Translational Research to Inform Interventions for Severe Challenging Behavior for Individuals with Intellectual and Developmental Disabilities

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1.0 Background

Extinction describes discontinuation of reinforcement that results in decreases in a measurable dimension of behavior (e.g., frequency, duration; Cooper et al., 2020). **Bursts are the most common collateral effect of extinction** (Ducharme & Van Houten, 1994) and are characterized by a temporary increase in behavior, relative to baseline (see Figure 1; Alessandri et al., 1990; Iwata et al., 1990; Laws et al., 1971; Lerman & Iwata, 1995). Although the general prevalence of bursts can be estimated (e.g., Lerman & Iwata), no method exists to control their occurrence.

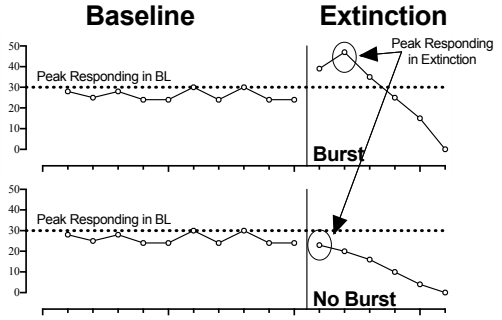


Figure 1: *Example of burst*

Notwithstanding, control is valuable. **Treatments of challenging behavior are less effective when they do not include extinction** (Fisher, et al., 1993; Hagopian et al., 1998; Mazaleski et al., 1993; Rooker et al., 2013; & Zarcone et al., 1994). However, when problem behavior is dangerous, practitioners may not risk increasing its rate or intensity. Thus, extinction is often omitted in the service of safety (and at the cost of efficacy). **If we understood why bursts occurred, we could proactively work to mitigate their occurrence; thereby making extinction a viable treatment option in more settings.**

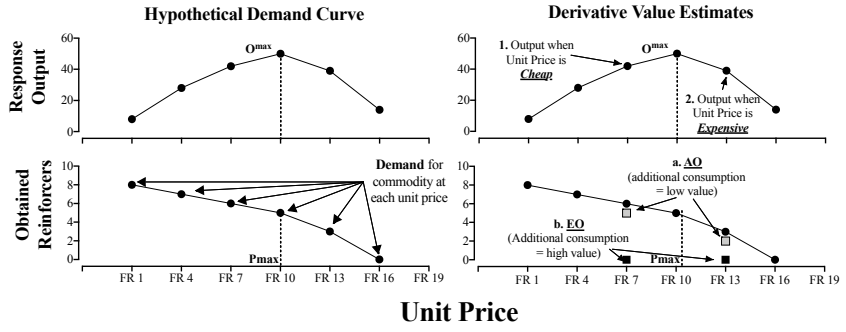


Figure 2: *Value estimates derived from demand curve analysis*

Available evidence suggests baseline reinforcement parameters influence responding (i.e., behavior) during extinction (Aiken, 1957; Holton, 1961; Nevin et al., 1990; Perin, 1942; Siegel & Foshee, 1953; Young, 1966). The reinforcing effects of stimuli; however, can be relative and volatile (Baum, 1974; Michael, 1975; Hineline, 1984; Perone, 2003). Simply put, different reinforcers support different magnitudes/ qualities of responding (e.g., Hodos, 1961). Thus, although someone might be willing to share a thought for a penny, they are unlikely to build a house for one. This "not all reinforcers are created equal" epiphany has inspired scientists to study "value" (i.e., variables which alter the degree to which specified consequences support specified outputs). **As bursts are likely a product of baseline reinforcement parameters, consideration of value is essential to understanding the phenomenon**.

Concepts in consumer-demand theory (Bickel et al., 2000) may prove useful to this analysis. Specifically, in behavioral economics, ***demand*** describes the quantity of a given commodity (e.g., 10 gallons of gas) an individual consumes at an established price (e.g., $2/gallon). When demand is *inelastic*, consumers work harder (or pay more) as prices increase, to maintain baseline levels of consumption. For example, motorists are unlikely to purchase less gas if price increases by $0.05. However, demand can become *elastic*. That is, as price increases, consumption begins to share an inverse relation with those increases. In the previous example, motorists may eventually purchase less gas and drive to fewer places if the price of a gallon were to increase by $5.00. The shift in demand from inelastic to elastic is a point of interest because it quantifies commodity (reinforcer) value and helps identify optimal prices. **The optimal price, or**

***Pmax*, is the price that supports maximum consumer spending** (or Omax, see top left panel of Figure 2). Prices below Pmax undervalue commodities because consumers *would* spend more than required. Similarly, prices above Pmax are suboptimal because these price points decrease the value of the commodity and consumers won't spend as much to obtain it as they would if pricing had been more reasonable. For reasons expanded upon below, the concept of Pmax may prove useful for understanding bursts.

