Study Title: Improving Future Thinking Among Mothers to Reduce Harsh Parenting and Improve Child Outcomes

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Protocol Title: The Parent-Child Memory Study: Improving Future Thinking among Mothers from a Traditionally Underserved Community to Reduce Harsh Parenting and Improve Child Outcomes

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1. STUDY AIM, BACKGROUND, AND DESIGN ABSTRACT

The aims of this study are to conduct a small case series (n = up to 60) to evaluate the preliminary feasibility of implementing a brief, episodic future thinking (EFT) intervention with mothers from a lowincome community.

Episodic future thinking (EFT) refers to the ability to imagine, in vivid detail, events that may occur in the future (Lin & Epstein, 2014). EFT relies on episodic memory, which allows for recollection of past, personal experiences. Research has shown that episodic memory supports the creation of positive, future events by combining past experiences with vivid detail of events that may occur in the future. Recent studies have shown that EFT intervention can decrease delay discounting (DD), which is a facet of impulsivity (Dassen et al., 2015; Snider et al., 2019; Stein et al., 2016).

The overarching goal of this EFT intervention is to increase mothers' focus on positive, future events associated with enhancing the parent-child relationship. Rather than trying to decrease negative parenting practices, the focus of this study is to promote positive parent-child relationships by envisioning future-directed events. To date, no research has examined EFT in relation to parenting behaviors. Moreover, the intervention requires limited time and financial resources to implement, suggesting it may be effectively delivered in a disadvantaged community.

The current application of EFT proposes to examine the efficacy of EFT in improving parent-child relationships in the low-resource, minority-majority community of Flint, Michigan. Results from this case series will inform a revision of the intervention with respect to dosage and feasibility outcomes. Aims of this case series include: (1) determining the implementation potential of this intervention (including feasibility, acceptability, and satisfaction) and (2a) examine preliminary efficacy of this intervention in reducing parental delay discounting (focus on immediate relative to long-term rewards) and (2b) improvements in parent-child relationships/parenting quality and related constructs.

2. SUBJECT POPULATION AND ELIGIBILITY

Subject Population

Up to 60 mothers of children ages 5-10 years old will be recruited from community-serving Flint, MI, agencies such as the R.L. Jones Community Outreach Center and/or Latinx Tech Community Center, or through snowball sampling in which interested participants will provide study information to other parents.

Inclusion criteria:

1. Be the mother from the Flint area of a child between the ages of 5-10 who can provide legal consent for that child to participate in this study
2. Self-report that the child lives with them for at least 50% of the time.
3. Willing to participate in the study
4. Able to participate in written assessments and an intervention conducted in English

5. Have a working cell phone that can receive and send text messages and be willing to receive/send text messages as part of the study
6. Have a phone or device that's able to use video conferencing software.

Exclusion criteria:
1. Self-disclosed active suicidality/homicidality
2. Self-disclosed current bipolar disorder, schizophrenia, or psychosis
3. Current and ongoing involvement with child protective services

Vulnerable Populations
Children will not directly take part in the intervention; however, they will be included in the observational tasks with enrolled mothers that are part of the larger assessment battery to evaluate changes in parenting. Children above age 7 will be verbally assented prior to participating in the observation. Outside of the assent procedures, research team members will not directly interact with children that are participating in the observation.

The current project targets this developmental period (ages 5 –10 years old) given changes in parenting immediately prior to adolescence and the subsequent increases in rates of psychopathology reported during adolescence. Based on demographics from the Flint community, we expect to enroll approximately equal numbers of boys and girls. The current research team has completed numerous studies with participants under the age of 18 and their guardians and are well-suited to work with these populations. The PI received her doctoral degree in child clinical psychology and has worked with both the recruitment/intervention and assessment sites. See Supplement A for additional information on inclusion of minors in this project.

Recruitment and Screening
Participants will be recruited in the following ways:

- RAs and/or study staff will hand out study flyers in the RL Jones and/or LatinX Centers' food and water distribution line or in food pick up bags
- Flyer distribution will occur at area community-serving agencies
- Presentations to parents and/or staff at community serving agencies
- Social media posts and targeted social media advertisements
- Targeted social media ads
- Snowball recruitment in which interested participants or community members will share the study flyer, social media posts or basic study information and contact information of study staff to other potential participants

We will work to maintain all Covid precautions and safety procedures as directed by the RL Jones Center, Latinx Center, or other agencies that we work with. Screening, consent, and study procedures will take place virtually or in-person, depending on the participant's preference

Interested individuals will reach out to study staff using the contact information provided on the study flyer; will indicate their interest through completing an online interest survey; or will complete a screener with a study staff in-person in a private area from the recruitment location, such as a private room at the

RL Jones or LatinX Community Centers. The online interest survey can be accessed through a QR code or web link on recruitment materials and will lead the participant to a REDCap survey that says:

Hi! Thank you for your interest in our parenting program. This program features an intervention that seeks to help mothers of children ages 5-10 years old improve their parent-child relationship, learn new parenting skills, and work with a peer in their community.
This project is funded by Henry Ford Health in collaboration with Mothers of Joy Institute for Parenting and Family Wellness and the R.L. Jones Community Outreach Center.

