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Original Research

Evaluation of mailed results versus telephone disclosure of normal cancer genetic test results in a low-risk underserved population

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Abstract

Scalable models for result disclosure are needed to ensure large-scale access to genomics services. Research evaluating alternatives to genetic counseling suggests effectiveness; however, it is unknown whether these findings are generalizable across populations. We assessed whether a letter is non-inferior to telephone genetic counseling to inform participants with no personal or family history of cancer of their normal results. Data were collected via self-report surveys before and after result disclosure (at 1 and 6 months) in a study sample enriched for individuals from underserved populations. Primary outcomes were subjective understanding of results (global and aggregated) and test-related feelings, ascertained via three subscales (uncertainty, negative emotions, and positive feelings) of the Feelings About genomiC Testing Results (FACToR) measure. Secondary outcomes related to satisfaction with communication. Non-inferiority tests compared outcomes among disclosure methods. Communication by letter was inferior in terms of global subjective understanding of results (at 1 month) and non-inferior to telephoned results (at 6 months). Letter was non-inferior to telephone for aggregated understanding (at 6 months). Letter was superior (at 1 month) to telephone on the uncertainty FACToR subscale. Letter was non-inferior to telephone on the positive-feelings FACToR subscale (at 6 months). Letter was non-inferior to telephone for satisfaction with mode of result delivery and genetic test results. Communication via letter was inferior to telephone in communicating the "right amount of information." The use of written communication to relay normal results to low-risk individuals is a promising strategy that may improve the efficiency of care delivery.

Lay summary

Genetic counseling services delivered in the usual way—during clinic visits—can take up a lot of time for patients and genetic counselors. Alternatives to this practice have been studied among genetic counseling patients to spare genetic counselors' time and expand access and flexibility for patients. Yet, in these studies, the participants have lacked diversity. So, it is not known how these research findings pertain to all populations. In this study, we looked at the use of an alternative care model, a mailed letter, for sharing normal genetic test results with study participants from underserved populations. We tested whether patients viewed the mailed letter as no worse than a telephone conversation with a genetic counselor, which has been shown to be well received by patients. We learned that study participants felt they understood their results, were not distressed to receive the results, and were satisfied with how their results were delivered. Lastly, we found that participants were more satisfied with the amount of information provided about their test results during the telephone conversation compared with the mailed letter. This study provides new information about different ways to deliver test results to individuals receiving genetic services.

Keywords: genetic counseling; normal test results; patient understanding; test-related feelings; patient satisfaction; alternative result delivery model

Implications

Practice: Alternative genetic counseling delivery models have not been researched adequately in underserved populations to date. The results show that written communication appears to be an acceptable delivery model for normal cancer genetic test results in low-risk individuals from underserved populations.

Policy: There is an opportunity to consider the utility of written communication as a scalable alternative delivery model for normal genetic test-result disclosure in low-risk individuals.

Research: Future research should continue to evaluate written communication methods, including secure electronic communication, in all populations, including those with a personal and/or family history of cancer.

Introduction

Genetic counseling can be time-intensive for patients and genetics providers as it requires real-time communication, typically at prescheduled clinic visits, either in-person or by telephone [1, 2]. Alternative approaches for result disclosure, particularly when results are normal (i.e. no pathogenic or likely pathogenic variants or variants of uncertain significance reported), would allow genetic counselors to spend their time and expertise with individuals who need tailored healthcare recommendations at the time of result disclosure. While some alternative genetic counseling service delivery models show early evidence of effectiveness and patient acceptability, the most common alternative models, such as group classes and telegenetics, still require a genetic counselor to communicate in real time, which limits the ability of these models to meet growing demand for services [3–5]. As such, alternative genetic counseling delivery models that rely less on real-time engagement with genetic counselors and are shown to be effective are in need.