Related, ***demand*** (defined above) can be used to quantify *temporary* shifts in value at a specified price because the value of *additional* consumption is decreased as consumption approximates demand. Individuals stop "paying" for reinforcers after they have crossed this threshold (see bottom panels of Figure 2). Laraway et al. (2003) accounts for this effect by distinguishing antecedent events (e.g., deprivation) that temporarily increase value of consequences (e.g. access to food) from other antecedent events (e.g., satiation) that work in the opposite direction and deplete value. The former is an establishing operation (EO) and the latter is an abolishing operation (AO). Using these terms, one might say the value of *additional* consumption is abolished (decreased) the closer consumption gets to demand. By contrast, the value of *additional* consumption is established (increased) when little/no consumption has occurred.

Generally, Pmax and demand have not been considered in published treatments of bursts. However, as bursts are likely a product of baseline reinforcement conditions, and because value can fluctuate according to molar (i.e,. unit price) and molecular (i.e., satiation/deprivation) variables (right panel, Figure 2), consumer-demand theory may provide a useful framework from which to formulate and test hypotheses relevant to bursts. For example, **it is possible that bursts are a product of baseline schedules of reinforcement (i.e., "unit prices"), relative to Pmax.** Specifically, if baseline prices (i.e., number of responses required to obtain a reinforcer) are a bargain because they are "cheaper" than Pmax, consumers may be more inclined to increase output to a value that approximates Omax during extinction (a pattern typified by "bursts"). Likewise, if baseline prices are "more expensive" than Pmax, then output has already been diminished and bursts may be less likely. **It is also possible that bursts are a product of the *timing* of extinction.** Specifically, if, prior to extinction, consumption has approximated demand (thereby abolishing additional consumption as a reinforcer), responding during extinction may be less than if the inverse were true. **Finally, it is possible that price (relative to Pmax) and timing (i.e., pre-extinction consumption relative to demand) interact.**

2.0 Rationale and Specific Aims

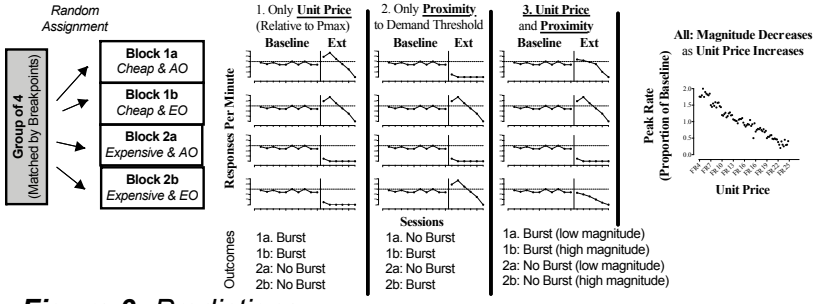


Figure 3: *Predictions*

The <u>Goal</u> of this application is to identify mechanisms responsible for bursts, and to facilitate strategic extensions toward discovery for treatments of challenging behavior. To accomplish this, we present two related but distinct objectives. **<u>Objective 1</u>** entails identification of an efficient, accurate, and reliable assessment of Pmax. **AIM 1: Evaluate correspondence between Pmax values derived from assessments of varying efficiency.** ***H1:*** *Progressive ratio (PR) reinforcer analysis (more efficient) will produce estimates which align with values obtained by progressive fixed-ratio reinforcer analysis (PFRA; less efficient).* **<u>Objective 2</u>** entails determining the degree to which relative price and the timing of

extinction interact to increase or abate responding during extinction (thereby highlighting mechanisms of control). **AIM 2: Evaluate utility of manipulating baseline parameters for controlling bursts when variables are set according to demand and Pmax.** ***H2:*** Peak response magnitude during extinction will decrease as unit price increases. Further, *baseline will moderate bursts in one of three distinct ways.* ***First***, only unit price, relative to Pmax, will influence peak-response magnitude. ***Second***, only timing of extinction (i.e., proximity of baseline consumption to demand threshold) will influence peak-response magnitude. ***Third,*** unit price relative to Pmax, and consumption relative to demand, interact to influence peak-response magnitude during extinction.

