

Examining Genetic Literacy and Numeracy in the General Population

NCT06994832

July 28, 2025

Clinical Trial Results Information

#NCT06994832

Participant flow

Consented: 1,045

Included: 1,041

Demographic and baseline characteristics

Age (n=1,041)

(Mean $\pm$ SD) 35.54 $\pm$ 9.43

Sex (n = 1,031)

Male: 695 (67.41%)

Female: 336 (32.59%)

Race (n = 1016)

White 933 (91.83%)

Asian 39 (3.84%)

Black or African American 28 (2.76%)

American Indian or Alaskan Native 10 (0.98%)

mixed 4 (0.39%)

Native Hawaiian or Pacific Islander 1 (0.10%)

prefer not to say 1 (0.10%)

Education (n = 1,041)

Bachelor's Degree in College (4-year) 685 (65.80%)

Master's Degree 244 (23.44%)

Some college but no degree 29 (2.79%)

Associate degree in college (2-year) 27 (2.59%)

Doctoral degree 21 (2.02%)

professional degree (JD, MD) 13 (1.25%)

high school graduate (high school diploma or equivalent, including GED) 21 (2.02%)

less than a high school degree 1 (0.01%)

Health literacy (n = 1,028)

Adequate 656 (63.81%)

Inadequate 372 (36.19%)

Statistical analyses

We used t-tests to compare risk estimates across visualization conditions and t-tests to compare intention to communicate across choice frames. To estimate effect size, we calculated Cohen's d to provide evidence for the direction of the effect as well as the 95% confidence intervals (CIs) of the difference between the two groups. To achieve 80% power to detect a small effect (Cohen's $d = 0.3$), 175 participants per group are needed. We collected responses from approximately 500 participants per group, giving us 80% power to detect an effect of $d = 0.18$. Nevertheless, in cases for which the p-value was greater than 0.05, we calculated Bayes Factors (BF10). Briefly, BF10 is the Bayes factor in favor of the alternative hypothesis. Values less than 1.0 indicate evidence for the null hypothesis, with values from 0.10 to 0.33 indicating moderate evidence and values from 0.03 to 0.10 indicating strong evidence for the null hypothesis. We used linear regression to test direct effects of a priori confounding variables and potential indirect effects by mediating the manipulations of visualization and choice frame on risk estimates and intention, respectively. A p-

value ≤ 0.05 was considered significant for all models, and Bonferroni correction was not used, given a priori predictions for each included confound. For Likert scales that have 5 or more categories (as was used to measure TPB), it is reasonable to use a t-test if there is sufficient sample size (i.e., 500 per group), and the assumptions of normality and homoscedasticity were met for intention outcomes (verified using QQ-plots, boxplots, and stripplots). All criteria were achieved, thus validating the use of t-tests.

Outcomes

In this hypothetical genetic testing scenario, trial results indicate that the type of visual array used to communicate colorectal cancer risk did not affect how participants estimated cancer risk. In addition, the way that colorectal cancer risk was presented (framed) in this study did not affect participants' intention to communicate the hypothetical genetic cancer risk to family members. Colorectal cancer risk for Lynch syndrome did not differ across presentation formats ($p = 0.58$, $d = 0.035$, 95% CI $[-2.51, 1.42]$, $BF = 0.08$). Colorectal cancer risk for the general population did not differ across presentation formats ($p = 0.09$, $d = 0.107$, 95% CI $[-6.46, 0.47]$, $BF = 0.29$). Potentially confounding factors (i.e., initial estimate of colorectal cancer risk, health literacy/numeracy, education, previous genetic testing, personal cancer history, family cancer history) neither affected risk estimation (all $p > 0.11$) nor how visualization condition affected risk estimation (all $p > 0.17$). Regardless of decision frame (i.e., choice vs. enhanced choice), the intention to share genetic test results with blood relatives was similar between presentation formats ($p = 0.23$, $d = 0.076$, $BF = 0.14$) and none of the potentially confounding variables were associated with intention to share genetic test results with blood relatives (all $p > 0.21$).

