assessments & video taping, we will also cover travel costs for any study participant who comes to Columbia University to complete her session.

Based on participant's home address: Participant will receive an additional $30.00 cash if they are traveling to us from

Manhattan, $60.00 cash if they are traveling to us from one of the outer boroughs (Bronx, Brooklyn, or Queens), & $80.00 cash if they are traveling to us from Staten Island. Enrolled subjects that are New York City residents will be eligible for the visit. We will also have a handful of subjects who no longer live in NYC during the in-person visit phone contact. If any one of these subjects are living outside of NYC & are within reasonable traveling distance to Columbia University's School of Social Work, they too will be eligible for the visit and will be offered the maximum travel incentive available, $80, the same amount offered to participants traveling from Staten Island. TRAVEL BONUS: We will offer a $40 bonus as a special incentive for study participants to travel to Columbia's campus to complete their visit.

*Maximum compensation a Subject can receive if he/she did both Part 1 & 2, received the childcare incentive, received the travel bonus, and traveled to us from Staten Island is $240.00

Participant is no longer interested in In-person Visit:

*If any study participant who travels to Columbia University to do a session but changes her mind during or after the consent process & no longer wishes to participate, we will answer any questions/concerns she may have & offer the participant $20.00 as a travel compensation for their time.

*If Columbia staff have gone to a study participant's home to do a session but the participant changes her mind during or after the consent process & no longer wishes to participate, we will answer any questions/concerns she may have & thank her for the time; no compensation will be offered

Partial completion of In-person/Home Visit: If any study participant, regardless of location: subject's home or Columbia University, only completes a portion of the assessments/session, he/she will receive $20.00 per completed assessment.

ROWPVT-4 (child, english) is an individually administered, norm-referenced assessment of how well persons age 2 years 0 months to over 80 years can match a word that is heard to objects, actions, or concepts presented in full-color pictures (in a multiple-choice format). The test consists of 190 items presented in a developmental sequence that reflects the concepts with which people currently have experience through home, school, or media. The examinee indicates (by pointing or saying) the correct color picture (out of four presented) that matches the word spoken by the examiner. Age-related starting points and ceilings (reached when the examinee makes a set number of consecutive errors) ensure that only a subset of items (the critical range) is administered.

ROWPVT-4 (child, Spanish monolingual and Spanish/English bilingual) Prior to administering ROWPVT-4 assessments to children in homes in which Spanish is spoken, we will use the Pre-LAS, a brief assessment of English/Spanish language proficiency, to determine whether the child is bilingual. We will administer the monolingual (english) or bilingual ROWPVT-4 based on Pre-LAS results. If the child is Spanish monolingual, Spanish-dominant bilingual, or English-dominant bilingual, the bilingual ROWPVT-4 will be administered. In the bilingual ROWPVT-4, if a child answers incorrectly when tested in one language, we will try the word again in the other language. Because examinees are permitted to respond in either language, the test measures total acquired vocabulary. Both responses will be recorded. If the child is only proficient in English, the monolingual ROWPVT-4 will be administered.

EXECUTIVE FUNCTION (EF) TOUCH (child only, English) The EF Touch assessment of executive function is administered to measure working memory, inhibitory control, & attention shifting for young children. These tasks have been associated with children's school readiness. The EF touch assessment will be administered using a laptop linked to an extra screen. The staff uses the laptop to control the assessment and the child uses the screen to select his/her answers. The assessment will include the following activities: Initially there will be a 30 seconds "Training" module, where the child will have the opportunity to become familiar with the touch-screen tablet. The staff will read a series of 5-7 items for the child to identify on the screen & the objective is for the child to touch the correct item. Every time the child touches correctly during the training, the child will be praised with automated responses such as: "nice job", "that's right", "you're doing great". We will then proceed to “Bubbles,” blue dots appear on the screen and the child is asked to touch each dot as quickly as he/she can. This activity lasts less than a minute. This is a fast paced activity that most children find to be fun & is usually used to motivate the 3-4 year old children to continue with the activities on the touch-screen tablet. If the child needs a quick break or a break from any other EF task, EF Touch suggests playing "Bubbles" again for its fun & fast paced style. Next we will administer "Houses," the child is shown first one, then, two, then three outlines of houses on the screen. Each house contains either an animal and a color. The staff confirms that the child correctly identifies the animal and the color. Afterward, the child is shown empty house(s) and is asked to tell the staff which animal and which color was in each house. This activity lasts about 10 minutes. This task is used to measure working memory. The next task is “Something’s the Same,” the child is presented with two pictures (animals, flowers, etc.) that are similar along a single dimension of either color, shape or size. The child is then presented with a third picture on the screen, and is asked to touch one of the original pictures that is similar to the new picture. (For instance, if the original two pictures are a red flower and a blue flower, and the new picture is a blue cat, the child should touch the blue flower.) This activity lasts about 10-12 minutes. Prior to beginning this activity, there is a short practice session; during the practice, the staff can help children if they are unsure about their colors. This task is used to measure attention shifting.