If you are interested in learning more about our program and seeing if you are eligible to take part, please provide your first name and phone number below. Someone from our team will reach out to you soon. Your contact information will be stored on a secure server and will only be used to reach you. Your information will not be shared or used for any other purpose. If you would prefer to reach out to the team, you may text or call (313) 623-5657. Please look out for this number if you fill out the information below. First name: _____
Phone number: _____

Adding the following logos to the landing page:

Once an individual expresses interest in taking part in the study (either in-person, over the phone, or by completing the online interest survey), the RA will speak with them to briefly explain the study and go through screening procedures at a time that is convenient for the parent. At screening, mothers will be asked several questions to determine eligibility (see revised Screening Script and Consent Overview). The RA will document whether the participant meets eligibility criteria and record this information in a secure REDCap database only accessible to study team members. No data beyond eligibility will be collected prior to enrolling in the study. No medical records will be accessed as part of this study. If the interested individual does not meet inclusion/exclusion criteria ("screens out"), they will be offered a resource list of free or reduced cost resources in the Flint area.

If eligible, the RA will review the consent information with the participant and allow time for questions. Participants will then be sent an electronic copy of the consent form via REDCap to review and document their consent electronically. Screening and consent processes will be conducted remotely – over the phone and through REDCap – or in-person, depending on the parent's preference and COVID safety protocols at participating agencies. During the screening and consent process, all individuals will be informed that participation is completely voluntary, will be kept confidential, and will not impact their access to services in any way.

3. STUDY PROCEDURES

See workflow document for a visual of this process called Study Workflow.

Introductory study procedures will happen over the phone or web-conferencing platform, or in-person in a private room at a public location.

Immediately following screening, the RA will review the consent information with eligible and interested participants. The RA will review the key information in the informed consent document with the participant (see Screening Script and Consent Overview) and allow enough time for any questions to be answered. During the consent process, all individuals will be informed that participation is completely voluntary, will be kept confidential, and will not impact their access to services in any way. The participant will also be informed that the intervention session, observation sessions, and key information interview will be recorded for research purposes. After reviewing the consent information with the participant and answering any questions, the RA will do one of the following:

1) For participants that are screened over the phone, the RA will send a link to the consent form via text or email, using REDCap's e-consent framework, for the participant to review and electronically sign prior to starting any study procedures. A PDF of the completed consent form will be available to the participant for download after they provide their consent.
2) For participants that are screened in person, the RA will pull up the e-consent form in REDCap for the participant to complete on a study computer.

Once consent is provided, the participant can immediately begin the online questionnaires that are part of the baseline assessment.

If the interested individual has more than one child in the age range (5-10 years old) we will ask them to complete the observation session with the child they identify as wanting to improve their relationship with or their youngest child in that age range. Verbal child assent will be obtained from participating

children aged 7 and older during the scheduled online observation meeting (via video conferencing platform) with the parent and child.

For those that complete screening and consent procedures remotely, once screening and consent procedures are complete, we will send a link (via text or email, depending on the parent's preference) to a short video that reviews all study procedures.

Pre-intervention Assessment

The pre-intervention assessment includes both online surveys, hosted in REDCap, and a parent-child interaction observation that will be conducted through a web-based conferencing software such as Zoom or in-person in a private room at a local agency (such as the RL Jones or LatinX Centers), depending on the parent's preference. After screening and consent procedures, the RA and the parent will schedule a time convenient for the parent and their child that will be participating with them to conduct the observation session that is part of the pre-intervention assessment. At this time, participants will also be asked to take a pre-intervention assessment battery (see Assessment Battery) online. The surveys will be housed in the study's REDCap database. Parents who wish to complete the online surveys on their own device/remotely will be sent a link to the assessment battery shortly after screening via text or email. Participants who wish to complete the online surveys in person will complete the surveys online using a study computer in a private room at a public location (e.g., RL Jones or LatinX Community Centers, a Flint Public Library Branch, a Flint MSU pediatrics clinic, etc. We will only utilize facilities at locations where we have permission from the agency to utilize the space). The participant will first need to provide their consent electronically and then will be directed to start the questionnaires.

Assessment battery

The online assessment battery will include measures of (1) delay discounting (DD) (Aim 2a), (2) consideration of future consequences (Aim 2a), (3) child behavior (Aim 2b), (4) parenting variables (Aim 2b), and (5) current alcohol and drug use (Aim 2b). To measure DD, we will use a Monetary Choice Questionnaire, in which participants will be asked to select between two amounts of money, one available immediately and the other available after a variable delay. The task includes 14 items and is the most widely used measure of delay discounting.

