Title

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Journal

JAMA, 312(12)

ISSN

0098-7484

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Publication Date

2014-09-24

DOI

10.1001/jama.2014.11479

Peer reviewed

HHS Public Access

Author manuscript

JAMA. Author manuscript; available in PMC 2015 May 27.

Published in final edited form as:

JAMA. 2014 September 24; 312(12): 1210–1217. doi:10.1001/jama.2014.11479.

Effect of Enhanced Information, Values Clarification, and Removal of Financial Barriers on Use of Prenatal Genetic Testing

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Abstract

Importance—Prenatal genetic testing guidelines recommend providing patients with detailed information to allow informed, preference-based screening and diagnostic testing decisions. The effect of implementing these guidelines is not well understood.

Objective—Toanalyze the effect of a decision support guide and elimination of financial barriers to testing on use of prenatal genetic testing and decision-making among women of varying literacy and numeracy levels.

Design—Randomized trial conducted from 2010-2013.

Setting—Prenatal clinics at three county hospitals, a community clinic, an academic center, and three medical centers of an integrated health care delivery system in the San Francisco Bay area.

Participants—English- or Spanish-speaking women who had not yet undergone screening and/or diagnostic testing and remained pregnant at 11 weeks gestation (n=710).

Interventions—A computerized, interactive decision support guide and access to prenatal testing with no out-of-pocket expense (n=357) or usual care as per current guidelines (n=353).

Main Outcome Measures—The primary outcome was invasive diagnostic test use, obtained via medical record review. Secondary outcomes included testing strategy undergone, and knowledge, risk comprehension, decisional conflict and decision regret at 24-36 weeks' gestation.

Results—Women randomized to the intervention group, compared to those randomized to the control group, were less likely to have invasive testing [5.9% vs. 12.3%, odds ratio (OR) 0.45,

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Trial Registration: Clinicaltrials.gov NCT00505596

95% CI 0.25-0.80] and more likely to forego testing altogether [25.6% vs. 20.4%, OR 3.30 (reference group screening followed by invasive testing), CI 1.43-7.64]. They also had higher knowledge scores (9.4 vs. 8.6 on a 15-point scale, mean group difference 0.82, CI 0.34-1.31), and were more likely to correctly estimate the amniocentesis-related miscarriage risk (73.8% vs. 59.0%, OR 1.95, CI 1.39-2.75) and their age-adjusted chance of carrying a fetus with trisomy 21 (58.7% vs. 46.1%, OR 1.66, CI 1.22-2.28). Significant differences did not emerge in decisional conflict or decision regret.

Conclusions and Relevance—Full implementation of prenatal testing guidelines using a computerized, interactive decision support guide in the absence of financial barriers to testing resulted in lesser test use and more informed choices. If validated in additional populations, this approach may result in more informed and preference-based prenatal testing decision making, and fewer women undergoing testing.

Keywords

Prenatal genetic testing; informed decision making; low literacy

Introduction

Since the introduction of amniocentesis,[1] prenatal genetic testing guidelines have focused on identifying women at increased risk of giving birth to an infant with Down syndrome or chromosomal abnormalities, for whom invasive diagnostic testing should be recommended. While initially advanced maternal age was the criterion for eligibility,[2] identification of serum and ultrasonographic markers that can quantify the risk of an affected fetus[3] led to incorporation of screening into routine prenatal care for women of all ages. The recent introduction of cell free DNA testing has intensified the complexity of prenatal testing decision making, generating concerns about the potential for erosion of informed choice.[4]

Studies have questioned the “routinization” of prenatal screening[5] and documented substantial variation in how women view the outcomes of decisions to undergo, or forego, testing.[6, 7] Low uptake rates of invasive testing among women who receive positive screening results also have been reported,[8] raising concerns about the extent to which the purpose and potential outcomes of screening are understood, particularly among women of lower literacy and numeracy levels.[9] Nonetheless, clinicians continue to use standardized approaches to counseling, often simply recommending screening and deferring conversations about invasive diagnostic testing, or non-invasive prenatal testing, until screen positive results are received.[10]

We conducted a randomized clinical trial of a multi-faceted approach to prenatal testing designed to promote preference-based decision making. Our primary goal was to assess the prenatal testing choices women make in the context of being fully informed about testing options, including the option to forego testing; having the opportunity to engage in values clarification exercises; and in the absence of financial barriers. We also sought to understand whether these women would make decisions characterized by greater knowledge and understanding of prenatal testing, and less decisional conflict and decision regret.

