

Study Protocol and Statistical Analysis Plan

Study Title: Impacts of Clinician-Mediated Report-Back

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Study design overview

We collaborated with two prospective pregnancy cohort studies, Puerto Rico Testsite for Exploring Contamination Threats (PROTECT) and Environmental Reproductive and Glucose Outcomes (ERGO), to report-back exposure results to participants. PROTECT is based in the northern karst region of Puerto Rico, an area with significant historical pollution, and is investigating the contribution of environmental contamination to adverse pregnancy outcomes such as pre-term birth. Participants are recruited from partnered community health clinics during early pregnancy. ERGO is based in Boston, Massachusetts, and studies the impact of environmental exposures from personal care products on maternal and child cardiometabolic health outcomes such as postpartum glucose intolerance. ERGO recruits participants from two Harvard teaching hospitals, Brigham and Women's Hospital and Israel Deaconess Medical Center, during prenatal visits. For both cohorts, participants provided urine samples during pregnancy and/or at postpartum. Samples were measured for phenolic compounds (parabens, antimicrobials, dichlorophenols, UV filters, and bisphenols) in PROTECT and phthalates in both cohorts.

The present study evaluated the impact of self-guided versus clinician-guided report-back. For both cohorts, participants were randomly assigned to the clinician-guided or self-guided intervention group. One ERGO participant was prospectively assigned to the clinician-guided group to ensure that all clinicians participated in ≥ 2 report-back visits with participants and increase the number of eligible participant interviewees.

Participants were contacted by phone, email, and/or text message for recruitment into the study. In ERGO, all participants were contacted by the ERGO study coordinator. In PROTECT, eligible participants randomly assigned to the clinician-guided group were contacted by a study-affiliated nurse who scheduled their in-clinic report-back appointment, while those assigned to the self-guided group were contacted by other study coordinators.

Following recruitment, participants in both groups completed baseline surveys. Participants assigned to the self-guided report-back group received an access code to view their report online, while those assigned to clinician-guided report-back were scheduled for an appointment to meet with a clinician in-person at a clinic (PROTECT) or virtually (ERGO). Because clinician involvement in environmental health report-back is novel, we recruited a subset of participants in the clinician-guided report-back group for semi-structured interviews to learn about their experiences in greater depth.

All study protocols were reviewed and approved by the institutional review boards at Harvard University and the University of Puerto

Digital Reports

Personal exposure reports were developed collaboratively by Silent Spring Institute and members of the cohort study teams using the Digital Exposure Report-Back Interface (DERBI) (Boronow et al. 2017). Reports could be viewed from desktop computers, tablets, and smartphones using a unique access code. Reports included participants' individual measurement results reported in text and displayed in graphs with comparisons to other study participants and to a representative sample of reproductive-aged women in the U.S. as calculated from the National Health and Nutrition Examination Survey (NHANES). Alongside individual results, reports included contextual information about chemical sources, associated health effects, and recommended ways to reduce exposure. Each report also included information about overall study results, suggested community actions, and a list of common questions and contact information for the study teams. An example PROTECT report can be viewed online (<https://protect-es.reportback.org/r/report/demo>).

Clinician involvement

We recruited 9 clinicians to report back exposure results to participants using DERBI. In PROTECT, all recruited clinicians (n = 6) were PROTECT-affiliated nurses who have supported research activities, including participant recruitment, sample collection, and administration of questionnaires. PROTECT nurses attended two in-person training sessions during which study staff provided information about the sources and health impacts of the chemicals included in the report and instructions for navigating the DERBI platform. Following a mock report-back demonstration, nurses practiced discussing participant results and answering common questions.

While our team initially intended to engage clinicians who were part of the ERGO study, due to significant staff turnover at participating hospitals (Brigham and Women's Hospital and Israel Deaconess Medical Center), we instead independently recruited clinicians with no connection to ERGO through existing networks, including direct invitations and advertisements over medical listservs. For ERGO report-back, clinicians (n=3) had no previous affiliation with the ERGO study and included one physician assistant, one genetic counselor, and one pediatric physician. Training sessions for clinicians returning results to ERGO participants took place over two virtual sessions totaling two hours and 30 minutes, and included the same components as the PROTECT training. In addition, as clinicians sharing results with ERGO participants had no previous experience with the study and requested additional support, they received a script to use during the report-back session.