Adverse events

none

Protocol

Background and Significance

The Massachusetts General Hospital Reproductive Endocrine Unit (MGH-REU) has a lengthy history of partnering with referring clinicians to return research genetic test results. However, practicing clinicians are challenged to stay up-to-date on rapidly changing standards and best practices for returning genetic test results. Moreover, limited genetic literacy/numeracy of patients/families pose barriers for using genetic results to improve health. Further, the complexity of information provided in the comprehensive report can complicate the effective return of results. The process could be refined and improved by providing clinicians with concise, evidence-based guidance for returning results and documents to help healthcare professionals convey complex genetic terms/numerical concepts in a way that is accessible, understandable and actionable to individuals with limited genetic literacy/numeracy. Drawing on neuroscience and cognitive psychology can help identify the optimal visual presentation of numerical concepts. Patients/families often express the desire for reliable, curated information that is accessible in lay language. Thus, this study will allow us to translate genetic discoveries into enhanced care and meaningful improvements in health and quality of life for patients/families.

Specific Aims and Objectives

The goal of this study is to understand how people understand risk from genetic testing. We want to understand what type of visual aid (i.e., array) helps people most accurately assess risk. We also want to understand how people relate risk to their health. The main study objectives are to determine:

1. Which visual aid most accurately conveys genetic risk?
2. What factors (i.e., tripartite risk model) predict more accurate risk perception of genetic test results?

3. What factors (i.e., theory of planned behavior) and frames predict intention to share genetic test results with family?

General Description of Study Design

We will distribute a 30-question online survey to members of Amazon's Mechanical Turk (MTurk) platform. The investigator-designed survey is intended to collect information on participant demographics, health literacy, numeracy, risk perception (based on the tripartite framework), and questions about familial communication about health (based on the theory of planned behavior). Participants will then be randomized 1:1 (see study schema) to receive either a single visual array (n=500) or a narrative sequential visual array (n=500). Participants will provide risk estimates for both positive and negative test results. Subsequently, participants in each group (i.e., visual array, narrative visual array) will be randomized (1:1) to a question regarding intrafamilial communication of risk using either a 'standard choice' frame (n=250 in each group) or an 'enhanced choice' frame (n=250 in each group).

Subject Selection

Inclusion criteria: age 18+ years old, able to read/write English, member of Amazon's Mechanical Turk (MTurk) community, providing opt-in electronic consent. Exclusion criteria: age <18 yrs, unable to read/write English, not providing opt-in electronic consent. MTurk is an effective and secure web-based crowd-sourcing tool for recruiting diverse participants. We will invite adult male and female users of MTurk to participate. We aim to recruit equal numbers of male and female participants (i.e. 50/50). Eligible adult males and females from all racial and ethnic groups will be included.

Subject Enrollment

Participants will complete an opt-in consent before beginning the survey. The opt-in consent includes language specifying that participation is voluntary and choosing not to participate will not affect their relations with Massachusetts General Hospital. English speakers will be recruited for participation due to the need to respond to a written questionnaire in English.

Study Procedures

The study will be conducted through an online REDCap survey that will take participants approximately 12 minutes to complete. The survey includes 30 questions (multiple choice, slider scale, and open response) designed to collect information on participant demographics as well as health literacy and numeracy, risk perception, and intrafamilial communication about health.

Participation is voluntary and users are free to withdraw or skip questions for any reason. Participants will be compensated for their completion of the survey. Captcha and validation questions are embedded in the survey to mitigate the risk of "bots" and participants not acting in good faith. In accordance with MTurk policies, we may reject responses work and/or withhold payment if the survey instructions are not followed.

The Principal Investigator will exert all reasonable efforts to keep responses and identities confidential. No personal information will be collected, tracking cookies will be turned off, and we will not record IP addresses. Responses will be aggregated and described in summary.

Risks and Discomforts

There are no risks anticipated with the online completion of this survey but participating could entail risks that are not now known. Participants are asked to anonymously provide survey responses. Participants' MTurk worker ID will appear in the data together with subject's survey responses. Investigators will not attempt to use the MTurk worker ID to identify or contact the individual connected to the MTurk worker ID.

Benefits

There are no direct benefits to participants. The data collected in this study will be used to create evidence-based guidance for conveying complex genetic terms/numerical concepts in a way that is accessible, understandable and actionable to the general public.