To assess how the participant considers the future while making decisions (both in general and with their child), an adapted version of the Consideration of Future Consequences Scale (CFC) will be used that focuses specifically on parenting. To assess child behavior, we will use the Eyberg Child Behavior Inventory (ECBI), Emotion Regulation Checklist, Revised Children's Anxiety and Depression Scale (RCADS-25) (limited to age 8+), Strengths and Difficulties Questionnaire (SDQ), and the DSM-5 Self-Rated Level 1 Cross-Cutting Symptom Measure – age 6-17 (limited to age 6+). To assess parenting characteristics, we will use the Aggravation in Parenting Scale (APS; a measure of parents' perceived aggravation related to parenting), the Alabama Parenting Questionnaire (APQ; a measure of different parenting behaviors), the Parenting Joy scale, Parenting Laxness (from the Parenting Scale), and revised Conflict Tactics Scale. Parents' use of alcohol and drugs will be assessed using the Alcohol Use Disorders Identification Test (AUDIT) and the Drug Use Disorders Identification Test (DUDIT). We will also include the Behavior Rating Inventory of Executive Function, Second Edition (BRIEF-2)

demographic measures of the mother (e.g., age, income, race/ethnicity) and child (e.g., age, sex at birth), and behavioral health questions from the Children's Health Questionnaire. At the last assessment only, parents will also complete a client satisfaction questionnaire (CSQ).

A table of the assessments and timepoints for each assessment is included below:

Measure	Reporter	Screening	Pre-	Intervention	Post-
Monetary Choice Questionnaire (MCQ)	Mother		X	X	X
Consideration of Future Consequences Scale-Parenting	Mother		X		X
Alabama Parenting Questionnaire	Mother		X		X
Aggravation in Parenting Scale	Mother		X		X
Parenting Laxness (from the Parenting Scale)	Mother		X		X
Parenting Joy	Mother		X		X
Revised Conflict Tactics Scale	Mother		X		X
Eyberg Child Behavior Inventory	Mother		X		X
Emotion Regulation Checklist	Mother		X		X
Strengths and Difficulties Questionnaire	Mother		X		X
RCADS (only kids age 8+)	Mother		X		X
APA_DSM5 Cross-Cutting Symptoms (only kids age 6+)	Mother		X		X
Demographics, socio-economic indicators, NDA elements, and items from the Children's Health Questionnaire	Mother		X		
Behavior Rating Inventory of Executive Functioning	Mother		X		
Client Satisfaction Questionnaire	Mother				X
AUDIT	Mother		X		

DUDIT	Mother		X		
EFT Rating	Interventionist			X	

All measures have proven psychometric properties and are validated for the parents of children ages 510, except where noted. Assessments will be housed on HFHS's REDCap in a study-specific database. REDCap (Remote Electronic Data Capture) is a secure, HIPAA compliant, web-based application for building and managing online surveys and databases. All surveys will be completed by the participant online via one of two options: 1) through a link sent to their phone (via text) or email, depending on the participant's preference, directly through REDCap or 2) online directly through REDCap on a study computer.

Observation session

As part of both the pre- and post- assessments, after the participant provides consent and if the participant's child assents to participate, we will complete a 20-minute observation of the parent and their child that will be videotaped. This will occur remotely (through a secure web-based conferencing software such as Zoom) or in-person in a private room at a public location, depending on the preference of the mom. Prior to starting the observation, verbal assent will be obtained from children age 7 and older and the date and person obtaining assent will be documented. During the observation, the mom and their child will complete a clean-up, homework, and play task and an RA will observe them and code their behavior using a standardized coding procedure (the DPICS). Although the observation will only last approximately 20 minutes, we will ask to schedule these sessions for 40 minutes to allow time for child assent and instructions.

We plan to supply each enrolled parent with a bag of toys, Bluetooth headset, math worksheets for the homework task, "where things go" worksheet for the cleanup task, and instructions for completing the observational assessment. For parents that are completing the observation virtually, these bags will be delivered before the assessment at an address that is most convenient for them. The bag will also include a copy of the consent form.

Compensation for the pre-assessment (surveys and observation session) will be $40.