Screen prompts provide the staff with a script to use in test administration. If the child says “none of them are the same,” the staff can prompt with “you can take a guess” or “just do your best” and then “which one is the same as ‘X’.” If the child says again that none of the pictures are the same, the response is coded as “child did not respond.” The last task is the “Pig,” a series of animals appears on the screen, one by one, and the child is told to touch a button on the screen every time they see an animal, except when the animal is a pig. This speeded item activity lasts about 4- 5 minutes. Prior to beginning this activity, there is a short practice session; during the practice, the staff can help the child identify the different animals. During the activity, the staff should not provide feedback, but may have to remind the child to “keep playing the game” if they become distracted. This task is used to measure inhibitory control. After each EF activity, the staff will complete a data quality rating using a 3-point scale.

EF TOUCH (child, Spanish-dominant) If the Pre-LAS indicates that Spanish is the dominant language, the EF TOUCH will be administered in Spanish.

VIDEOTAPED interactive play session ("three bag"): For the three-bag activity, the child and parent/subject sit on a yoga mat on the floor and are asked to play for a total of 10 minutes with the contents of 3 different bags in sequence: (1) a picture book (The Very Hungry Caterpillar), (2) a cash register, play money, and plastic foods, and (3) a set of Lego DUPLO blocks. To ensure that the parent-child interaction is as natural as possible, the subject is not told when to switch from one bag to the next or given any other instructions or cues. This play session is video-recorded. Note: if the subject's health/physical condition makes it uncomfortable to sit on the floor, the parent and child will be asked to sit on a couch or at a table, with the parent near enough to the child that both can be seen simultaneously in the video.

Below is the step by step video protocol.

POST-ASSESSMENT: After the in-person visit (Part 1-computer activities &/or Part 2-video) is complete the interviewer will fill out a study document documenting the parent and child's behavior with one another, as well, observations about the home. If the visit was done on the Columbia campus the questions regarding home observations will be skipped.

VIDEO Protocol: WHEN THE STAFF ARE READY TO SET UP, THEY WILL READ THE FOLLOWING: "Now we are going to videotape you and FOCAL CHILD playing together with three sets of toys. Before the activity begins, I will provide you with detailed instructions and you'll have a chance to ask questions. Just so you know, all the toys I will be giving you have been cleaned before this session. Once we start, I'd like to complete the activity without interruptions. It will take approximately 10 minutes. If you or FOCAL CHILD needs a break, now would be a good time. During the taping, we prefer that FOCAL CHILD not eat or drink anything. We also ask that you silence your cell phone for the next 10 minutes. Can you please do that now?"

IF OTHER FAMILY MEMBERS ARE PRESENT, ADD THE FOLLOWING: Could you please let the other people here (e.g., other children, other parent, etc.) know that you'll need some time now with FOCAL CHILD without interruptions? If you wouldn't mind, if any family members forget and come into this area while we are taping, I will ask them to leave so that you are not interrupted. Is that OK?

IF PARENT OR CHILD IS WEARING A HAT, ASK THEM TO TAKE IT OFF BEFORE THE ACTIVITY BEGINS. IF THE CHILD HAS A PACIFIER, ASK THE PARENT TO REMOVE THE PACIFIER BEFORE THE ACTIVITY BEGINS.