Statistical Analysis

We will use multi-variate analyses to examine the response (accuracy of risk estimation per visual array and narrative sequential visual array) and predictors (literacy, numeracy, tripartite risk scores, theory of planned behavior scores) and interaction effect using F-test - along with posthoc t-tests using Tukey's HSD post-hoc for multiple comparisons. If the F-test is non-significant, we will fit the main effects only model and test for pairwise differences using post-hoc t-tests also adjusted for multiple comparisons. We will then use two-way ANOVA to examine the response (risk estimation) and predictors as described. We will fit a linear regression model with family communication of risk and predictors (message condition/frame and interaction with each subscales (a tripartite risk scores, theory of planned behavior scores). Likelihood ratio test will be used to test for significance of interaction terms and if significant, we will examine the differential effect of the moderation among the two message conditions (frames) by examining regression coefficients and testing for significance using the usual Wald-type test for regression coefficients. A power calculation was based on multivariate analyses testing for pairwise differences using post hoc t-tests adjusted for multiple comparisons using Tukey's HSD. We assumed a significance level of 0.05. For a Cohen effect size = 0.25 (error standard deviation assumed to be 1.0). We estimated 340 subjects would be needed per treatment level combination (680 total subjects) to achieve a power level of 0.80. We set target recruitment at 1000 participants (i.e., 500 in each arm – visual array and narrative sequential array).

Monitoring and Quality Assurance

N/A

Data and Research Material Sharing

No identifying data will be collected in this study. Anonymous survey will be collected via REDCap. A data use agreement with MGH and Boston College is in place for de-identified data generated for this project. All electronic data transmitted between MGH and Boston College will use MGB secure email or secure file transfer. Electronic data will be saved on a dedicated, secure space on the Boston College CSON department server with password protection. Analysis of de-identified data will be conducted by collaborator (Dr. Jessica Witt) at Colorado State University. Data will be shared using secure DropBox. A data use agreement has been established between MGH and Colorado State University for this project. Participants' MTurk worker ID will appear in the data together with subject's survey responses. Investigators will not attempt to use the MTurk worker ID to identify or contact the individual connected to the MTurk worker ID

Privacy and Confidentiality

Only data and/or specimens necessary for the conduct of the study will be collected. Data collected (paper and/or electronic) will be maintained in a secure location with appropriate protections such as password protection, encryption, physical security measures (locked files/areas). Data and specimens will only be shared with individuals who are members of the IRB-approved research team or approved for sharing as described in this IRB protocol. Data and/or specimens requiring transportation from one location or electronic space to another will be transported only in a secure manner (e.g. encrypted files, password protection, using chain-of-custody procedures, etc.). Identifiers will be coded or removed as soon as feasible and access to files linking identifiers with coded data or specimens will be limited to the minimal necessary

members of the research team required to conduct the research. All staff are trained on and will follow the Mass General Brigham policies and procedures for maintaining appropriate confidentiality of research data and specimens. The PI will ensure that all staff implement and follow any Research Information Service Office (RISO) requirements for this research.

Statistical analysis plan

We will use multi-variate analyses to examine the response (accuracy of risk estimation per visual array and narrative sequential visual array) and predictors (literacy, numeracy, tripartite risk scores, theory of planned behavior scores) and interaction effect using F-test - along with posthoc t-tests using Tukey's HSD post-hoc for multiple comparisons. If the F-test is non-significant, we will fit the main effects only model and test for pairwise differences using post-hoc t-tests also adjusted for multiple comparisons. We will then use two-way ANOVA to examine the response (risk estimation) and predictors as described. We will fit a linear regression model with family communication of risk and predictors (message condition/frame and interaction with each subscales (a tripartite risk scores, theory of planned behavior scores). Likelihood ratio test will be used to test for significance of interaction terms and if significant, we will examine the differential effect of the moderation among the two message conditions (frames) by examining regression coefficients and testing for significance using the usual Wald-type test for regression coefficients. A power calculation was based on multivariate analyses testing for pairwise differences using post hoc t-tests adjusted for multiple comparisons using Tukey's HSD. We assumed a significance level of 0.05. For a Cohen effect size = 0.25 (error standard deviation assumed to be 1.0). We estimated 340 subjects would be needed per treatment level combination (680 total subjects) to achieve a power level of 0.80. We set target recruitment at 1000 participants (i.e., 500 in each arm – visual array and narrative sequential array).

Administrative information

Mass General Brigham IRB
Protocol #2025P000889

Boston College IRB
Protocol #26.0042

Open Access Publication
<https://doi.org/10.3390/cancers18091369>

Data Availability
<https://dataverse.harvard.edu/dataset.xhtml?persistentId=doi:10.7910/DVN/T2JJHA>