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Evaluation of an education intervention to support genomics research participation: a community-based pre–post study among participants under-represented in diabetes genomics research

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ABSTRACT

Objective Develop and study a culturally tailored genomics education tool to better inform future consent processes for genomics research participation among a medically underserved population with diabetes.

Design A single-arm, cohort pre/postsurvey study to assess an educational intervention developed using a community engaged approach.

Setting Federally Qualified Health Centers in San Diego.

Participants Adults (18 years or older) self-identifying as Latino or Hispanic with type 2 diabetes or a history of gestational diabetes were invited to participate. A total of 111 enrolled and completed the preintervention survey; 60 completed the education session and postsurvey. Lay healthcare *promotoras* previously trained to offer bilingual diabetes education and support were also invited; 34 enrolled and completed the study.

Intervention Using community-engaged research approaches, we developed a genomics education programme to include required elements of informed consent for future diabetes genomics research. The 1-hour, face-to-face genomics education programme was delivered 14 times with a variety of day versus evening and weekday versus weekend options, across a 9-month period. Participants completed a 21-item survey, which included 12 items measuring genomics knowledge and 9 items assessing attitudes towards genomics in healthcare.

Primary and secondary outcome measures Primary outcome was the difference between pre and posteducation mean total genomics knowledge scores among the patients who completed the education session and postsurvey. Secondary outcomes included comparison of baseline survey scores between patient and *promotora* subgroups, difference between patient pre and posteducation mean total attitude scores, and prescore to postscore changes within each knowledge and attitude survey item. An exploratory analysis of associations between preintervention scores and sociodemographic characteristics was also completed.

Results Among 60 patients, mean genomics knowledge scores significantly increased from 7.3 (SD=1.9) preintervention to 9.4 (SD=1.5) postintervention (p<0.0001). Preintervention, *promotoras* (mean 8.1, SD=2.0) had significantly higher knowledge scores than patients (mean 6.9, SD 2.3) (p=0.01). Similarly, *promotoras* (mean 6.8, SD1.3) demonstrated a more positive attitude than patients (mean 6.0, SD=1.4) (p=0.0008). Patient attitudes towards genomic testing did not change significantly from preintervention to postintervention (6.2 (SD=1.4) vs 6.3 (SD=1.4), p=0.51).

Conclusions A community-informed education intervention improved genomics knowledge in an under-represented population, providing a model to foster more adequately informed consent for advanced technology research participation.

STRENGTHS AND LIMITATIONS OF THIS STUDY

⇒ Community-engaged research methods were used to develop and deploy the education intervention and the survey instrument.
⇒ *Promotoras*, bilingual lay healthcare workers, supported patient participants throughout enrollment and conduct of the study, including as study participants themselves.
⇒ The genomics education intervention incorporated concepts and adapted language from the US Surgeon General's 'My Family Health Portrait' and 'Does it Run in the Family?' to impart lessons about genetics and heredity.
⇒ The intervention was tailored to the cultural and linguistic characteristics of our patient population, limiting direct application without adaptation.

INTRODUCTION

Type 2 diabetes (T2DM) represents a critical public health crisis, with Latinos or Hispanics

(Hispanics/Latinos hereafter) experiencing disproportionate burdens in disease susceptibility, prevalence and severity.[1] Genome-wide association studies (GWAS) have enhanced our understanding of these population-level differences.[2] However, the accuracy of genomic prediction decreases with greater genetic divergence between discovery and target populations.[3] Consequently, researchers are working to diversify genebank participation to improve the validity and applicability of GWAS findings.[4 5] Despite these efforts, diversifying genebank participation remains challenging, particularly among populations with low baseline knowledge of genetics and heredity or historical experiences of research mistrust, including Hispanics/Latinos who remain significantly under-represented in genomic studies.[6–9] Community engagement is essential to understand barriers and develop culturally appropriate strategies that can effectively increase participation.

Beginning in 2011, our genomics research team collaborated with Project Dulce diabetes researchers to explore strategies for improving genebank diversity, including understanding knowledge and attitudes about genomics research among Hispanics/Latinos. Project Dulce is a community-based diabetes self-management education and support programme designed to improve diabetes care among diverse populations and has been shown to improve clinical and behavioural outcomes among Hispanic/Latino adults with T2DM.[10 11] Using community-engaged research (CEnR) principles,[12] we developed a tailored genomics education intervention to enhance genomics knowledge in order to foster inclusive genomics research among Hispanic/Latino people with T2DM.