The use of written communication for test results can scale efforts by avoiding in-person or telephone result disclosure. Recent studies evaluating disclosure of normal genomic screening results via mailed letter found that patients valued receiving the results, were satisfied with this method, and did not experience distress [6, 7]. Studies exploring other scalable delivery models (such as a prerecorded video, web-based platform, and/or online report) in populations not known to be at increased risk and in those with normal test results found that participants report high certainty in understanding their results (findings from studies using prerecorded video and online report), and that a web-based platform was found to be non-inferior to genetic counseling as measured by participant knowledge and test-specific distress [8–10]. Yet, these studies report a lack of diversity within their research populations. An evaluation of alternative delivery models in populations underrepresented in clinical genomics research can inform the development and assessment of scalable models that benefit all who undergo clinical genetic testing [11–13].

The NIH-funded Cancer Health Assessments Reaching Many (CHARM) study is part of the Clinical Sequencing Evidence-Generating Research (CSER) consortium, which prioritized the evaluation of genomic medicine implementation in underserved populations at risk for barriers in access to care [14]. CHARM assessed a number of clinical interventions with the potential to reduce inequities in cancer genetics services among these individuals [15]. The CHARM study provided an opportunity to generate and assess novel hypotheses across multiple interventions implemented in the process of cancer genetic services delivery.

Herein we present the design and execution of a non-inferiority study to assess outcomes following delivery of normal exome-based genetic test results to participants within the CHARM study who were not known to be at increased hereditary cancer risk. In contrast to usual care genetic counseling [16], we implemented a mailed letter for communication of normal test results. Non-inferiority analyses can be used to assess whether a newer method (a mailed letter) is no worse than the "standard" (genetic counseling by telephone). We hypothesized that the delivery of results via a mailed letter would be non-inferior to a genetic counselor reporting out results and answering questions by telephone.

Methods

Study population and recruitment

CHARM recruited English- and Spanish-speaking patients aged 18–49 years from two healthcare systems, Kaiser Permanente Northwest (KPNW) and Denver Health (DH). KPNW is an integrated health care delivery system serving Oregon and southwest Washington. DH is an integrated safety-net health system in Denver, Colorado. CHARM focused on recruiting individuals who were "at risk of being medically underserved," defined as those participants who reported low income, low education, Spanish as preferred language, being uninsured, identified as Hispanic ethnicity, a race other than White, as LGBTQ+, or were residents of medically underserved areas. The recruitment period for CHARM was from August 2018 to March 2020.

Eligibility criteria

To clarify how the patient experience upstream of result disclosure differed from usual care, two other CHARM interventions are described briefly. Patients received pretest written genetics information via an online consent process, rather than pretest genetic counseling. It included educational elements covered in a typical genetic counseling visit. Patients were eligible for CHARM if their family history indicated an increased risk for hereditary cancer as determined by a family history collection and risk assessment tool developed within the study [17]. The study also assessed "limited family structure" (<2 female relatives living beyond age 45 on either side of the family) and "limited knowledge of family history" via the tool so that patients with limited health information on biological relatives met inclusion criteria for genetic testing [15]. Participants were required to receive results related to cancer risk and could choose to receive results related to other medically actionable conditions; a subset of participants were also offered carrier findings [18].

Participants were not randomized to receive a specific mode of result disclosure (telephone or letter). For the first part of the CHARM study, result disclosures for all participants were conducted over the telephone by a study genetic counselor. However, to streamline the result disclosure process (Fig. 1) the study design was altered partway through the study. Participants who (i) qualified for CHARM based on "limited family structure" or "limited knowledge of family history"; (ii) did not report a personal history of cancer; and (iii) had a normal test result in all categories, received their results via a mailed letter. These criteria minimized the chance that participants receiving a letter would be in need of personalized cancer screening recommendations that would have been provided by a genetic counselor.

Mode of result disclosure

Four board-certified genetic counselors, each with at least 8 years of clinical experience, disclosed the test results by telephone. Telephone visits were conducted in English or with a professional Spanish-language interpreter if the participant's preferred spoken language was Spanish or if a Spanish-language interpreter was requested. Participants whose results were disclosed by telephone also received a mailed letter summarizing their conversation with the genetic counselor.

CHARM genetic counselors designed a normal results letter (Supplementary Materials) that contained key content elements relevant to result disclosure in an *a priori* low-risk individual. The letter encouraged participants to contact the study if they wanted to speak with a genetic counselor. For accessibility, the letter was written at a seventh-grade reading level, using plain language and active voice and with a minimum of genetic terms and jargon, in keeping with CHARM communication goals. The letter was translated into Spanish to "generate an accurate and culturally coherent product" [19]. The Spanish-language letter was sent to participants who stated a preference for communication in Spanish.