Intervention Session

As soon as possible after the observation task is completed the participant (mom only) will take part in the EFT intervention, led by a trained peer parent, a trained member of the research team. The intervention will be completed either via secure web conferencing platform or in-person in a private room at a public location, depending on the parent's preference, and will be recorded. The intervention session will last 75-90 minutes, and participants will receive $25 for completing the session. The session will begin by the interventionist providing a general overview of the session and reviewing confidentiality. The participant will be asked to discuss their relationship with their child and to give examples of both positive and negative parenting from their personal experience. The interventionist will ask the participant to think about their long-term parenting goals and will discuss how to create a vivid event that will be easy to remember. Finally, several timepoints (six months, five years, ten years,

and twenty years) will be used to create EFT events of future scenes that the parent envisions with their child. The interviewer will complete the EFT rating sheet with each mother. After identifying each event, the interviewer will ask the mother to rate the event on several dimensions (see EFT Rating Sheet in the Assessment Battery). Data from the EFT rating scales will be used with the baseline assessments. The interventionist will create short cues from these events which will be entered into the REDCap database and incorporated in the text reminders (referenced to as "EFT CUE" in the Text Message Template).

During the intervention, immediately after completing the EFT section, the interventionist will read participants items from the Monetary Choice Questionnaire and ask them to respond to each item. The interventionist will then record the participants' responses and enter them into REDCap.

Finally, mothers will also be briefly instructed in a widely-used evidence-based parenting technique called special play time and given a pamphlet on this technique. They will be asked to practice special playtime with their child every day for the next two weeks.

Post-intervention Practice and Text Messaging

Once a day over the two weeks following the intervention session, participants will be sent brief text messages including the EFT event cue phrase (designed to trigger recall of a future scene or event with their child that they identified during the intervention) and a reminder to think about the scene they envisioned. Each time the participant replies to this text message within 24 hours indicating that they thought about the scene they envisioned, they will be compensated an additional $1.00 for a possible total of $14 over the course of the two weeks. The cumulative earned incentive amount will be paid at the end of the two weeks. Following confirmation of receipt of the EFT, participants will then be sent a second daily text message asking whether they practiced special playtime with their child that day. Following their response to the special play time text, participants will then be sent a third daily text message asking if they are interested in receiving additional tips for conducting special playtime. If they respond yes, they will receive a short text with a tip for special playtime. The texts with tips for special playtime are completely optional.

Post-Intervention Assessment

Two weeks after the intervention, participants will complete a post-intervention assessment. This assessment will include the same surveys as the pre-assessment battery, with the exception of the demographics and items from the Children's Health Questionnaire, the RCADS-25, the BRIEF-2, and the alcohol and drug screen measures. Additionally, participants will complete a brief measure of intervention satisfaction. Like the baseline assessment, these will either be conducted online through a link sent via email or text (depending on patient preference) directly from REDCap, or in-person in a private room at a public location using a study computer depending on the mother's preference. The participant does not have to choose the same mode of completion as the baseline surveys.

The post-assessment will also include a second observation session with the parent and the same child with similar tasks to the initial observation session.

Participants will be given $40 for completing the post-assessment activities (surveys and observation).

Reminders

Participants will be reminded of their scheduled meetings prior to the observation, intervention and final interview and will be contacted to reschedule, if a meeting time is missed, up to 3 times.

Key Informant Interview

Following completion of the intervention, participants will take part in a 30-minute key informant interview (KII; see KII script) that gauges participants' views on their perceived acceptability and satisfaction with the intervention. This is the final study task. Participants will receive $15 for completion of the KII.

KIIs with participants will focus on: (1) difficulties with parenting in a low-resource environment and perceptions of harsh parenting; (2) acceptability of recruitment and retention procedures as well as content and delivery modality of the intervention: and (3) level of engagement and feasibility of taking part in the intervention. Given the payments for responding to text reminders, we also plan to ask parents how often they "really" completed the EFT following text reminders as part of these interviews as a useful check on this process measure. Answers given will not affect payments parents received for their text responses during the post-intervention period.

KII guides will specify open-ended questions and process. Feedback will be used to modify the intervention and ensure that the protocol is acceptable and feasible for delivery by peer interventionists in a community setting, as well as issues related to scalability and wider dissemination. These interviews will also provide insight regarding barriers and facilitators to implementation at the organizational level and will inform wider dissemination and subsequent clinical trials.

After completing all study procedures, all participants will be offered a resource guide of free and lowcost resources in the Flint area.

Thus, in total, there will be five study visits/interactions: (1) the initial (baseline) assessment (including the online survey and observational task); (2) the intervention (including the delay discounting and parenting joy online surveys); (3) daily text messages with the EFT cue and special playtime reminder; (4) the post-intervention assessment; and (5) the key informant interview.

The interventions will be conducted by a peer parent or trained member of the research team. Peer parents not already trained in the intervention will be trained by the PI (Felton) and provided weekly and as-needed supervision, including individual review of recorded sessions for fidelity and training purposes. Recordings of peer-participant interactions will be labeled with the participants study ID and will be stored on password protected servers and will be destroyed following the three-year requirement for data storage. The peer parent will be added to the IRB as key personnel and complete all required human subjects training. We elected to utilize peer parents given strong evidence that peers are perceived as less stigmatizing and, with training, are able to implement straight-forward interventions with fidelity. We estimate that it will take 2-4 months to recruit and train peer parents, 2-4 months for recruitment of participants, 2-4 months for running the study, and 2-4 months for project wrap-up and data analysis from the time of grant award.