In this paper, we describe our CEnR approach to tailoring and implementing a genomics education programme, including adapting content and developing surveys to assess genomics knowledge and attitudes about the use of genomics in healthcare, with a goal of better informing future consent processes to engage Hispanic/Latino patients in genomics research participation. We examine whether the tailored education increased genomics knowledge and changed attitudes regarding the use of genomics in healthcare. Understanding how to effectively engage Hispanics/Latinos and enhance their genomics literacy is critical for ensuring informed participation in research that could ultimately lead to more personalised and effective diabetes prevention and treatment strategies for this disproportionately affected population. We report our model as a CEnR framework for participant education preceding informed consent for studies using methods or technologies unfamiliar to potential enrollees.

METHODS

Patient and public involvement

Using CEnR principles, patients and community members were actively involved in developing the genomics education materials and adapting the survey for this study. Their contributions ensured that these components were culturally appropriate, accessible and aligned with community priorities. Below we outline their specific roles and contributions throughout the research process.

Informed consent

Written informed consent to participate in the pre/post education survey study was obtained by trained members of the research staff before participants completed the study. Accommodation for low-literacy participants was provided by offering to read the consent form to potential enrollees. The option of signing the consent form with an X was offered for participants who were unable to write. Participants signed in the presence of a witness from the research team, in addition to the team member assigned to the informed consenting process.

Survey

To develop the survey, we conducted a comprehensive literature search (PubMed database) for validated survey tools measuring genomic knowledge and/or attitudes towards genomics research in the USA and world communities, attempting to identify validated questions/wording covering genomics knowledge and attitudes for our research project, in an effort to use standardised methods that would allow for comparison of results among diverse communities and world populations.[13–15] We developed our survey taking into account the low-literacy, mostly immigrant population targeted in this initiative, by using language at or below eighth grade education level, avoiding technical words, and developing bilingual English-Spanish materials expecting that Spanish would be the preferred language in the projected study population.

Our CEnR study partnerships (figure 1) allowed for multiple perspectives for design and review of the study survey. Item wording and options for answering were revised and culturally adapted for the targeted predominantly low-literacy Hispanic/Latino population, as per the bilingual and bicultural research team, including the study principal investigator and a team of academic behavioural scientists from San Diego State University (SDSU) with particular expertise in assessing health-related behaviours and attitudes among Hispanics/Latinos in Southern California. A second review and round of editing was performed in collaboration with *promotoras* from Scripps Whittier Diabetes Institute to ensure understandability and acceptability of the survey questions by the community. These *promotoras* are lay-health care workers with close ties to the targeted community, who provide bilingual diabetes education classes and patient support groups on an ongoing basis. We also conducted three focus groups to obtain input from community members and pilot the survey among Hispanic/Latino patients with T2DM (N=18) recruited from Federally Qualified Health Centers (FQHCs). Each focus group session lasted approximately 2.5 hours and

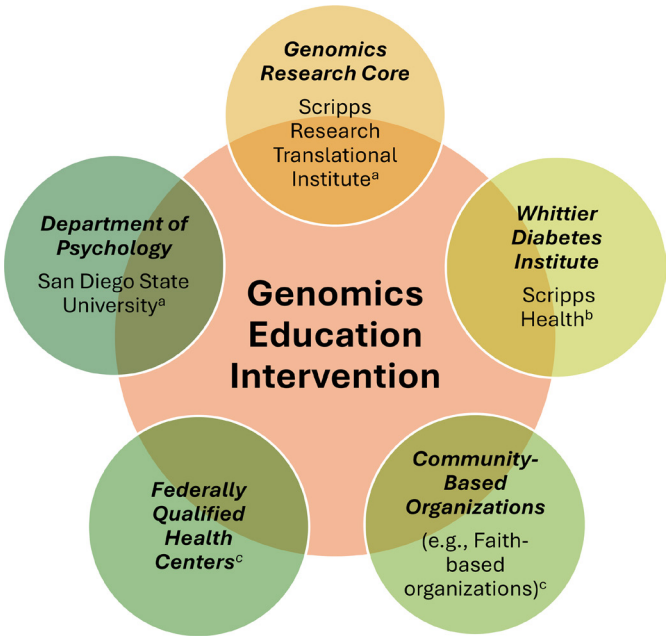

Figure 1 Partnership for community-based genomics education intervention. [a]Academic partner. [b]Healthcare partner. [c]Community partner.