3.0 Inclusion/Exclusion Criteria

Inclusion Criteria

(a) Biological age of 18 years or older
(b) IDD diagnosis
(c) Ability to correctly manipulate all items used in the study
(d) Consent/assent prior to and throughout the study

Exclusion Criteria

(a) Biological age of 17 years or younger
(b) No disability
(c) Cannot correctly manipulate all items used in the study
(d) Does not consent (or assent) to participate

4.0 Enrollment/Randomization

Recruitment. Participants will be recruited across seven primary research sites. PLACEMENTS AND POINTS OF CONTACT ARE REDACTED will mediate contact and communication between potential participants and researchers. Importantly, these points of contact have no connection to the research study, are not invested in its execution, and have been commissioned to prioritize the rights and safety of their clients. Thus, recruitment efforts will be filtered by an unbiased third party.

Participants interested in the study will then reach out to KSP, who will initiate the informed consent process and who will ask participants pertinent information about relevant disabilities. In the case that a participant's legal guardian reaches out on their behalf, we will follow the same procedures. However, after obtaining informed consent, we will also obtain assent from participants who understand language. If participants are non-verbal, we will ask their legal guardians to describe non-verbal actions accepted as proxies for assent or dissent, and we will treat these proxies as demonstrations of assent or dissent (and will honor them accordingly) throughout all phases of the study.

Because REDACTED requires human rights committee (HRC) approval of all client programming (i.e., behavior intervention plans, medication changes, study participation), we have included additional documents relevant to that organization. The first is their established policy for research participant. The second is a consent from their clients for them to share client contact information with us (i.e., to learn more about study procedures and to provide informed consent), the third is a consent to share information document which will allow us to inform REDACTED administrators of client consent to participate so that said participation can be reviewed and approved by REDACTED regional HRC.

Thus, for REDACTED, interested participants will complete a "consent to share information" document and this information will be delivered to us by a director or coordinator. We will then set up a meeting to obtain informed consent. If consent is obtained, prospective participants will sign a "consent to share information" document which will allow us to report to REDACTED about their consent so that the process fo regional HRC review can be initiated. Contingent upon both participant consent and subsequent HRC approval, study activities can then begin.

Enrollment & Randomization. Because this is a low-risk trial with a limited budget, the PI (Lambert) will be responsible for carrying out randomization procedures and for monitoring data. Enrollment and randomization procedures will entail:

1. Enrolling participants in batches of 10
2. Matching two blocks of four participants based on similarity in pertinent baseline assessment scores (i.e., progressive-ratio reinforcer analysis), and relegating participants with outlier scores to block participation with the next batch of enrolled participants.
3. Using the randomization and sorting functions of Microsoft Excel, we will randomly assign each member of each block within each batch of participants to one of four experimental conditions (i.e., cheap+EO, cheap+AO, expensive+EO, expensive+AO).

Registration. We have initiated the study registration process with clinicaltrials.gov.

5.0 Study Procedures

We will schedule 1 to 4 appointments per week with each participant across a 1-month period. All participants will complete the same progression: (1) interview (i.e., set appointments, identify programmed reinforcers and target-responses), (2) target-response training, (3) PRA, (4) PFRA, (5) extinction challenge.

Experimental Design. Following completion of a small battery of intake assessments (listed above), we will evaluate between-groups differences in peak-response magnitudes during a single exposure to extinction using a 2x2 factorial, crossed, and randomized matched blocks design, employing batched randomization logic. Specifically, we will recruit participants in batches of ten and will match two tetrads according to similarity in PRA results (described below). The two participants not assigned to a group will be matched to subsequent tetrads. Or, (if recruited in the final batch), paid for their time and discharged. To assign members of each tetrad to one of four experimental groups (i.e., cheap EO, cheap AO, expensive EO, expensive AO), we will use randomization functions of appropriate computer software (e.g., Microsoft Excel).