WHEN SET-UP IS COMPLETED, STAFF WILL READ THE FOLLOWING: This activity will take about 10 minutes. We would like you and FOCAL CHILD to spend this time with the materials in these three bags. During this activity, you may play with FOCAL CHILD if you like. Please face the camera and try to stay on the mat. Please start with Bag #1, move onto Bag #2, and finish with Bag #3. You can spend as much time on each bag as you like. I will let you know when the play time is over. Do you have any questions? STAFF WILL SET THE STOPWATCH FOR 10 MINUTES AND SAY TO THE PARENT, "You can begin now." AT THE END OF 10 MINUTES, STAFF WILL SAY: That's the end of this activity. We are very grateful for your time and cooperation in this important part of the study. Do you have any questions about anything we've done? POSSIBLE PARENT QUESTIONS AND ANSWER PROMPTS: Q: How long should I spend on each toy? A: You can divide the time as you like. Q: Should I open bag #1 first? A: We would like you to give FOCAL CHILD the bag with #1 on it first. Q: Can FOCAL CHILD and I play with all the toys in the bags? A: Yes, if you like. Q: Should we try to play with all 3 bags? A: You may play however you like. IF THE PARENT OR CHILD MOVES SO THAT HIS/HER FACIAL EXPRESSIONS ARE NO LONGER VISIBLE FOR 30 SECONDS OR MORE, SAY TO THE PARENT: Sorry to interrupt, but please stay on the mat and face the camera.

IF THE PARENT SAYS THEY ARE FINISHED BEFORE 8 MINUTES HAVE PASSED, SAY TO THE PARENT: You still have a few more minutes to play. I will let you know when it's time to stop. IF THE PARENT STOPS BEFORE 8 MINUTES AND SAYS THEY'VE ALREADY PLAYED WITH ALL THE BAGS, SAY TO THE PARENT: That's okay.

You can go back to one or more of them. IF ANOTHER PERSON OR CHILD ENTERS THE FRAME FOR 10 SECONDS OR MORE, TRY TO QUIETLY DIRECT HIM OR HER OUT OF THE FRAME WITHOUT DISTURBING THE INTERACTION. IF THAT DOESN'T WORK, REMIND THE PARENT: We just really want to see you and FOCAL CHILD.

LINKAGE TO ADMINISTRATIVE DATA

The administrative data (DOE & ACS/CPS/SCR records) will be provided by DOE & ACS. After we have requested permission for linkage to administrative data, we will request data linkage from NYC DOE & ACS/CPS/SCR. At the NYC DOE, we will request the data through the DOE Research and Policy Support Group, which manages data requests. Personal identifying information may be removed and records may be sent back to CUSSW with a unique ID only. At ACS, we will request the data through the ACS Research Review Committee.

*NOTE: After consulting with the Data Request Committee for the DOE's Research and Policy Group it was determined that we are not able to obtain approval from the DOE prior to the research taking place because

the children in the study are still too young and are not in the DOE system. We have been advised to submit a data request for administrative data linkages in Fall 2023 for the previous year's records. At the time the research is taking place we will only be obtaining consent from the parent or guardian to request data when we are able to do so. To request this data we will use primary match criteria information such as child's name and date of birth as well the parent's name and date of birth. This same primary match criteria was used in an approved protocol also requesting administrative data linkages to DOE data. Please see protocol #AAAR8158.

Data analysis

Focus group and interviews data will be transcribed and later analyzed using open and selective coding. During open coding, data will be broken into categories representing emergent themes. Selective coding will be utilized to determine core categories and describe relationships among the categories.

Suspected Child Abuse/Neglect

With regards to a plan for taking appropriate actions if child abuse is suspected based upon participants' responses to the questions concerning spanking, we do not believe that any pattern of responses to this or any other questions in our telephone survey provide sufficient evidence for a suspicion of child abuse. It should be noted that spanking is normative in the United States and approximately 50 percent of U.S. parents engage in spanking. Any suspicion of child abuse would thus have to arise based on information communicated by the subject outside of their responses to the study's survey questions. Based on investigators' experiences in prior studies, such incidents are exceedingly rare. If an incident does occur, however, all interviewers will be advised to report the incident to their supervisor, who will consult with protocol members Jeanne Brooks-Gunn and Jane Waldfogel, both experts in parenting, child development, and child abuse and neglect, and both of whom have worked on numerous studies on such issues in the past. In the event that the team decides a risk of abuse is present, the supervisor would make a report to the NYC Administration for Children's Services.