The laboratory test report, written in English, was mailed to all participants, either with the normal results letter or the letter summarizing the telephone conversation. After result disclosure, a clinical summary note and the laboratory test report were placed in the participant's electronic medical record. In the CHARM study, the decision was made to use the term "normal results" rather than "negative results" in patient-facing materials and genetic counseling visits with the goal of clearly conveying the meaning of the results.

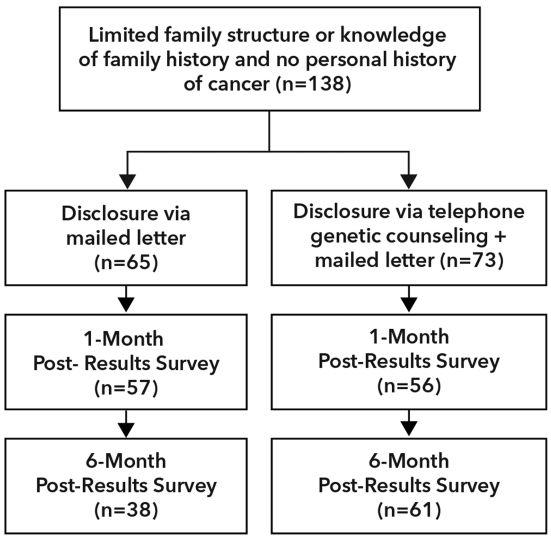

Figure 1 Study flow of the disclosure of normal genetic test results.

Outcomes

Data for this study were primarily collected using participant surveys. A baseline survey, administered before result disclosure, collected demographic information. Some missing demographic data, including race/ethnicity information, were gathered from the electronic medical record. Two surveys were administered after result disclosure: the 1-month post-results survey was administered for completion within 1 month of result disclosure, and the 6-month post-results survey was administered for completion 5–7 months after result disclosure. Participants who did not complete the 1-month survey were still able to complete the 6-month survey. Data about mode of result disclosure (letter or telephone visit) and language (English or Spanish) of result disclosure were collected through a secure CHARM study tracking system. Primary outcomes were subjective understanding of results using two measures and test-related feelings using three subscales (uncertainty, negative emotions, and positive feelings) of the Feelings About genomiC Testing Results (FACToR) measure, assessed in the 1- and 6-month surveys. This allowed evaluation of both the initial and longer-term impact of results. Secondary outcomes were degree of satisfaction with aspects of communication, assessed in the 1-month survey. All measures used for these analyses were harmonized CSER consortium measures (https://anvilproject.org/consortia/cser/resources) with the exception of the aggregated subjective understanding measure, which was CHARM study-specific and novel.

Subjective understanding of results

Two measures were included to assess subjective understanding. A one-item assessment of global understanding: "How well do you understand your test results?" was measured on a five-point, Likert-type scale (1 = Not at all to 5 = Extremely). Additionally, the following four items related to the impact of cancer genetic test results were used to assess subjective understanding: "I understand what my test result means for my health," "I understand what I need to do based on my test result," "I understand what my test result means for my family," and "I understand which family members I need to share my test result with" and each were measured on a five-point, Likert-type scale (1 = Strongly disagree to 5 = Strongly agree). We used principal-axis factor analysis to determine whether the items could be aggregated into one measure to limit multiple testing. Aggregation is supported if all the items load on one factor that explains at least 60% of the variance of the items, each item has a minimum loading of 0.50, and the internal consistency of the items as measured by Cronbach's alpha is at least 0.70. One factor explained 73% (1-month; 74% 6-month) of the variance in the four subjective understanding items, and all items loaded >0.83 (1-month; 0.80 6-month) and had a Cronbach's alpha of 0.91 (1-month; 0.91 6-month), all of which met the criteria for aggregation. We performed aggregation by taking the mean of the items [20].