Incentive schedule

Study Visit/Interaction	1	2	3	4	5
Activity	Assessment 1 (online surveys and parent-child observation)	Intervention session + Monetary Choice Questionnaire	Daily text messages sent over 2 weeks	Assessment 2 (online surveys and parent-child observation)	Key Informant Interview
Incentives	$40	$25	$1/ positive EFT cue text message response (possible total =$14)	$40	$15

Additional Information:
* Since this is a pilot feasibility study, the sample size was selected to provide sufficient information regarding implementation outcomes and detect signal on outcomes. Findings from this project will be used to adapt the intervention for a larger RCT.
*The PI will conduct all analyses. She received a minor-specialization in qualitative methods as part of her doctoral studies and serves as the statistical consultant on two NIH-funded treatment development grants.
This project is funded by NIMH

National Data Archive

We are required by the funding agency, NIMH, to submit de-identified study data to the National Institute of Mental Health Data Archive (NDA) quarterly throughout the life of the study. De-identified data will be coded using a unique code known as a Global Unique Identifier (GUID). Use of the GUID minimizes risks to study participants because it keeps one individual's information separate from that of another person without using names, addresses, or other identifying information. The unique code also allows the NDA to link together all submitted information on a single participant, giving researchers access to information that may have been collected elsewhere. The GUID is a computer-generated alphanumeric code [example: NDA-1A462BS] that is unique to each research participant (i.e., each person's information in the NDA—or each subject's record—has a different GUID). In order to generate the GUID, we will need to collect PHI from the participant, including: full legal name, date of birth, place of birth, and address. The GUID is generated on HFHS computers; thus, the PHI required to generate the GUID is maintained securely at HFHS, is only available to the study team, and is never shared outside of HFHS. PHI to generate the GUID will be destroyed as soon as possible, but no later than the completion of data collection. For any parent that opts out of sharing their data with the repository, either at consent or prior to baseline surveys (via alerting study staff), information for generating the GUID will not be collected.

The NDA provides basic descriptive and aggregate summary information for general public use. Such summary information may include summary counts and general statistics on completed assessment instruments. Access to subject level datasets submitted and stored in the NDA will only be provided for

research purposes through the completion of the NDA Data Use Certification: OMB Control Number: 0925-0667. For the majority of the data available in the NDA, Data Use Certifications will only be accepted from researchers who are sponsored by an institution registered in the NIH's eRA Commons with an active Federal-wide Assurance issued through the Office for Human Research Protections (OHRP). Additionally, the application must include a reason for access related to scientific investigation, scholarship or teaching, or other form of research. Based upon this information, an appropriate Data Access Committee (DAC) with relevant expertise may authorize access.

Participants will be provided with information about the NDA during the consent process, both verbally and in the written consent form. Participants are able to opt out of the NDA by checking a box in the consent form or contacting the study team and letting them know that they would like to opt out. In such cases, opt out will be documented in REDCap and that participant's data will not be uploaded to the NDA.

4. ANTICIPATED RISKS

One foreseeable risk to participants in this study is possible discomfort (such as frustration or embarrassment) in answering questions about their own or their child's behaviors or their parenting methods. If participants report feeling uncomfortable answering certain questions at any point, they will be reminded that they are allowed to skip items and still be compensated for participation or can stop participation at any time with no penalty. Based on previous experiences collecting data from lowincome adults, we anticipate very low levels of non-response. We will also discuss with all participants the nature of the Certificate of Confidentiality during the consent procedures and clearly outline what information the Certificate protects.

Another possible risk is boredom or tiredness while completing the study assessments. Participants will be able to stop the assessment and come back to it at a later time if needed. We will also remind participants that they can skip any questions they don't want to answer and still be compensated.

There is a small risk that parents may feel frustrated with their child during the observation session. If this happens, we will remind the parent that they can stop at any time without penalty.

We expect any discomfort participants may feel while completing assessment questionnaires, intervention, or parent-child interaction sessions to be short-lived. However, in the event that participants are either disturbed or concerned about reactions to the questionnaires or parent-child interaction, we will encourage them to discuss these concerns with the research staff. They will be put in touch with mental health staff at Latinx Tech Center, the Community Center, and/or the PI (Felton), a licensed clinical psychologist, if concerns are not satisfactorily addressed.

Finally, there is a small risk of loss of confidentiality. To mitigate this risk, all research staff, including peer parents, will be trained in the protection of human subjects, and will be instructed in maintaining confidentiality. We will assign each participant a random identification number and only these numbers will be associated with the assessment materials. One master document that links participant names and numbers will be retained in a password protected computer file accessible only to study staff. Only study staff will have access to the REDCap database and other study materials. Community Center staff will not have access to any assessment materials and will not be informed of anyone's

participation in the study. Peer parents will be trained to take reasonable precautions to prevent revealing parents' participation in the program, including not referring to participants' status in the intervention. While participation in the program can involve receiving daily texts reminders (thus making it possible for other individuals to observe participants receiving study-related communications), we believe this risk is minimal.