was audio-recorded with consent of participants. Recordings were transcribed and then reviewed by our genomics research team and SDSU collaborators to assess acceptability and feasibility of the projected pre/postsurvey and suggested survey edits. The answers to the survey questions given by focus group participants were analysed as pilot data for the full education intervention study. The final version of the survey also included a 15-item sociodemographic questionnaire that queried age, sex, marital status, parental status, number of children, place of birth, years living in the USA, formal education level, family income and language(s) spoken at home. This questionnaire was provided to the participants as part of the preintervention survey.

The pre/post survey included 12-items assessing knowledge related to genetics in complex diseases; heredity of diseases and relation of heredity to genes; racial and ethnic health disparities; differentiating presence of a gene variant from the risk for, or presence of, a disease; basics of transmission of genes; pharmacogenomics; US antidiscrimination laws for genetics; benefits (or lack thereof) of genetic testing; samples for genetic testing and existence of genetic biobanks. For attitudes about use of genomics in healthcare, the pre/post survey contained nine items related to stigmatisation of people with genetic markers as 'unhealthy'; curiosity about own genetic makeup and disease risk prediction; interference with laws of nature; use of genetics in own healthcare; privacy concerns about sharing genetic information outside the healthcare system, including at the workplace; and altruism as a reason to participate in genomic research (online supplemental table 1).

After integrating community focus group input, response options for the knowledge/attitude instrument were changed from a 5-point Likert scale to Agree/Disagree/Don't Know choices. Other changes—labelling it a survey rather than a questionnaire, changing the title from the original 'Survey of Knowledge and Attitudes towards Genomics Among Hispanics/Latinos with Type 2 Diabetes' to 'Survey about Heredity and Diabetes', and replacing the word 'Attitudes' within the survey sections to 'Opinions'—were deemed more understandable and less 'intrusive' and to avoid being 'too much like a school test'. In the final version, higher knowledge scores indicated greater genomics knowledge, and higher attitude scores indicated more positive attitude towards use of genomics in healthcare.

The knowledge and attitude survey was administered before and after the genomics education intervention, individually or during small group gatherings, per participant preference. The option to read the survey item by item was offered to participants. Members of the study team reading the surveys to participants were trained to read each question as many times as requested, but not to explain the question or change the wording in any way, to ensure standardised administration.

RECRUITMENT

Hispanic/Latino patients with type 2 diabetes or a history of gestational diabetes receiving care at FQHCs in San Diego were invited beginning in 2011 to participate in diabetes genebank research. The genomics research team expressed concern about participants' ability to provide truly informed consent given variability in baseline genomic knowledge. To address this, they partnered with Project Dulce researchers and *promotoras* to establish a CEnR collaboration (figure 1) that informed the design of the educational intervention and the pre–post survey. Patients expressing interest in diabetes genebank participation were invited into this education intervention study by FQHC clinicians or Project Dulce *promotoras* as a prerequisite to genebank participation. Inclusion criteria were age ≥18 years, self-reported Hispanic or Latino ancestry, English or Spanish speaking, and a diagnosis of diabetes, pre-diabetes, metabolic syndrome or a history of gestational diabetes. Exclusion criteria were medical conditions expected to interfere with participation in a 1-hour education session. Bilingual *promotoras* were also recruited into the study as participants to learn the education material; they were not required to meet inclusion criteria.

GENOMICS EDUCATION INTERVENTION

The study was a single-arm pre/post comparison around a 1-hour, face-to-face genomics education programme created to deliver required elements for future genomic study informed consent.[16] Specifically, the programme included information about human genetics, genebank purpose, procedures, potential benefits and possible risks for future genomics study participation. An education

Figure 2 Examples of pictorial genomics education content.

script was developed adapting language and concepts from the US Surgeon General's 'My Family Health Portrait' and 'Does it Run in the Family?'" to impart lessons about genetics and heredity.[15 17 18] Figure 2 illustrates an example of the education material, which accommodated varied literacy levels by utilising explanatory pictures and graphics with minimal text, delivered in 15 didactic minutes allowing 45 min for questions, clarification and discussion. Participants chose a presentation in Spanish or English by a bilingual endocrinologist or bilingual study coordinator with expertise in clinical research and genomics. Fourteen education intervention sessions were offered between February and November 2012, including day/evening and weekday/weekend options. The study was approved by Scripps' Institutional Review Board, and informed consent was obtained from each participant.