Test-related feelings

The FACToR measure, with 12 items and four subscales (negative emotions, positive feelings, uncertainty, and privacy concerns) was developed to assess personal responses to receiving genomic test results [21]. For this analysis, we used three of four subscales: uncertainty, negative emotions, and positive feelings. The subscales were scored based on CSER consortium validation results, which recommended a realignment of one item from the uncertainty subscale (dealing with frustration) to the negative emotions subscale. The privacy concerns subscale of FACToR was not used for this analysis due to minimal expected privacy concerns for normal results in participants without a reported personal or family history of cancer.

Satisfaction

Five items assessed satisfaction with aspects of communication regarding result disclosure. The first item asked: "How satisfied were you with receiving your genetic test results this way?" and included response choices of "Very satisfied," "Somewhat satisfied," "Somewhat dissatisfied," and "Very dissatisfied." The second item asked: "Would you have preferred to receive your genetic test results in a different way?" and included response choices of "No" and "Yes." If a respondent chose "Yes," additional choices provided were "In-person," "Over a videoconference," "Other," "By mail" (telephone disclosure participants only) or "By phone" (letter participants only). The third item asked: "Is there anything else you wish you could change about how your genetic test results were communicated to you in the CHARM study?" and included response choices of "No" and "Yes." If a respondent chose "Yes," they were asked to explain in an open text field. The fourth item asked: "Overall, how satisfied are you with your genetic test results?" and included response choices of "Very satisfied," "Somewhat satisfied," "Somewhat dissatisfied," and "Very dissatisfied." The fifth item asked: "Overall, how much information did you receive about your genetic test results?" and included response choices of "Too much," "About right," and "Too little."

Statistical analyses

We assessed for differences between the two modes of result disclosure, mailed letter and telephone visit with a genetic counselor, using Fisher's exact tests and Cramer's V as a measure of magnitude for categorical variables and independent samples *t*-test for continuous variables for various sociodemographic characteristics and baseline measures.

For examining the non-inferiority of letter versus telephone visit (reference) on the primary and secondary outcomes, we calculated the mean difference between mode of result disclosure with a 2-sided 95% CI [22]. Non-inferiority is supported if the CI did not exceed the prespecified non-inferiority margin (δNI) which was based on a 75% ratio of means for subjective understanding and FACToR subscales and 80% for communication satisfaction and the CI contained zero. For example, if the mean for the telephone group on global subjective understanding was 4, then the δNI is 1 (75% of 4 = 3; non-inferiority margin = 4 − 3 = 1). Thus, for a δNI of 1, a treatment that was 0.4 worse with a 95% confidence interval of 1.1 worse to 0.3 better is not non-inferior (because it could be as much as 1.1 > 1 worse). However, if the confidence interval was from 0.9 worse to 0.1 better, it would be considered non-inferior for this δNI.

The subjective understanding and satisfaction measures are novel, and the test-related feelings measure via FACToR have not, to our knowledge, been used in published non-inferiority analyses to date. Given the lack of precedence for determining clinically meaningful δNI for these measures, we reviewed prior literature evaluating alternative delivery models for genetic test results to inform the decisions for clinically meaningful δNI [9, 23]. We expected few negative outcomes in our study population of *a priori* low-risk individuals receiving normal genetic test results, so decided on a conservative δNI for the FACToR subscales. Satisfaction with genetic counseling is commonly reported as high [24, 25], so we adapted the δNI accordingly to capture a clinically meaningful difference between mode of result disclosure.

Results

Study population

One hundred thirty-eight CHARM participants were eligible for inclusion in this study. Regardless of whether they received results by letter or telephone, participants had similar distributions of age, gender identity, education, health literacy score, and numeracy score (Table 1). Of participants who received results by telephone, 8% (6/73) used a Spanish-language interpreter. Of participants who received results by mail, 23% (15/65) received the normal results letter in Spanish. The higher proportion of Spanish as the preferred language for those who received results by letter may be explained by a later recruitment start date at DH and higher proportion of Spanish speakers at DH, given that we implemented a mailed normal results letter partway through the study.