In the event that a person answers that they are currently having thoughts of harming themselves or others on the screening form, they will be immediately provided with the Suicide Prevention Lifeline or a Crisis Line number and encouraged to call. Screening procedures will immediately end.

In the event that an enrolled participant discloses suicidal ideation or intent, involvement in physical abuse/neglect, and/or urgent physical and mental health concerns arise for the parent or child, the RA or interventionist will confer with Dr. Felton to determine next steps. Dr. Felton, along with Drs. ChronisTuscano (Co-I and licensed clinical psychologist), and O'Connell (Co-I and board-certified developmental pediatrician) if needed, will determine the appropriate course of action. In extreme circumstances, this may involve contacting authorities. The PI (Felton) and Co-Is Chronis-Tuscano and O'Connell have all conducted similar clinical trials and Drs. Felton and O'Connell have also used similar methods and interventions with Flint, MI-based samples and, from this experience, believe the possibility of having to report participants to authorities is extremely rare. Given that we are not specifically asking about suicidality beyond the screening form, we also expect any spontaneous disclosure of suicidality by an enrolled participant to be extremely rare. Nevertheless, any enrolled participant disclosure of harm to self or others will be treated seriously and the PI will directly follow-up with the participant within 24 hours to clarify their report of harm to self/others and gather more information. In the rare event that such disclosures are determined to be required by law, we will report only information directly provided by the participant related to child maltreatment (defined as physical or mental injury, sexual abuse, neglect, or other circumstance whether the welfare of the child is threatened). Prior to participation, participants will be given clear verbal and written details (during consent procedures) around these requirements and informed of the research team's ethical and legal obligations to protect the safety of vulnerable individuals. Participants will also be given multiple opportunities to ask questions regarding both reporting requirements and the reporting process and encouraged to reach out to the PI (a licensed clinical psychologist) to address any concerns that they may have. Participants who are reported to authorities under these circumstances will be allowed to remain in the study, but their data will not be used and a replacement participant will be recruited. The research team has already fully discussed these reporting requirements and received support for these procedures from agency leadership at both recruitment sites. Researchers have worked extensively to forge strong relationships with community partners and will continue to work together on the development of research procedures, including addressing any concerns the community may have that may arise during the completion of this project.

5. ANTICIPATED BENEFITS

There are no known direct benefits to participants. It is possible that mothers participating in the current study could have improvement in delay discounting and subsequent improvement in their relationship with their child.

More broadly, knowledge gained from this study will be used to inform future parenting interventions and will also help to refine dissemination procedures. Thus, the primary benefit to the community is to inform future interventions that may reduce rates of harsh parenting and child mental health problems and improve public health in a traditionally underserved area.

6. RENUMERATION/COMPENSATION

Participants will be offered payment for taking part in each assessment (assessment questionnaires

and key informant interviews), as well as completing daily practices of the intervention over two weeks. Participants will be provided a ClinCard and money will be loaded onto that ClinCard at five time points: (1) after completing the first assessment (online surveys and parent-child observation), (2) after completing the intervention; (3) after completing the text messages (loaded at the end of 2 weeks; sum dependent on the number of text responses received); (4) after completion of the second assessment (surveys and observation); and (5) after completing the key informant interview.

Weeks from Enrollment	1	2	3	4	5-6
Activity	Assessment 1 (baseline surveys and observation)	Intervention Session + Monetary Choice Questionnaire	Daily text messages sent over 2 weeks	Assessment 2 (surveys and observation)	Key Informant Interview
Incentives	$40	$25	$1/text message response (possible total =$14)	$40	$15

For any participants that complete in-person study tasks, we can offer a round trip MTA Flint bus pass for either the mother (for any study task outside of an observation session) or for both the mother and the child participating in the study (for completing an observation session). For the mother only, in most cases the bus pass would total $6 ($3 each way). For the mother and participating child, the bus pass in most cases would total $12 ($3 each way per person).

7. COSTS

There are no costs to the participant to take part in this study outside of possible messaging rates for sending and receiving text messages. While text messaging is included in most modern phone plans without additional charges, it is possible that the participant could incur small charges for text messages if this is not included in their phone plan. Participants will be asked at screening if they are willing to send and receive text messages as part of the study.

8. ALTERNATIVES

The alternative to participants is not participating in this research.