STATISTICAL ANALYSES

Participants completed the 21-item pre/post knowledge and attitude survey at the time of study consent and again immediately after the education intervention. The primary outcome was the difference between pre and posteducation mean total genomics knowledge scores among patient participants. Secondary outcomes included comparisons of mean total knowledge and attitude preintervention scores between patient and *promotora* subgroups, pre to postmean attitude scores among patients, and pre to postscores for each individual knowledge and attitude survey item among patients. Baseline versus posteducation mean scores were compared using a paired t-test for the overall score and McNemar's χ^2 tests for the categorical values of individual survey items. An analysis exploring associations of preintervention scores with sociodemographic characteristics was conducted using one-way or two-way analysis of variance, depending on category options. Type 1 error rate was set at $p<0.05$ (two-tailed). No adjustments were made for multiple comparisons.

RESULTS

A total of 308 patients expressed interest in participating in a future genebank. Of these, 111 enrolled in the education intervention and completed the sociodemographics questionnaire and preeducation survey, and 60 (54%) completed the 1-hour intervention session and postsurvey. The most common reasons for not completing the education intervention were lack of transportation and lack of time (data not shown). Total presurvey participants included 111 Hispanic/Latino patients with type 2 diabetes or history of gestational diabetes and 34 *promotoras*—overall median age 52 (SD 12.8), 70% female, 91% with children, 49% middle school or less education, 66% income <US$30 000, 91% born outside the USA, and 75% living in the USA>10 years (table 1). Preferred survey language was Spanish for 91%, with Spanish the only or predominant language at home for 82%.

The mean baseline, pre-education knowledge score was significantly lower in patient than *promotora* participants (6.9 (SD 2.3) vs 8.1 (SD 2.0) (p=0.01), respectively) (table 2). Patients also had a less positive baseline attitude towards genomics in healthcare compared with *promotoras* (6.0 (SD 1.4) vs 6.8 (SD 1.3) (p=0.0008), respectively). Because of these differences, *promotoras* were excluded from our analysis of the intervention's knowledge and attitude effectiveness for patients.

Among the 60 patients who completed the intervention, mean knowledge score rose from 7.3 (SD 1.9) before education to 9.4 (SD 1.5) afterward (p<0.001) (table 3). Attitude did not change significantly (6.2 (SD 1.4) vs 6.3 (SD 1.4) (p=0.51), respectively). Among individual knowledge survey items, all scores increased significantly except one, a statement that all people will benefit from genomic testing, for which all 60 incorrectly answered 'Agree' pre and posteducation. For one item, mean postscore reached 100% correct with 0 variance preventing

statistical testing. Among individual attitude survey items, patient mean scores were not significantly changed pre to post except for one, a statement labelling as unhealthy individuals with a genetic marker for a disease, which significantly increased to 'Disagree'.

In an exploratory analysis of the 111 consented patients who completed the sociodemographic questionnaire