Primary outcomes

Receipt of results via letter was inferior to receipt via telephone for global subjective understanding of results on the 1-month survey and non-inferior on the 6-month survey (Fig. 2). For aggregated subjective understanding related to cancer genetic test results, telephone was significantly better than letter, but letter was non-inferior to phone on the 1-month survey; letter was non-inferior to telephone on the 6-month survey. Evaluation of the FACToR uncertainty subscale revealed that receipt of results via letter was superior to receipt of results via telephone counseling on the 1-month survey and inconclusive on the 6-month survey. For the negative emotions subscale, non-inferiority testing was inconclusive on both the 1-month and 6-month survey. The positive-feelings subscale indicated that result disclosure via telephone was significantly better than letter, but letter was non-inferior to telephone on the 1-month survey. Receipt of results via letter was non-inferior to receipt of results via telephone for the positive-feelings subscale on the 6-month survey.

Secondary outcomes

The receipt of a letter was non-inferior to genetic counseling by telephone for satisfaction with the mode of results delivery and satisfaction with the genetic test results themselves (Fig. 3). When participants were asked whether they would want to receive their results in a different way, and whether there was anything they wished they could change about how their genetic test results were communicated, non-inferiority tests were inconclusive. Five participants who received a normal results letter suggested email or other

Table 1 Demographic characteristics of study population

Characteristic	Participants with normal results (telephone) *N* = 73 *N* (%)	Participants with normal results (letter) *N* = 65 *N* (%)	*P*-value	Cramér's V
Gender identity			.79	0.15
Female	47 (64)	42 (65)		
Male	15 (21)	13 (20)		
Transgender female	0 (0)	0 (0)		
Transgender male	1 (1)	0 (0)		
Non-binary/Genderqueer	3 (4)	1 (2)		
Not sure/Questioning	0 (0)	0 (0)		
Another gender identity	0 (0)	0 (0)		
Prefer not to answer	0 (0)	1 (2)		
Missing[a]	7(10)	8 (12)		
Race/Ethnicity			.10	0.28
American Indian, Native American, or Alaska Native	1 (1)	0 (0)		
Asian	8 (11)	4 (6)		
Black or African American	4 (6)	4 (6)		
Middle Eastern or North African/Mediterranean	0	1 (2)		
White or European American	37 (51)	23 (35)		
Chose two or more categories, not including Hispanic	5 (7)	2 (3)		
Chose two or more categories, including Hispanic	1 (1)	2 (3)		
Hispanic/Latino(a)	17 (23)	29 (45)		
Results communication language				
English	67 (92)	50 (77)	.02	0.21
Spanish	6 (8)	15 (23)		
Education			.14	0.28
Less than high school	3 (4)	4 (6)		
Some high school	2 (3)	9 (14)		
High school graduate	6 (8)	9 (14)		
Some post-high school training	17 (23)	9 (14)		
Associate or vocational degree	7 (10)	4 (6)		
Bachelor's degree	24 (33)	16 (25)		
Graduate or professional degree	7 (10)	6 (9)		
Missing[a]	7 (10)	8 (12)		
Household income			.66	0.18
"Less than $20,000"	12 (16)	6 (9)		
"$20,000 to $39,999"	16 (22)	12 (19)		
"$40,000 to $59,999"	12 (16)	14 (22)		
"$60,000 to $79,999"	6 (8)	10 (15)		
"$80,000 to $99,999"	7 (10)	5 (8)		
"$100,000 to $139,999"	8 (11)	5 (8)		
"$140,000 or more"	5 (7)	3 (5)		
Missing[a]	7 (10)	10 (15)		
Age in years (mean, SD, and min-max)	36.0, 8.7, 18–49	35.5, 7.8, 18–49	.76	Cohen's *d* = 0.05
Subjective numeracy scale-3 score (mean, SD, and min–max)[b]	13.6, 3.9, 4–18	12.2, 4.5, 3–18	.08	Cohen's *d* = 0.32
Health literacy score (mean, SD, and min–max)[b]	18.3, 2.4, 11–20	17.9, 2.2, 10–20	.39	Cohen's *d* = 0.15
Population at elevated risk for being underserved[c]	52 (71)	53 (82)	.16	0.12

[a] Missing includes participants who did not take the baseline survey or skipped the relevant question.

[b] Assessed only for individuals completing this portion of the baseline survey.