Recruitment And Consent

Recruitment:

Late-term pregnant mothers are typically referred to RtG from outside service providers, most of which are hospital staff across New York City and a few non-profits. From these referral forms, select directory information is entered into a Google document that is shared with Drs. Duch, Wimer, and their staff: client's first and last name, due date, referral date, phone number and email, age bracket of over or under 18, and referral agency. No other information, including any health-related information, is passed on to Columbia staff. Columbia staff then initiate contact with referred clients over the phone (see attached phone pitch documents)—-after a client agrees to study participation and schedules their baseline survey appointment they are randomized by Columbia staff to either the treatment or control group. If a client refuses study participation the client is not randomized by Columbia staff and the referral is passed back to Room to Grow, where the referral is randomly assigned to either be in our out of the program; this process ensures that all referrals undergo randomization regardless of their decision to participate in the study.Additional funding has allowed for the expansion of recruitment size; the current goal is to recruit 160 treatment group subjects and 160 control group subjects. Additionally, 9 RtG program graduates will be invited to participate in Focus Groups; 20 RCT participants will be randomly selected and invited to participate in qualitative interviews; the three clinicians at Room to Grow will be invited to participate in qualitative interviews.

Columbia staff are the first line of contact for all referrals as the study is designed to include a maximum amount of willing participants. Columbia staff are most qualified to explain the study to participants and, in order to keep consistency, all referrals receive the same study pitch from CU staff before being randomized either by CU or by RTG (depending on if they agree to participate).

All study materials, including recruitment scripts, will be translated into Spanish by an approved translator, and will be added as a modification after English language materials are approved by the IRB.

For qualitative interviews and focus groups:

Twenty current RtG/RCT participants will be randomly selected when their baby is 9-10 months old; Columbia research staff will call selected participants and invite them to participate in an in-person qualitative interview. During the scheduling call, Columbia staff will answer any questions or concerns participants might have and convey that their participation will have no impact on their current RtG services.

With the assistance of the RtG team, a maximum of 9 RtG graduates will be contacted by phone and invited to participate in 4-5 person focus groups about their experience at RtG.

The three clinicians at RtG will be invited to participate in individual qualitative interviews about their experience at RtG. Columbia staff will answer any questions or concerns the clinicians might have and convey that their participation will have no impact on their current employment status or work at RtG.

10 Month Follow-Up Recruitment Strategy

Using the subject's projected due date, Columbia staff will initiate phone contact with subjects who agreed to be contacted for follow-up approximately one week before their baby is 10 months old. Columbia interviewers will use contact information that was collected at baseline (provided by the subject at the time of the interview) as well as any updated contacted information that the subject may have provided with the jotter outreach letter. For adult participants, interviewers will call and remind subjects of the purpose of the study, describe what the follow-up entails and invite them to participate using the attached 10M Adult phone pitch. The subject can agree to participate at the time of the call or can schedule the survey at a later time. A subject is free to refuse participation in the follow-up. If the subject agrees, a consent script will be read verbatim and verbal informed consent will be obtained at the start of the survey (see attached 10M Phone Consent). For subjects that were below the age of 18 at baseline, interviewers will ask their current age--for those who have turned 18 since the baseline guardian contact/permission will not be attempted. For subjects who are still under the age of 18, the interviewer will ask for the guardian's contact information (see attached 10M Pitch Minor). However, in the event that the minor cannot provide the guardian's information, the interviewer will proceed with obtaining consent from the minor. We will do our best attempt guardian contact for minors, however, because all minors who are enrolled in the study received guardian consent at baseline and because the minors have given birth since baseline, we will proceed with allowing the minor to consent to participation if the guardian is not available.

Worth noting is that in NYC the following exemption applies to minors who are pregnant and/or parents:

-"The child must get a parent’s permission to get routine health care unless it is an emergency or for sexually transmitted disease, family planning services, drug treatment or mental health treatment. The child does not need a parent’s permission if the child is pregnant, a parent, or married." - NYlaw.org

Once we make contact with the subject on the phone we will use previously approved protocols to pitch, schedule and complete the 9-10 month survey with the subject’s consent.

25 Month Follow-Up Recruitment Strategy

Using the subject's projected due date, Columbia staff will initiate phone contact with subjects who agreed to be contacted for follow-up approximately one week before their baby is 25 months old. Columbia interviewers will use the most up to date contact information available (from the 10 month follow-up and baseline interview). At this point in the study, all enrolled mothers will be 18 years of age or older, thus only adult recruitment and consent procedures will be used by experienced interviewers.