9. CONSENT PROCESS AND DOCUMENTATION

Immediately following screening, the RA will review the key information from the informed consent document with the participant over the phone or in-person (see Screening and Consent Script) and will allow time for any questions to be answered. During the consent process, all individuals will be informed that participation is completely voluntary, will be kept confidential, and will not impact their access to services in any way. The participant will also be informed that the intervention session, observation sessions, and key information interview will be recorded for research purposes. The RA will also clearly explain situations in which confidentiality would need to be broken. For those that choose to complete the consent and online surveys remotely, after reviewing the consent information with the participant, the RA will send a link to the consent form, using REDCap's e-consent framework, via text or email for the participant to review and electronically sign prior to any study procedures. For participants that choose to complete the consent and online surveys in-person, a study computer will be set up in a private room at a public location and the participant will complete everything directly in REDCap. A study team member will be present if consenting in person. To maintain consistency across all participants, we plan to utilize the REDCap e-consent framework regardless of mode of consent (virtual/in-person). The e-Consent document contains all elements of a paper consent, including signature, and is securely stored in REDCap. A PDF of the completed consent form will be available to the participant for download after they provide their consent. Once the completed consent is received through REDCap, the staff member that reviewed the consent information with the participant over the phone will verify completion and will document their name, date and signature in REDCap.

All children age 7 and older participating in the observation session will be assented before the observation with their mother begins. Prior to taking part in the observational assessment, a research assistant will explain their participation in the study (over phone or web conferencing or in-person, depending on whether the observation takes place virtually or in-person) and allow for time for the child to ask questions. Verbal assent will be documented in REDCap.

10. WITHDRAWAL OF SUBJECTS

There are no anticipated circumstances under which participants will be withdrawn from the research without their consent. Participants who decide to withdraw will not face any penalty or denial of services.

11. PRIVACY AND CONFIDENTIALITY

We will take extensive precautions to maintain privacy, confidentiality, and security of data and participant information. Access to study data and identifiers will be limited to only study staff. All participants will be assigned a random study ID. Only one log linking participants names and their IDs will exist and access will be limited to a small number of study team members. Contact information (for the purposes of sending survey links, providing materials, reminders and study text messages) will be destroyed after completion of study activities. Study materials will be kept in encrypted data files on a password protected computer. All study materials, including audio and video files will be destroyed no later than three years after the completion of the study, consistent with recommended guidelines.

All video recordings will be saved on a secure folder on HITECH-compliant servers at HFHS. Only study personnel will have access to this folder and the video recordings. Videos of the parent-child interaction will be shared with the University of Maryland (UMD) for research coding and quality assurance purposes. Videos will be labeled with ID only and will be shared via secure file transfer. Once coding and QA procedures are complete, UMD will delete the file. A data use and material transfer agreement will be executed with UMD before videos are transferred.

Similarly, all audio recordings will be saved on a secure folder on HITECH-compliant servers at HFHS. Only study personnel will have access to this folder and the audio recordings. Audio files will be uploaded to a secure AI-based transcription platform for transcription purposes. Transcripts will be reviewed by the study team and any PHI will be removed before saving to a secure study folder accessible only to the research team. Audio files and transcripts will be saved with a study ID only. Once transcribed, audio files will be deleted as soon as possible.

Patient-level data needed for creation of the GUID for de-identified data upload to the National Institute of Mental Health Data Archive (NDA) will be stored securely on HITECH-compliant servers at HFHS. Only a limited number of study personnel will have access to this data. Only completely de-identified data will be submitted to the NDA. A data submission agreement will be executed with the NDA before data is uploaded. PHI collected for GUID creation will be deleted as soon as possible but no later than the end of study data collection.

In addition, a Certificate of Confidentiality (CoC) was granted by the National Institutes of Health to protect the privacy of research subjects by prohibiting disclosure of identifiable, sensitive research information to anyone not connected to the research except when the subject consents, or when required by law for reporting medical emergencies, serious threats of harm to self or others, child abuse or neglect, or elder abuse.

Important HIPAA Concerns

The study involves video-recorded observations of the parent and their child that will be created for research purposes and sent to an external collaborator, the University of Maryland, for coding. The video files will be labeled with the study ID but will still contain the video image and voice of the participant and their child. Although we are not asking questions directly of the parent or child during this observation, it is possible that the participant or their child could provide personal information (e.g., name) unprompted.

Important information about the collection and sharing of this information is included as part of the HIPAA authorization section of the consent form. The RA will review this information during the consent process with the participant. The participant will be given sufficient time to ask questions and will ask to give their authorization for collection and use of this data verbally. Consent and authorization will be provided by the participant electronically in REDCap.

Videos will be sent to University of Maryland via secure file transfer only after a Material Transfer Agreement and Data Use Agreement are in place. Videos will be deleted as soon as possible at UMD. Coded data will be stored in a password protected computer folder on a secure server at Henry Ford Health System.