Settings, Participants, Consent, & Compensation. Recruitment will occur across six primary research sites. Best Buddies Tennessee, The Metro Parks DisABILITIES program, Habilitative and Training Services (HATS), Down Syndrome Association of Middle Tennessee (DSAMT) Next Steps at Vanderbilt, Friends Life Community, and MillarRich. ll have offered letters of support. Across the life of the study, we will recruit 80 adults in batches of 10. We do not anticipate biological variables (e.g., sex) to impact study outcomes. Inclusion criteria call for participants: (a) to be older than 18 (we exclude children to obey labor laws), (b) to have a developmental disability (unconstrained to specific diagnoses. We chose to work with a heterogenous sample to increase the generality of our findings), (c) to correctly manipulate all study items, and (d) to consent prior to and throughout the study. If participants cannot legally consent, we will obtain consent from guardians and will assess assent throughout the study (i.e., at the beginning of every session). **Importantly, pilot-study participants consented to all procedures on an ongoing basis.** We will pay participants with gift cards, on a schedule commensurate with minimum wage ($7.25/hr).

Materials and Target Response. For each participant, we will individualize and define (a) a target response with a corresponding apparatus, (b) a preferred edible item or sound manipulation (Lambert et al., *in press*), and (c) a moderate- to low-preferred tangible item. All target responses will involve a two-step manipulation and restoration. The final step of each target response (i.e., restoration) will automatically set up another opportunity to complete the task (e.g., fold/unfold a hand towel).

Dependent Variables, Procedural Fidelity, and Interobserver Reliability. We will collect continuous timed-event measures of the frequency of target responding and reinforcer delivery, latency from session onset to delivery of programmed reinforcers, and overall session duration. Derivative measures appropriate to each analysis will serve as our dependent variables and will include breakpoint (i.e., the schedule of the last obtained reinforcer prior to response cessation [PRA]), demand (i.e., the number of reinforcers obtained prior to response cessation [PFRA]), Pmax (defined above [PRA & PFRA]), and peak response rate during extinction (Figure 1), depicted as a proportion of baseline (e.g., Figure 4). We will monitor fidelity, and a second trained observer will collect reliability data on all dependent variables across no fewer than 30% of sessions.

General Appointment Protocol. To minimize unintended coercive practice, all assessment-related activities will be framed as a choice. Specifically, facilitators will initiate appointments with a 5-min casual conversation. Prior to each session, facilitators will display the apparatus for target response and a low-preferred alternative activity and will say, "We are going to start a session, now. This just means I'm going to give you an opportunity to earn (reinforcer). During sessions I cannot talk to you. That's just a rule I have to follow. It doesn't mean I don't want to talk or that I'm not happy. If you want (reinforcer) after the session starts, you can work on (target response). If you don't want (reinforcer), or would rather talk to me, you only need to stop (target response) for one minute. You can also just say, 'I'm done'. While you wait, you can (alternative activity) if you like." All appointments will terminate the moment a participant indicates they would like it to end.

Response Training. Will entail a forced-choice exposure and 10 opportunities to independently earn reinforcers (1/response). If independence is not achieved, we will target different responses and reinforcers.

Progressive Ratio Reinforcer Analysis (PRA). Begins with free-access, followed by three PRAs interspersed with controls. Control will occur prior to PRA. To avoid satiation, only one PRA will be conducted per appointment. Thus, including free access, this assessment requires four appointments. **Free access.** Carefully measured units of the reinforcer will be delivered freely, independent of target responding. Participants will be informed they can consume (e.g., eat, listen to) reinforcers at will, and that reinforcers will be replaced (when relevant) as they are consumed. Sessions end when no reinforcers are consumed for one minute. **Control.** Facilitators will place the target-response apparatus in front of participants and indicate that responding will not result in reinforcement. Sessions end following 1 min without responding. **PRA.** Facilitators will indicate that responding results in reinforcement, but that more work will be required as time passes. Following every other reinforcer delivery, price will increase by three responses (i.e., FR1, FR4, FR7, etc.).