[c] Population at risk of being medically underserved is defined by the CHARM study as participants meeting at least one of these criteria: a race other than White, Hispanic ethnicity, low-income, low-education, Spanish as preferred language, residents of medically underserved area, uninsured, or who identify as LGBTQ+.

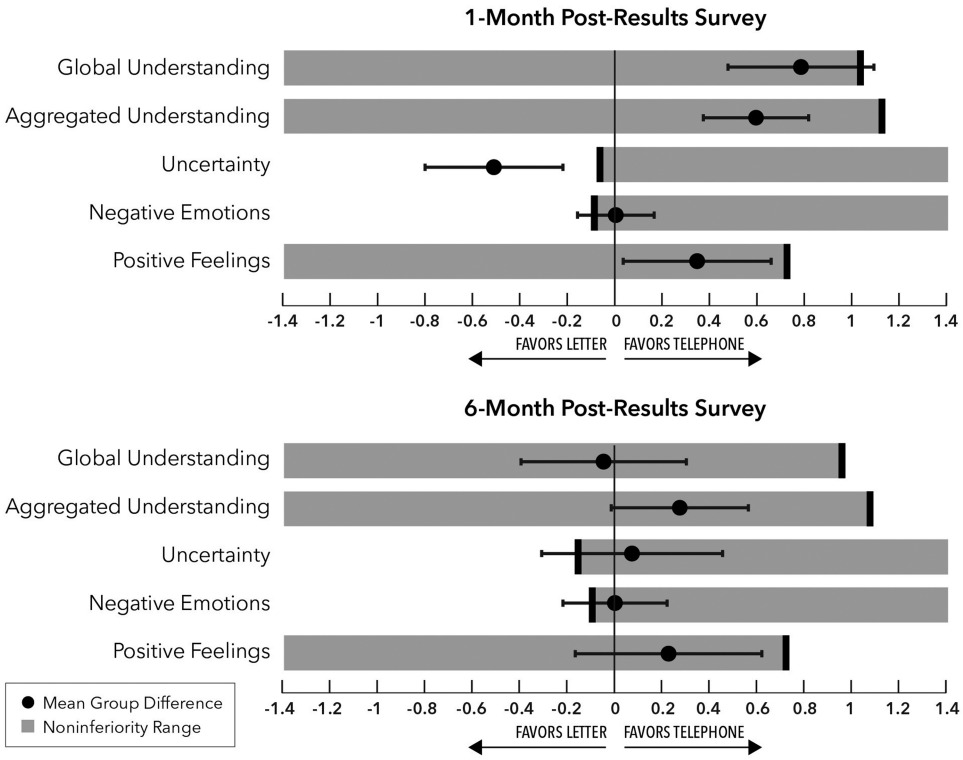

Figure 2 Participant response to receiving genetic test results.
The shaded area represents the zone of non-inferiority. The bold line at the end of the shaded horizontal bar represents the non-inferiority margin (δNI) for a given measure. If the confidence interval is contained within the shaded area, it is considered non-inferior. A result is inconclusive if the confidence interval crosses over both the δNI (the bold line) and 0.