Methods

Participants

English- and/or Spanish-speaking pregnant women were recruited from clinics affiliated with three county hospitals (San Francisco General Hospital), Santa Clara Valley Medical Center, Alameda Health System (Highland Hospital) and one community clinic serving primarily low income women (La Clínica de la Raza); one academic center (the University of California, San Francisco); and three medical centers of an integrated health care delivery system (Kaiser Permanente Northern California). Eligibility criteria included being at ≤20 weeks gestation with a singleton or twins and not having undergone any prenatal testing for fetal aneuploidy in the current pregnancy.

Procedures

At two of the sites, potentially eligible participants were sent letters describing the study with postage-paid opt-in/opt-out cards; a bilingual research associate called women who did not return the opt-out card and screened those who indicated interest. At the other sites, patients were referred to an on-site bilingual interviewer who assessed interest and eligibility and obtained written informed consent. Participants then completed an interviewer-administered baseline before being randomized to the intervention or control group.

A computer-generated random allocation sequence assigned participants to experimental groups within permuted blocks of random size, with a 1:1 allocation ratio, stratified by age (<35 vs. ≥35 y), clinical site, parity (nulliparous vs. parous) and interviewer. Women randomized to the intervention group were provided access by the interviewer to a computerized, interactive prenatal testing decision support guide in their preferred language (English or Spanish), located at the interview site, and were told that after using it, the study would pay for any tests discussed for which they lacked insurance coverage. Women who were randomized to the control group received no study intervention, and the study did not pay for prenatal genetic testing for them. The protocol involved no specified interaction with any clinicians.

At 24-36 weeks gestation, patient-reported outcomes were measured during a 20-minute telephone interview. Prenatal test use was assessed postpartum via chart review. Different research associates were employed for baseline and follow-up interviews and chart review, to ensure blinding to the randomization assignment. The randomization code was not available to any study-related personnel until data analysis was complete.

This study was approved by the Institutional Review Boards each of the sites. All participants were enrolled between January 2010 and June 2012 and followed through their deliveries, the last of which occurred in January 2013. Participants were given $40 as remuneration after each of the two interviews.

Experimental Intervention and Control Group

The goal of our study was to determine what women of varying literacy levels and sociodemographic backgrounds would choose after being fully informed about the benefits

and risks of differing prenatal testing strategies and having the opportunity to clarify their values around these options, without the disincentive of having to pay for tests not covered by their insurance.

Women randomized to the experimental group were provided access to "Prenatal Testing: Exploring Your Options," a decision support guide created with input from a wide range of clinicians (including perinatologists, geneticists, obstetricians, nurse midwives, genetic counselors, and nurses), decision scientists, and communication and literacy experts[11] and adapted for use by women of varying literacy levels. It is an audio, video, and text-based interactive computer program narrated by a bilingual actress who speaks in a style that emulates a warm and knowledgeable friend. She emphasizes the personal nature of prenatal testing decisions, noting that foregoing testing altogether, starting with a screening test, or going straight to invasive diagnostic testing are all reasonable options, and that the goal of the program is to help the user decide which option would be best for her.