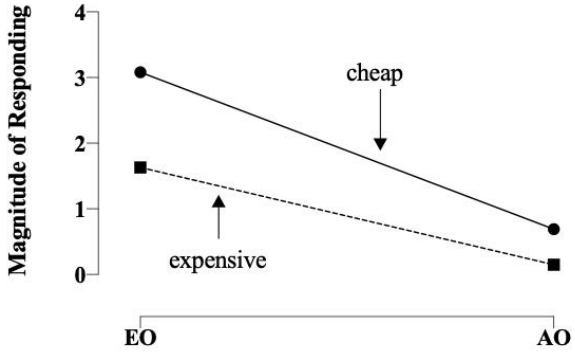
Progressive Fixed-Ratio Reinforcer Analysis (PRFA). Will be similar to PRA with a few exceptions. First, no control condition. Next, within-session schedules are fixed. That is, requirements increase by 3 across sessions, rather than across reinforcers (this allows us to establish demand at each schedule). To control for satiation, we'll conduct one PRFA session per appointment (session ends following 1 min without responding; or after 1 hour). The assessment ends after aggregate responses for one session fall below those of previous sessions (thus avoiding premature exposure to extinction). During our pilot study, this assessment was completed in six or fewer appointments, each ranging from 5 to 27 min.

Extinction Challenge. ***Baseline*****.** Facilitator does not inform participants of active contingencies and reinforces responding according to participant-assigned schedule for participant-specific session duration (see below). This will continue for 10 sessions, with multiple session completed each day. ***Extinction*****.** Occurs during a single appointment. Session format is similar to baseline but no programmed consequences for target responding. Sessions continue until responding reaches 10% (or less) of mean of the final three baseline sessions for two consecutive sessions (or until dissent). ***Individualization.*** *Baseline schedules* will be set according to PRA and PFRA results. Specifically, we will compare the difference of each participant's PFRA-identified Pmax and their PRA-identified mean breakpoint. For participants assigned to *expensive*, we will add half of the calculated difference to Pmax and round up to the nearest whole number. For example, if Pmax was FR4 and breakpoint was FR8, half of the difference would be two, which we would add to Pmax to establish an expensive baseline of FR6. Similarly, for participants assigned to the *cheap* condition, we will *subtract* half of the difference from Pmax and round down to the nearest whole number (i.e., FR2). *Default session duration* for baseline and extinction will be five minutes. However, to ensure opportunity to obtain no fewer than five reinforcers per session, we will reference latency to the first obtained reinforcer of the *matched PFRA session* (i.e., the session with a schedule that most closely approximates the baseline schedule). For example, in our pilot study, participant AC was assigned to *expensive*. Based on the distance between his breakpoint and Pmax, baseline was set at FR6. We thus considered latency (i.e., 56 s) to first reinforcer obtained during the matched PFRA (FR7) to predict the number of obtained reinforcers during a typical 5-min session. Projecting consumption from this value, we concluded he could obtain at least five reinforcers at the default duration when the schedule was set at FR6, and thus maintained the 5-min session duration. However, had latency been 90 s, we would have increased session duration to 7.5 min. To *set a maximum appointment duration*, we will use the matched PFRA session duration as a proxy measure of AO (e.g., fatigue, satiation) and will ensure appointment duration approximates, but falls below, this value. Similar considerations will be made to ensure appointment-reinforcer consumption never surpasses demand. For example, AC consumed a maximum of 55 reinforcers during the FR1 session of his PFRA. At FR6 (his assigned baseline schedule), we projected it would have taken 11 sessions to consume 55 reinforcers, estimating (roughly) 60 s to earn each reinforcer (justified above). In response, we ensured that no appointment exceeded 10 sessions. For ***AO*** participants, we will introduce extinction after appointment-reinforcer consumption falls one below demand. Previous appointments will thus be coordinated in such a way that extinction for the AO group is introduced toward the end of the relevant appointment (however, we will not cap appointment duration during extinction). Similarly, we will introduce extinction to ***EO*** participants during the first session of the relevant appointment, when consumption has been low. The first EO-extinction session will be preceded by a single reinforcer delivery.