Interviewers will call and remind subjects of the purpose of the study, describe what the follow-up entails and invite them to participate using the attached 25M phone pitch. The subject can agree to participate at the time of the call or can schedule the survey at a later time. A subject is free to refuse participation in the follow-up. If the subject agrees, a consent script will be read verbatim and verbal informed consent will be obtained at the start of the survey (see attached 25M Phone Consent).

Once we make contact with the subject on the phone we will use previously approved protocols to pitch, schedule and complete the 25 month survey with the subject’s consent. These same procedures will be used to pitch, schedule and complete the 42 month survey with the subject's consent.

For subjects who indicate they are no longer living with their child, and voluntarily provided contact information for the new primary caregiver of the child, interviewers will call and explain to the primary caregiver the purpose of the study and invite them to participate using the 25M PCG phone pitch. If the PCG agrees to participate, a consent script (see attached PCG Phone Consent) will be read verbatim and verbal informed consent will be obtained at the start of the survey.

Added 4/14/2021

For subjects who indicate they are no longer living with their child and voluntarily provided contact information for the primary caregiver of the child or if the study team already has contact information for the primary caregiver, interviewers will call and explain to the primary caregiver the purpose of the study and invite them to participate using the 42M PCG phone pitch. If the PCG agrees to participate, a consent script will be read verbatim and verbal informed consent will be obtained at the start of the survey.

IN-PERSON VISIT:

At the end of the 42M survey, which is administered after the focal child turns 3 ½ years old, each subject (not including primary caregivers) is asked if they would be interested in participating in an in-person visit that includes assessments for their child at a later date.

The wording of the question is as follows:

“Thank you for your responses. As part of the study, we would like to arrange an in-person visit with you and your child at Columbia University. The visit includes age appropriate assessments with your child using a Touch Screen laptop and a video-recorded play session. We are offering $80 for your participation in the visit, as well as an incentive to compensate for your travel time. Is this something you would be willing to participate in? Do you have any questions or thoughts at this time?

YES

NO

MAYBE/NOT SURE”

TELEPHONE: If the participant answers yes to this question, study staff will call and will schedule the visit if the participant is interested. If the study participant answers maybe, study staff will call and ask if they would be interested in hearing more. A separate document, Scheduling Script, provides the script used for arranging the in-person visit after study participants have expressed interest in participating. Study staff can also use text as a way to also pitch the visit.

EMAIL: Should study staff be unable to reach the participant via phone, staff will email the participant all pertinent information from the scheduling script. Staff will only use the email address that was provided by the participant as a mode of communication/contact.

Informed Consent Process:

At the time of the scheduling call, Columbia staff explain how the client's information was obtained (they were referred to Room to Grow by their healthcare provider/nonprofit); the voluntary nature of the study; and the random lottery system that their name will be entered in, regardless of study participation. Columbia staff emphasize the voluntary nature of the study and that participation in the study does not impact a client's chances of receiving Room to Grow services. Any questions will be answered by experienced Columbia staff. If the subject agrees to schedule a time for the baseline interview, the subject is then randomized by Columbia staff. The subject learns about their randomization status approximately 4 business days after completing the baseline survey. Similarly, subjects who refuse study participation learn about their randomization status from RtG approximately four business days after their last contact with Columbia staff. The subject does not give formal consent to study participation until the in-person appointment, at which time the interviewer goes over the consent form and obtains signed consent from the subject before beginning the baseline survey. A subject can refuse participation at any given time.

Prior to beginning the baseline survey, the interviewer will read aloud an approved consent form and answer any questions the subject may have (note the only difference between the "control" and "treatment" consent forms is in the compensation section--the control group receives a tote bag in addition to the $50 incentive). If the subject agrees to participate they will be asked to sign the consent form and will be given a copy for their records. The consent form will include information about the purpose of the study, potential risks and benefits, compensation, contact information for Chris Wimer (PI) and the Columbia University IRB, and the voluntary nature of the study. The consent form will ask permission for future contact. Informed consent with written documentation will be obtained from the research participant for the baseline survey. Subjects will be informed that they will be notified of their lottery status in four business days.