Clinicians met with participants assigned to the clinician-guided report-back group in brief (20-30 minutes), one-on-one appointments. In PROTECT, participants travelled to study-

affiliated community health clinics to review their online reports with a clinician, whereas ERGO appointments took place virtually through Zoom and clinicians shared their screen. At the end of the appointment, participants were given the access code to log into their reports so they could revisit them independently. Participants assigned to the self-guided group logged into their online reports independently and did not review their results alongside a clinician or other research staff.

Pre- and post-surveys

Participants completed a 15-minute pre-survey at baseline and a 20-minute post-survey at least two weeks after accessing their reports. Surveys were comprised of a series of questions across domains, including feelings, satisfaction, perceived self-efficacy, knowledge, exposure behaviors, and, for PROTECT only, study relationships.

For the feelings section, using a six-point Likert-scale (from “Not at all” to “Very Strong”), participants rated how strongly they experienced feeling respected, empowered, worried, and (post-survey only) surprised in relation to report-back. Satisfaction was assessed in the post-survey across four questions using a 5-point Likert scale from “Strongly disagree” to “Strongly agree.” In the knowledge section, participants were asked to answer whether a series of statements were “True”, “Probably true”, “Probably false”, or “False.” The knowledge section contained 9 questions in ERGO and for PROTECT, two additional knowledge questions relevant to compounds included in PROTECT reports. The perceived self-efficacy section asked participants to rate their confidence across seven different statements using a seven-point scale from “Cannot do it at all” to “Highly certain I can do it.” In the exposure behaviors section, participants rated how frequently they performed certain actions using a four-point scale from “never” to “almost every day” or from “never” to always.” The post-survey behavior section also included yes/no questions about changes made after receiving reports and open-ended questions for further elaboration. In PROTECT, pre- and post-surveys also included a set of questions asking about relationships to clinical care and the PROTECT study, which participants answered on a five-point scale from “strongly disagree” to “strongly agree.” For each question, participants also had the option to select “Don’t Know” or “Decline to Answer.” Full survey instruments can be found in supplemental material.

Based on the preferences of partnering study teams for participant communications, PROTECT participants completed pre- and post-surveys over the phone with a study staff member or PROTECT-affiliated nurse who was not involved directly in reporting back results to participants, while ERGO participants completed surveys online in REDCap, a web application for building and managing surveys.

Survey Analysis

All data analysis was restricted to participants who completed the pre- and post-surveys and viewed their DERBI reports. We first conducted stratified analyses to summarize participant responses across domains and characterize changes before and after report-back. For each cohort and intervention group, we calculated descriptive statistics on pre- and post-survey responses. To assess pre- and post-survey changes over time, we used Wilcoxon signed-rank tests with the Pratt method. For the knowledge section, true/probably true and false/probably false questions were re-coded to indicate correctness, and McNemar's tests were conducted to assess changes in item-level responses.

To further explore the impact of the interventions, we used multiple regression to model survey responses of both cohorts and intervention groups (clinician-guided and self-guided). Our main model was a linear mixed effects model that included intervention group, cohort, and survey timepoint as predictors and an interaction between survey time point and intervention group. We also included a random intercept for each participant. Report-back group and cohort were factorized with the online-only group and the PROTECT cohort as reference levels.

Self-efficacy was modeled as a scale by summing responses across all self-efficacy questions for each participant at the pre- and post-survey. Internal consistency of the self-efficacy scale was evaluated using Cronbach's alpha. Knowledge was modeled as an index, and we summed the number of correct responses and normalized to the number of questions included in the survey (11 questions in PROTECT and 9 in ERGO). For binary yes/no behavior changes, we used an analogous logit link function. For post-survey-only outcomes (the feeling "surprised", satisfaction, and behavior changes), we used multiple regression models that included fixed effects for intervention group and cohort only (no random effect).

To evaluate the robustness of these models, sensitivity analyses were conducted by comparing our main regression models with alternate models. Model performance was compared using Akaike Information Criterion (AIC) and we report model effect estimates and confidence intervals for key predictors. All analyses were conducted using R version 4.1.1 using the `lm()` and `lmer()` functions from the `stats` and `lme4` packages, respectively.