Data Analysis Plan. We will evaluate between-groups differences in peak magnitudes of responding during a single exposure to extinction using a 2x2 factorial, crossed, and randomized matched blocks design, employing batched randomization logic. First**,** we will calculate *observed* and *analytic* Pmax values (Gilroy et al., 2019) generated from logarithmically transformed PRFA outcomes to evaluate accuracy, reliability, and correspondence of Pmax estimates generated from PRA calculations (Reed et al., 2009). PRFA-PRA Pmax comparisons will be performed for each of the 160 PRA/PRFA assessments. Correspondences in Pmax will be assessed using Pearson correlations. Then, we will conduct a simple linear regression to assess relations between unit price and peak response magnitudes. Then, to evaluate (a) the effect of the timing of extinction (EO/AO) on peak response magnitude, (b) the effect of relative price (cheap/expensive) on response magnitude, and (c) price by timing interaction (whether the effect of timing on peak response magnitude changes depending on price) we will conduct a multiple linear regression analysis with price and timing as dummy coded categorical predictors. We will replicate this

analysis to evaluate collateral effects on *duration* of responding during extinction (a secondary analysis we anticipate will produce a less robust but potentially meaningful outcome).

Predicted relationship between timing, price, and response magnitude.



We predict that the mean magnitude of peak responding for participants assigned to cheap conditions will be higher than those assigned to expensive conditions, holding timing constant. Additionally, we predict the mean magnitude of peak responding will be higher for those participants assigned to EO as compared to AO, holding price constant. Further, we predict a timing by price interaction such that the difference in mean peak responding in cheap and expensive conditions will be bigger in EO relative to AO.

Power Analysis. Power analysis and sample size calculations were conducted using G*power software. Since our study represents a novel contribution to the field, we cannot rely on previous literature to estimate the population value of R-squared or the appropriate effect size. However, our pilot data suggest the effect size will not be small. Thus, we calculated sample size based on a benchmark value for Cohen's f^2 of 0.15 that corresponds to a medium effect size for R-squared (Cohen, 1988). To achieve 80% power in a regression model with three predictors and $\alpha = .05$, the number of required participants is 77. With a sample of 77, the power to find any one of the three predicted effects (given medium effect size) is 88. Since participants will be equally distributed across four groups, we budgeted time/effort for 80 participants. Under our most conservative study assumptions, AIMS 1 & 2 are adequately powered.

6.0 Reporting of Adverse Events or Unanticipated Problems involving Risk to Participants or Others

This is a low-risk study. The PI (Lambert) will review all data on a weekly basis and all adverse events (AE) will be logged on an AE form and will immediately be reported to the IRB.

7.0 Study Withdrawal/Discontinuation

Prior to each appointment, we will re-assess assent to participate by asking clients if they would like to work with us. When/if assent is not given, we will not conduct appointments. We will individualize appointment parameters (i.e., appointment duration, responses targeted, reinforcers delivered) based on ongoing assessments of participant preferences (see study procedures). We will also provide periodic reminders of how participants can terminate sessions and/or appointments (by simply saying that they would like to stop). If participants indicate they no longer wish to participate in the study, we will promptly terminate their participation with no consequence to them (i.e., participants will be paid for all time spent in research activities, RAs will not try to convince participants to stay in the study, and RAs will continue to interact with participants in pleasant and respectful ways).

8.0 Statistical Considerations

Power Analysis. Power analysis and sample size calculations were conducted using G*power software. Since our study represents a novel contribution, we cannot rely on previous literature to estimate the population value of R-squared or the appropriate effect size. However, our pilot suggests the effect size will not be small. Thus, we calculated sample size based on a benchmark value for Cohen's f^2 of 0.15 that corresponds to a medium effect size for R-squared (Cohen, 1988). To achieve 80% power in a regression model with three predictors and $\alpha = .05$, 77 participants are required. With this sample, the power to find any one of the three predicted effects (given medium effect size) is 88%. As participants will be equally distributed across four groups, we budgeted effort for 80 participants. Under our most conservative study assumptions, AIMS 1 & 2 are adequately powered.

9.0 Privacy/Confidentiality Issues

Participant names will be replaced with pseudonyms on all study-related documents. A single Excel file will link participant names and contact information to pseudonyms. All other research documents will not include participant names and will only include associated pseudonyms.

The above-mentioned Excel file will be stored on a secured and password protected computer, as well as on a server provided by Vanderbilt University and only accessible to research personnel. This file will be destroyed at the study's conclusion, leaving no remaining link between identifying information and participant data.

10.0 Follow-up and Record Retention

We anticipate that this study will require two years to complete. Intend to maintain all de-identified records obtained during the study indefinitely. However, files linking participant names and contact information to pseudonyms will be destroyed (deleted) once the study has been completed.

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