12. DATA AND SAFETY MONITORING PLAN

Dr. Felton will be responsible for overseeing the implementation and execution of the data and safety monitoring plan. All research staff (including peer parents) will complete relevant human subjects protection training. Dr. Felton will also ensure that all participants in the study meet specified inclusion/exclusion criteria by reviewing enrollment with research staff at regular study team meetings. Data will be monitored on an ongoing basis and reviewed by the PI at regular intervals to identify any problems or concerns. Analyses will be conducted only after all data is collected, deidentified, and cleaned, thus limiting the possibility of deidentification. Any findings shared with the community stakeholders will be done in aggregate and reflecting mean-level trends. Data will be safeguarded against breaches of confidentiality using the procedures outline above. These processes include removing identifiable information from data and coding assessment forms with ID numbers only. All data will be kept securely in locked file cabinets accessible only to research staff or on secure servers in files only accessible to study staff. Community partners will not have access to any assessment materials. Any computers containing electronic data files will be password-protected, stored in locked cabinets in locked offices, and accessible only by study personnel. Only the research staff will have access to the data. A Certificate of Confidentiality was provided by NIH which will protect against requests to disclose sensitive research information, within the bounds of the law.

Adverse Events (AEs) and Serious Adverse Events (SAEs), as defined by the DHHP Office of Human Research Protections, will be monitored by the PI (Felton). Any AEs will be recorded by research staff and discussed by the research team during regularly scheduled meetings. If required per HFHS IRB or NIH protocols, the PI will then prepare a written report for submission to the HFHS IRB and/or the appropriate NIH program officer. The report will specify all relevant information regarding whether these events are expected or unexpected, the severity of the event, a brief narrative of the event, and a determination regarding any causal connection between the event and the ongoing research study. Any such events will also be included in the annual progress report sent to NIH. In the unlikely event an SAE were to occur, research staff will alert the PI immediately. Per IRB and NIH protocols, subsequent reports to the HFHS IRB and NIH will be completed within the appropriate timeframe.

13. QUALIFICATIONS OF THE INVESTIGATOR(S)

Dr. Felton is an Assistant Scientist at Henry Ford Health System located in Detroit, MI. She earned her PhD in child clinical psychology from Vanderbilt University with a minor specialization in quantitative methods. Her program of research centers on identifying risk factors for the onset of substance use in children and adolescents (e.g. Felton et all, 2015) as well as examining the role of early environmental and parenting factors associated with the trajectory of drug and alcohol use over time (e.g. Felton et al., 2020). She has specific expertise in assessment, research design, and data modeling techniques, having served as the PI, Co-I, or statistical consultant on a number of NIH-funding grants and published over 65 manuscripts and book chapters on development of vulnerabilities to mental and behavioral health problems and targeted preventative interventions to reduce these risk factors.

14. REFERENCES

Dassen, F. C. M., Houben, K., & Jansen, A. (2015). Time orientation and eating behavior: Unhealthy eaters consider immediate consequences, while healthy eaters focus on future health. Appetite, 91, 13–19. https://doi.org/10.1016/j.appet.2015.03.020

Felton, J.W., Collado, A., Cinader, M., Lejuez, C.W., Chronis-Tuscano, A., & Yi, R. (2020). Exposure to maternal depressive symptoms and growth in adolescent substance use: The mediating role of delay discounting. Development and Psychopathology.

Felton, J.W., Collado, A., Cinader, M., Lejuez, C.W., Chronis-Tuscano, A., & Yi, R. (2020). Exposure tomaternal depressive symptoms and growth in adolescent substance use: The mediating role of delaydiscounting. Development and Psychopathology.

Felton, J.W., Collado, A., Ingram, K.M., Doran, K., & Yi, R. (2019). Improvement of working memory is a mechanism for reductions in delay discounting among mid-age individuals in an urban medicallyunderserved area. Annals of Behavioral Medicine.

Lin, H., & Epstein, L. H. (2014). Living in the moment: Effects of time perspective and emotional valence of episodic thinking on delay discounting. Behavioral Neuroscience, 128(1), 12–19. https://doi.org/10.1037/a0035705

Moreland, A.M., Felton, J.F., Hanson, R.F., Jackson, C., & Dumas, J.E. (2016). The relation between parenting stress and parenting locus of control: Mechanisms of change in parenting interventions. Journal of Child and Family Studies, 25, 2046-2054.

Snider, S. E., DeHart, W. B., Epstein, L. H., & Bickel, W. K. (2019). Does delay discounting predict maladaptive health and financial behaviors in smokers? Health Psychology, 38(1), 21.

Stein, J. S., Wilson, A. G., Koffarnus, M. N., Daniel, T. O., Epstein, L. H., & Bickel, W. K. (2016). Unstuck in time: Episodic future thinking reduces delay discounting and cigarette smoking. Psychopharmacology, 233(21), 3771–3778. https://doi.org/10.1007/s00213-016-4410-y