Table 1 Baseline characteristics

Characteristic	All subjects (n=145) n (%) (or mean (SD))	Patients (n=111) n (%) (or mean (SD))	Promotoras (n=34) n (%) (or mean (SD))
Age (years)	52 (12.8) range: 20–77	51.8 (13.2) range: 20–77	52 (11.6) range: 21–76
Sex			
Male	43 (29.7)	39 (35.1)	4 (11.8)
Female	102 (70.3)	72 (64.9)	30 (88.2)
Marital status			
Single	15 (10.3)	12 (10.8)	3 (8.8)
Married	78 (53.8)	60 (54.1)	18 (52.9)
Separated	9 (6.2)	4 (3.6)	5 (14.7)
Divorced	11 (7.6)	8 (7.2)	3 (8.8)
Widowed	14 (9.7)	11 (9.9)	3 (8.8)
Living with partner	18 (12.4)	16 (14.4)	2 (5.9)
Have children	132 (91.0)	101 (91.0)	31 (91.2)
Years in USA			
0	10 (6.9)	8 (7.2)	2 (5.9)
1–4	7 (4.8)	5 (4.5)	2 (5.9)
5–9	13 (9.0)	10 (9.0)	3 (8.8)
10–14	15 (10.3)	12 (10.8)	3 (8.8)
15–19	13 (9.0)	9 (8.1)	4 (11.8)
20–24	25 (17.2)	20 (18.0)	5 (14.7)
25–50	56 (38.6)	42 (37.8)	14 (41.2)
Unknown	6 (4.1)	5 (4.5)	1 (2.9)
Education			
None	9 (6.2)	8 (7.2)	1 (2.9)
Elementary	37 (25.5)	31 (27.9)	6 (17.7)
Middle	25 (17.2)	23 (20.7)	2 (5.9)
High school	39 (26.9)	30 (27.0)	9 (26.5)
Trade/vocational	12 (8.3)	5 (4.5)	7 (20.6)
University	18 (12.4)	9 (8.1)	9 (26.5)
Other	5 (3.5)	5 (4.5)	0 (0)
Income			
<US$30 K/year	96 (66.2)	77 (69.4)	19 (55.9)
>US$30 K/year	22 (15.2)	14 (12.6)	8 (23.5)
Did not report	27 (18.6)	20 (18.0)	7 (20.6)
Language at Home			
Spanish only	87 (60.0)	74 (66.7)	13 (38.2)
More Spanish than English	32 (22.1)	17 (15.3)	15 (44.1)
Spanish and English equally	17 (11.7)	11 (9.9)	6 (17.7)
English more than Spanish	3 (2.1)	3 (2.7)	0 (0)
English only	6 (4.1)	6 (5.4)	0

Table 2 Baseline knowledge and attitude scores

	Patients (n=111)	Promotoras (n=34)	
Outcome	Mean (SD)	Mean (SD)	P value*
Knowledge (12 possible points)	6.9 (2.3)	8.1 (2.0)	0.01
Attitude (9 possible points)	6.0 (1.4)	6.8 (1.3)	0.0008

One point for each answered correctly out of 12 knowledge items; one point for each answered positively out of 9 attitude items.
*From paired t-test.

and the preintervention survey, a positive association was found between baseline genomics knowledge and more formal education, with levels categorised as none or at least some of elementary, middle, high school, trade/vocational or university (p=0.003) as well as for years in the USA categorised as 0–<1, 1–4, 5–9, 10–14, 15–19, 20–24 or 25–>50 (p=0.006). More positive attitude was associated with USA versus other place of birth (p=0.008), higher level of education (p<0.001) and English >Spanish language used at home (p<0.001). No association was seen for either genomics knowledge or positive attitude with age, sex, marital status, parenthood or income level (data not shown).

DISCUSSION

Genomic applications hold great promise for individualising diabetes patient care but only insofar as GWAS-identified variants are discovered in diverse genebanks that include all communities affected by this disease.[19] A CEnR approach,[20–22] including *promotora* participants as a community bridge between investigators and patients, allowed us to incorporate community norms and the specific linguistic needs of the study population into our

Table 3 Mean pre- and postintervention knowledge and attitude scores for patient participants completing the 1-hour genomics education session (n=60)

Outcome	Preintervention, mean (SD)	Postintervention, mean (SD)	P value *
Knowledge (out of 12)	7.3 (1.9)	9.4 (1.5)	<0.0001
Attitude (out of 9)	6.2 (1.4)	6.3 (1.4)	0.51
Knowledge Item	n correct (%)	n correct (%)	
1	48 (80.0)	59 (98.3)	0.0009
2	51 (85.0)	58 (96.7)	0.02
3	45 (75.0)	53 (88.3)	0.05
4	33 (55.0)	49 (81.7)	0.002
5	45 (75.0)	59 (98.3)	0.0005
6	20 (33.3)	42 (70.0)	<0.0001
7	9 (15.0)	18 (30.0)	0.04
8	48 (81.4)	58 (96.7)	0.01
9	44 (73.3)	53 (88.3)	0.02
10	0 (0)	0 (0)	NA
11	52 (86.7)	60 (100)	NA
12	40 (66.7)	57 (95.0)	<0.0001
Attitude item	n positive (%)	n positive (%)	
1	31 (51.7)	40 (66.7)	0.04
2	49 (81.7)	52 (86.7)	0.26
3	41 (68.3)	43 (71.7)	0.59
4	37 (61.7)	40 (66.7)	0.44
5	59 (98.3)	60 (100)	NA
6	23 (39.0)	16 (26.7)	0.09
7	45 (75.0)	42 (70.0)	0.51
8	26 (43.3)	25 (41.7)	0.79
9	57 (95.0)	59 (98.3)	0.16