Subjects who agreed to be contacted for the 10 month phone follow-up will be called and invited to participate in a 40 minute phone survey. They will be offered $35 in check form as compensation. Once a subject agrees to start the survey (either at the time of the initial call or at a future scheduled time), the interviewer will read an informed consent script (10M Phone Consent) prior to beginning the survey. Verbal consent will be obtained after the consent script is read; the subject will have the opportunity to ask questions prior to giving verbal consent. The consent outlines the purpose, the risks, and the confidentiality procedures in place. Subjects will be informed of the voluntary nature of the study and their ability to skip any question or withdraw at any given time.

25 month follow-up procedures will mirror the 10 month follow-up procedures. Subjects who agreed to be contacted for follow-up will be called and invited to participate in a 45 minute phone survey. They will be offered $40 in check form as compensation. Once a subject agrees to start the survey (either at the time of the initial call or at a future scheduled time), the interviewer will read an informed consent script (25M Phone Consent) prior to beginning the survey. Verbal consent will be obtained after the consent script is read; the subject will have the opportunity to ask questions prior to giving verbal consent. The consent outlines the

purpose, the risks, and the confidentiality procedures in place. Subjects will be informed of the voluntary nature of the study and their ability to skip any question or withdraw at any given time.

42 month follow-up procedures will mirror the 25 month and 10 month follow-up procedures. Subjects who agreed to be contacted for follow-up will be called and invited to participate in a 55 minute phone survey. They will be offered $40 in check form as compensation. Once a subject agrees to start the survey (either at the time of the initial call or at a future scheduled time), the interviewer will read an informed consent script (42M Phone Consent) prior to beginning the survey. Verbal consent will be obtained after the consent script is read; the subject will have the opportunity to ask questions prior to giving verbal consent. The consent outlines the purpose, the risks, and the confidentiality procedures in place. Subjects will be informed of the voluntary nature of the study and their ability to skip any question or withdraw at any given time.

IN-PERSON VISIT:

At the beginning of the visit, the lead staff member will give the study participant the In-Person Visit Consent Form, ask her to read it, and give an opportunity for the study participant to ask questions.

IN-PERSON VISIT SURVEY: The subject will be offered $20 in cash as compensation for completing the survey at the in-person visit. The lead staff member will read an informed consent script before beginning the survey. Verbal consent will be obtained after the consent script is read; the subject will have the opportunity to ask questions prior to giving verbal consent. The consent outlines the purpose, the risks, and the confidentiality procedures in place. Subjects will be informed of the voluntary nature of the study and their ability to skip any question or withdraw at any given time.

For Minors (16+ years of age): Baseline Survey Recruitment

Because Room to Grow serves mothers under the age of 18, the research team has decided to expand the study sample to include expectant mothers who are 16+ years of age (though, we expect this to to be less than 5% of our sample). After speaking with Gloria Gaines we have developed and attached a minor assent form and a parent consent form.

If a minor mother is referred and randomized into the study, Columbia staff will be provided with her guardian's phone number (this information comes in with a typical referral). Columbia staff will first contact the guardian and using the Guardian phone script explain the study and ask for permission to contact the minor. If permission is granted, Columbia staff will contact the expectant mother and inform her that her guardian gave us permission for contact, but that the decision to participate in the study is solely hers (this is explained in the Minor phone script).

If the minor agrees to schedule a survey meeting we will coordinate a time that the guardian and minor are home together, as the Columbia interviewer will need to obtain signed consent from the guardian and a signed minor assent form from the expectant mother. During the home visit, Columbia staff will answer any questions the participant or guardian may have and provide them with copies of their consent documents. Following the guardian's consent, the interviewer will ask to conduct the survey with the expectant mother in privacy to ensure her comfort and provide a safe and honest space for participation. Once the interviewer is one-on-one with the expectant mother she will obtain the minor assent form and begin the survey.

In cases where the minor mother is emancipated or if the guardian cannot be reached, Columbia staff will initiate contact by calling her directly; if the subject agrees to participation she will sign the adult ICF and not the minor assent form at the time of the baseline visit.

As with adult participants, minor participants can withdraw at anytime and their participation in the Room to Grow lottery is not contingent on participation in the study.

Consent forms will be translated into Spanish by an approved translator following approval of the English versions by the IRB.