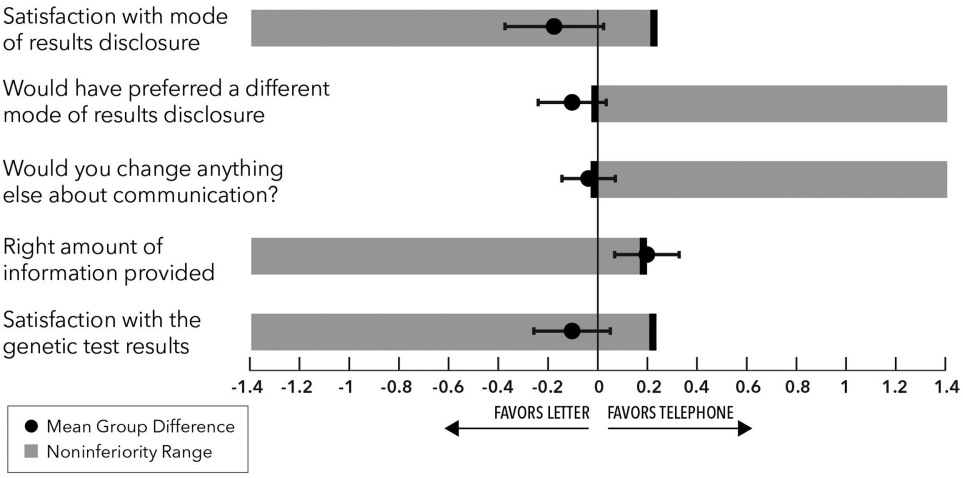

Figure 3 Degree of participant satisfaction with result disclosure.
The shaded area represents the zone of non-inferiority. The bold line at the end of the shaded horizontal bar represents the non-inferiority margin (δNI) for a given measure. If the confidence interval is contained within a shaded area, it is considered non-inferior. A result is inconclusive if the confidence interval crosses over both the δNI (the bold line) and 0.

online communication as an alternative delivery method. When evaluating the "right" amount of information provided about their test results, receipt of results via letter was inferior to receipt of results via telephone conversation with a genetic counselor. The normal results letter encouraged participants to contact CHARM if they wanted to speak with a genetic counselor, and no participants contacted the study to pursue this option.

Discussion

This analysis provides evidence for the acceptability of written communication via mailed letters for disclosing normal cancer genetic test results to *a priori* low-risk individuals. Our study found that mailed letters were non-inferior to result disclosures by telephone for subjective understanding of results (global and aggregated) and the positive-feelings FACToR subscale at 6 months after result disclosure. Additionally,

mailed letters were non-inferior to result disclosures by telephone for satisfaction with mode of result delivery and genetic test results. However, mailed letter was inferior to result disclosure by telephone in conveying the "right amount of information" at result disclosure.

The short-term inferiority of mailed letter as measured by global subjective understanding may be due to the interpersonal aspect of real-time communication where participant questions and/or concerns can be addressed. The initial aggregated subjective understanding results are challenging to accurately interpret. The 6-month timepoint likely represents long-term subjective understanding of results (global and aggregated) for disclosure of normal test results. It is important to consider if sufficient value is added by having a genetic counselor disclose results by telephone, when in the long term a mailed letter was "as good as" telephone genetic counseling for subjective understanding in individuals where there are no personalized care recommendations to act upon. These findings are aligned with prior research exploring understanding of normal results disclosed via mailed letter [7], while also providing evidence of subjective understanding from a more diverse study population.

Analysis using the FACToR subscales assessed personal responses to receiving genomic test results in CHARM. The short-term preference for mailed letter result disclosure on the FACToR uncertainty subscale may be explained by the hypothesis that the content of the mailed letter conveyed key information directly and succinctly, and allowed participants to revisit the letter content immediately after result disclosure. While it is challenging to accurately interpret the initial positive-feelings subscale results, at 6 months a mailed letter was "as good as" telephone result disclosure, which is likely an acceptable outcome in low-risk individuals with normal genetic test results. This 6-month time point likely represents the long-term perspective of participants related to positive feelings associated with receiving their genetic test results. We had inconclusive results for some of the FACToR subscales (uncertainty on 6-month survey, negative emotions on both 1- and 6-month survey); an inconclusive result indicates that no statistically significant difference was seen between the two result disclosure methods (telephone and letter), while at the same time, there was not sufficient evidence for non-inferiority [26].

For secondary outcomes of satisfaction with communication, letter was non-inferior to telephone for mode of results delivery and satisfaction with the genetic test results. Additionally, we found that mailed letter was inferior to telephone genetic counseling for the "right amount of information" provided about the genetic test results. Previous research evaluating participant response to receiving normal genetic test results by mailed letter revealed participant disappointment about lack of detail and risk information they received from their results [27]. The current study expands upon this prior finding by evaluating mailed normal results in a study population with increased diversity, which informs the broader generalizability of the findings. We had inconclusive results for the items assessing the preference for a different mode of test-result disclosure and changing anything else about the communication of results. None of the 65 participants who received their normal results via letter reached out to speak with a study genetic counselor, as offered in this letter, which may not be surprising given they received normal results and there was overall satisfaction with receiving their results in this way. This observation is consistent with other recent studies that also found minimal uptake of optional genetic counseling after receipt of normal results by mail [28, 29]. Previous reviews of cancer genetic counseling communication have acknowledged overrepresentation by people who identify as White, are older, and those of higher socioeconomic status [30, 31]. Exploratory research evaluating the concept of mailed letters for pharmacogenomic results with individuals who self-identified primarily as African American found overall acceptability of receiving non-life-threatening genetic results this way [32]. Similarly, our results show that a results letter is "as good as" a telephone call from a genetic counselor for disclosing normal genetic test results in an underserved population, as measured by both global and aggregated subjective understanding and the positive-feelings subscale.