*From paired t-test for comparing mean total score and McNemar's χ^2 test for comparing mean scores of individual survey items.

education session. This culturally tailored intervention resulted in significantly increased genomic knowledge scores compared with baseline in a medically underserved group interested in participating in diabetes genomics research. Two knowledge items—certain disease if a variant is present and all people benefitting from genomic testing (K7 and K10, online supplemental table 1)—continued to be answered incorrectly as true by most patients postintervention, highlighting key educational gaps for improving subsequent content. Interestingly, other than decreasing the belief that a disease variant makes someone unhealthy (A1, online supplemental table 1), our intervention did not significantly change attitudes. This may reveal a design limitation, such as the need for more use cases of genomics improving patient outcomes, or might be attributable to relatively high baseline scores demonstrating curiosity, physician trust and altruism regarding diabetes genomics (A2, A5 and A9, respectively, online supplemental table 1). Unchanged postintervention concerns about privacy and discrimination indicate that our information about legal protection did not adequately assuage these fears and potentially raised awareness of privacy risks. Similar concerns have been reported among other Hispanic/Latino populations, in whom willingness to consent to genetic data use is strongly influenced by trust in researchers, perceived risk of discrimination and clarity regarding data protection.[23]

Despite day or evening and weekday or weekend options, the major limitation of our study was that 51 of 111 consented patients did not complete our education intervention. This potentially biased our results towards more effectiveness due to primary outcome analysis determined among only those participants having time and transportation for 1 of our 14 sessions. This left our study underpowered to adjust for sociodemographic differences and their effects on our primary outcome of genomics knowledge improvement. Additionally, adhering to CEnR standards meant time-intense development and focus group phases that lengthened study completion and increased expense. However, for our investigational team, the investment was worth the groundwork it provided in building an education workflow into an informed consent process for community participants to enter studies that use new scientific methods. It additionally propelled us towards advancements that shorten time and decrease resource needs, including site-less enrollment and virtual education sessions. A further strength of our approach is that the pre/post survey method provides a tool to iteratively improve the next education iteration, for genomics knowledge in our case, and a framework to incorporate into consenting the inevitably occurring newer research innovations such as digital health monitoring and machine learning.

Emerging technologies present a particular challenge to meaningful informed consent. For our example of genomics research, there remains a lack of consensus regarding what constitutes informed consent for genomic sequencing.[24] Our CEnR approach, including community health champions from study design to completion, promotes tailoring of education materials and provides a valuable model for engaging communities racially, ethnically, socially, economically, educationally and/or geographically under-represented in biomedical research. The goal is accessibility for all people affected by unmet health needs, such as diabetes and its related conditions, for more equitable and applicable research discoveries. While our analysis not unexpectedly found knowledge and attitude positively associated with level of education, many rapidly advancing health innovations would be expected to be new to a majority of participants of any education level, requiring thoughtfully developed information or tutorials for ethically informed consent of any research participant not versed in these technologies. For inclusive research producing results relevant to all communities, policymakers may consider using a similar CEnR model to aid investigators in adding a community-tailored education prerequisite to consenting participants. Future directions include larger study cohorts to allow correction for sociodemographic attributes and different community populations to pursue survey validation, in addition to increased use of online education platforms and smartphone apps with the potential to increase participant engagement and individual benefit.

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Competing interests None declared.

Patient and public involvement Patients and/or the public were involved in the design, conduct, reporting, or dissemination plans of this research. Refer to the Methods section for further details.

Patient consent for publication Not applicable.

Ethics approval This study involves human participants and was approved by Scripps Institutional Review Board, 4555 Executive Drive, San Diego, California, 92121, study number IRB-11-5725. Participants gave informed consent to participate in the study before taking part.

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