For qualitative interviews and focus groups:

Columbia staff will contact the selection of current RtG participants (all of whom agreed to future contact at the baseline survey), RtG graduates provided by the RtG team, and clinicians.All participants will be informed of the voluntary nature of the qualitative interviews/focus groups and reminded that their participation status will have no impact on their status at Room to Grow. If the participants agree to schedule an appointment/attend a focus group, Columbia staff will coordinate appropriate time slots.

Informed written consent will be obtained at the time of the in-person interview or focus group. Trained research staff will go over all procedures, answer any questions, provide copies of consent forms to all participants and obtain written consent from all participants before beginning data collection.

1/16/18, clarification on RtG clinician recruitment/consent: Clinicians were invited to participate through the RtG director. A RtG Program coordinator arranged a time for each clinician to meet individually with Dr. Maria Marti at the RtG NY office for the qualitative interview. Dr. Maria Marti met individually with each clinician, presented the study and obtained consent. Clinicians were informed of the voluntary nature of the interview; they did not receive financial incentives as the interviews took place during regular work hours and were approved by the RtG director. Once clinicians agreed to participate interviews were conducted.

Describe how participants' consent will be obtained and whether an information sheet will be used:

During the scheduling call, subject are informed of the voluntary nature of the study and are invited to set up a time to meet for the baseline survey; at the time of the meeting formal written consent will be obtained before proceeding with the baseline survey or any further study participation.

During recruitment for the 10 month follow-up, 25 month follow-up, & 42 month follow-up, subjects who agreed to follow-up at baseline will be called and invited to participate in the follow-up phone survey. Because the survey will be conducted over the phone, interviewers will read an informed consent script and obtain verbal consent from the subject before proceeding with the survey. Subjects will be informed of their right to refuse participation and the right to skip any question. All materials will be translated to Spanish and interviewers who are fluent in Spanish will obtain consent and conduct interviews with Spanish-speaking subjects.

Subjects will be invited to participate in an in-person visit once their child is at least 3 1/2 years old and once they have completed their 42 month follow-up survey. They may refuse to participate in the visit. Written consent for participation in the in-person visit activities with the child (EF-Touch, ROWPVT-4, and the 3 Bag Task) and parent will be obtained at the meeting, which will take place at Columbia University. A separate informed consent script will read to the subject for the in-person follow-up survey. The lead staff member will obtain verbal consent from the subject before proceeding with the survey. Subjects will be informed of their right to refuse participation and the right to skip any question. All materials will be translated to Spanish and interviewers who are fluent in Spanish will obtain consent and conduct interviews with Spanish-speaking subjects. We will obtain written/documented consent if a study participant completes a paper version of our in-person survey and mails it back.

Subject Language

Enrollment of non-English speaking subjects is expected.

Languages anticipated: Spanish

Research Aims & Abstracts

Research Question(s)/Hypothesis(es):

1) Does random assignment to RtG alleviate parents' experiences of material hardship and financial stress? 2) Does random assignment to RtG enhance the quality of parents' home environment and interactions with children? 3) Does random assignment to RtG enhance parents' connection to essential community and health services?

Scientific Abstract:

Our research project is to launch a small-scale randomized controlled trial (RCT) of an innovative program in New York City called Room to Grow (RtG). RtG's mission is to enrich the lives of babies born into poverty throughout their critical first three years of development. The research-informed program model combines tailored, one-on-one sessions with an expert clinical social worker in-person every three months plus ongoing communication (phone and email), provision of essential baby items including books, toys, clothing, and equipment (retail value of in-kind items over three years averages

$10,000), and connections to vital community resources (e.g., housing, entitlements, child care, social services). The goal of RtG's innovative program is to help parents increase the probability that their children will enter school ready to learn and continue on to meet their full potential in education, work, and citizenship. The therapeutic, psychodynamic approach and robust three-year long relationship with families is designed to act as the catalyst for sustainable, long-term change in parenting methods and family system stability. Critically, and in contrast to other programs aimed at improving parenting and child development, RtG believes that providing concrete material assistance enhances the effectiveness of counseling and referrals to low-income families by reducing economic stress and freeing up scarce resources. The program builds on decades of research on the importance of parenting supports for low-income families and their children, the significance of concrete material support and poverty reduction in enhancing children's health and development, and the recognition that the early years are an effective time to provide critical supports that influence long-term outcomes. Numerous programs, such as home-visiting models that provide parenting supports to low-income new mothers have shown promising results (Cates et al., 2016; Peacock et al., 2013). After decades of correlational research establishing relationships between income, poverty, and children's health and development, there is an emerging literature providing convincing causal evidence that income matters for child outcomes (Duncan, Morris, and Rodgrigues, 2011; Chaudry and Wimer, 2016). Both strains of this research build upon additional research that clearly suggests early childhood is a key period of vulnerability where interventions can make a lasting difference in the fortunes of low-income children and their families (Duncan, Magnuson, Kalil, and Ziol-Guest, 2012). Our research will build upon this literature, by testing an intervention that combines *both* parenting supports and meaningful provision of material support - in essence, assessing whether a combined approach can prove potentially more powerful than the sum of its parts.