Our evaluation of satisfaction with aspects of results-disclosure communication reveals that written communication via mailed normal results letter can be improved. Future iterations of written communication content could alter the amount of information provided, which may increase satisfaction related to receipt of the "right amount of information." Qualitative studies could facilitate generation of future iterations of the normal results letter, with a focus on assessing what information people would like to receive with their normal results. However, alterations to the normal results letter must take readability into account. Previous research has found that explaining genome sequencing results, including normal results, at an appropriate reading level in writing is difficult to accomplish [33]. Last, in keeping with ways providers in other specialties often return normal results, sharing written communication via a secure electronic method (such as the patient portal of the electronic medical record) could be utilized, which was suggested in open text field survey responses by a small number of CHARM participants.

Limitations

The number of participants in this study limits the generalizability of the findings. Participants were not randomized and not everyone completed both surveys. The feelings of those who did not complete the surveys may have influenced the results if they preferred one method over the other. Because participants self-reported their understanding, we do not know the specific aspects of communication they did or did not understand. However, the groups were similar and not significantly different on various characteristics (Table 1), which provides some confidence that the groups are comparable. Additionally, while we have data from both the 1-month and 6-month timepoints for our primary outcomes, we did not perform a longitudinal analysis, so there could be other reasons for the differences observed between these two timepoints. We did not evaluate how other materials mailed to participants could have impacted our outcomes. Prior research on the use of mailed letters to disclose normal genomic-sequencing results concluded that almost half of respondents found the laboratory report difficult to understand, suggesting that the inclusion of such a report could negatively impact understanding [6].

Conclusion

The delivery of normal cancer genetic test results by mail to low-risk individuals is a promising model that, to our

knowledge, has not been thoroughly evaluated in underserved populations. Our research found that normal results letters sent to low-risk individuals resulted in adequate—albeit subjective—understanding, did not cause significant distress related to the receipt of the test results, and were acceptable to participants. These findings provide an initial understanding of the impact of results delivered via mailed letter for normal cancer genetic test results in low-risk, underserved populations. Further research is needed to determine whether normal results letters would be acceptable to patients at higher *a priori* risk due to a personal and/or family history of cancer. Our findings may be used to contribute to the implementation of broad, equitable services among all populations in a scalable manner.

Supplementary Material

Supplementary material is available at *Translational Behavioral Medicine* online.

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Authors' Contributions

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Ethical Approval

All procedures performed in studies involving human participants were in accordance with the ethical standards of the institutional and/or national research committee and with the 1964 Helsinki declaration and its later amendments or comparable ethical standards. The KPNW IRB approved this study and all collaborating IRBs relied on KPNW except Dana Farber Cancer Institute and Columbia University, which reviewed the study separately.

Informed Consent

Informed consent was obtained from all individual participants included in the study.

Welfare of Animals

This article does not contain any studies with animals performed by any of the authors.

Transparency Statements

Study registration: The study was preregistered at https://clinicaltrials.gov/ct2/show/NCT03426878.

Analytic plan registration: The analysis plan for this work was not formally preregistered.

Availability of data: The datasets generated and/or analyzed during the current study are not publicly available due to privacy and ethical restrictions, but de-identified datasets will be made available upon request by emailing the corresponding author.

Availability of analytic code: Analytic codes used to conduct the analyses presented in this study are not available in a public archive. They may be available by emailing the corresponding author.

Availability of materials: Some of the materials used to conduct the study are presented in a public archive: https://anvilproject.org/consortia/cser/resources.

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