Lay Abstract:

Room to Grow is a program that provides low-income pregnant mothers with a combination of parenting supports, connection to community-based resources, and direct provision of in-kind supports such as books, toys, strollers, clothes, etc. for their child. Through a small scale randomized controlled trial, we hope to assess whether the program makes an impact on a variety of short-term outcomes related to financial stress, material hardship, and positive parenting behaviors.

Risks, Benefits & Monitoring

Potential Risks:

There are two identifiable risks: 1) subjects may experience some distress answering questions and 2) disclosure of information. To protect against the first, the initial script informs subjects that they are free to skip questions that make them feel uncomfortable, they can take breaks at any time, and can stop the interview at any time. Interviewers will have a referral manual if a subject appears to require counseling. Our confidentiality and data protection protocols described in section 10 safe guard against the 2nd risk.

IN-PERSON/HOME VISIT:

The two identifiable risks are (1) distress about the in-person/home visit and (2) disclosure of information about the subject.

(1) Distress about the in-person visit – Although the in-person/home visit activities are similar to activities carried out in everyday life, a study participant might feel self-conscious about having strangers come into her home, or be embarrassed participating in a study in person. Lastly, the parent might become embarrassed or annoyed if the child has trouble focusing on the activities or becomes upset or acts out in some way. To protect against this risk, the staff will:

- Emphasize that all activities in the visit are voluntary and they can skip or withdraw from any activity. Offer to schedule the visit on campus if the study participant has any hesitation about inviting staff to her home.
- Tell the study participant before the ROWPVT-4 that the activity may become more difficult over time and people are not expected to get all the answers right.
- Be patient with a child who is distractible, re-direct his/her attention back to the activity, and suggest taking a short break if the child becomes upset or is having great difficulty focusing.

(2) Disclosure of information about the subject -- To protect against this risk, staff will follow the data security measures described inthe Privacy and Data Security section.

Potential Benefits:

There are no direct benefits to subjects from participating in the study. We hope that the study will help Room to Grow be most effective in its work going forward and also provide information on poverty and child development to policy makers working to better serve low-income mothers and children.

Child Involvement

RISK/BENEFIT DETERMINATION

Baseline Participation:

Only mothers who are 16+ years of age will have the opportunity to participate in the study. First, if the guardian can be reached, the Columbia team will obtain their consent to contact the minor. If the minor agrees to a survey appointment, the home visit will be scheduled at a time that the minor and guardian are both home--they will both sign consent/assent documents and will be provided with copies for their records. Columbia staff will emphasize the voluntary nature of the study, answer any questions, and ensure that the participant is in a private and safe space during the survey and assent signing. The survey will 30-45 minutes and the topics are relatively neutral; we do not anticipate distress, but will have a manual with resource referrals if necessary. Chris Wimer (PI) spoke with Gloria Gaines about the inclusion of expectant mothers who are 16+ years of age in the study.

In-person visit:

The child will participate in up to 3 study components: four game-like activities on a laptop, a vocabulary activity using a picture cue book, and one videotaped activity in which the child plays with the parent using researcher-provided toys and a book. These study components are similar to activities that are commonly part of a young child's life.

ASSENT OF SUBJECTS

Baseline:

All minors in this study will be 16+ year old expectant mothers in their third trimester of pregnancy and the questions are about their circumstances--we expect them to fully understand all survey topics. We expect less than 5% of our sample to fall into this category.

In-person Visit:

None of the children participating in the in-person visit are expected to be capable of providing assent. The children will be ages 3 ½ to 5 years old when they participate in the in-person visit.