Prenatal Testing: Exploring Your Options takes about 45-60 minutes to complete. It begins with an educational module that provides general information about prenatal testing and the role of values and preferences in prenatal testing decisions, a description of Down syndrome over the life course, more abbreviated descriptions of trisomies 13 and 18 and structural defects, and details on the diagnostic accuracy and other features of the various screening and diagnostic tests. Optional "Learn More" sections are included throughout this component. In the second part, the user is presented with her personalized, age-related chances of carrying a fetus with aneuploidy. She is then asked to complete values clarification questions focusing on three decisions: 1) whether or not to have any testing; 2) if testing is desired, whether to start with screening or to go straight to invasive diagnostic testing; and 3) which specific screening and/or diagnostic test(s) to undergo, and a graphic highlights the testing strategy that is most consistent with the user's responses. The user is told she can click on it to get detailed information on the features of that strategy, or any of the other strategies. The program concludes by encouraging the user to discuss questions with her clinician, while emphasizing that the testing strategy to undergo is her choice (see eAppendix 1 for screen shots and values clarification questions).

Women randomized to the control group had no study intervention beyond completion of the baseline and follow up questionnaires. Consistent with current guidelines,[12, 13] the official policy at all recruitment sites was to offer women, regardless of age, information on both screening and diagnostic tests and to inform them that testing was optional. Discussions with clinicians at these sites suggested variable adherence to these guidelines, however, and all reported a greater focus on counseling and diagnostic testing for women aged ≥35.

Outcomes and Measures

Our primary outcome was use of invasive prenatal diagnostic testing, obtained from medical chart review. Secondary outcomes included testing strategy undergone, as well as knowledge, risk comprehension, decisional conflict and decision regret, measured during the follow-up telephone interview. To measure knowledge, we used a 15-item measure adapted from the Maternal Serum Screening Knowledge Questionnaire (eAppendix 2).[14] Risk comprehension was assessed by asking participants to estimate, out of 1000 pregnant

women who had amniocentesis, how many would experience a miscarriage (women reporting the risk to be >0 but ≤10 were scored correct), and out of 1000 pregnant women their age, how many are carrying a fetus affected by Down syndrome (risks consistent with the participant's age-related Down syndrome risk were scored correct). Decisional conflict and regret were assessed using 15-items from the Decisional Conflict Scale,[15] and the 5-item Decision Regret Scale.[16]

Statistical Analysis

Our primary hypothesis was that women who were randomized to the intervention group would undergo invasive diagnostic testing at a lower rate than women randomized to the control group, due to better understanding of the likelihood that their fetus was affected by a chromosomal disorder and a greater appreciation that declining testing altogether is a reasonable choice. We conducted power analyses, partially informed by our prior research, to estimate the appropriate sample size to test this hypothesis. In our study of trends in the use of invasive diagnostic testing among women who delivered at an integrated health care system in California, we found that the number of amniocenteses or CVS procedures performed as a percentage of the number of deliveries in 2006 was 12%.[17] We selected a minimal detectable difference of 6%, or half of the rate in the control group, corresponding to an odds ratio of 0.47 (a small to medium effect size). To achieve 80% power, with a two-tailed alpha equal to 0.05 and 90% retention at follow-up, the required sample size was 396 per group, or 792 in total. Secondary hypotheses focused on patient-reported outcomes: compared to women randomized to the the control group group, women randomized to the intervention group would have better testing knowledge and risk comprehension as well as reduced decisional conflict and decision regret; the design was capable of detecting a minimum group mean difference (*d*) equal to 0.21 standard deviations.

All reported analyses were based upon a modified intention-to-treat (mITT) sample that excluded women who reported (or had chart data indicating) a pregnancy loss prior to 11 weeks (the earliest gestational age at which prenatal testing was available at the participating sites; none of those women were yet eligible for to undergo testing.) Group comparisons of 24-week outcomes were tested via linear and logistic regression, as appropriate. We report odds ratios (OR) or linear regression coefficients (b), with 95% confidence intervals (CI) and *p*-values. All models were fit to 20 multiply imputed data sets created via a Markov Chain Monte Carlo method[18] using SAS PROC MI (SAS Institute Inc. 2008). Imputation models were stratified by randomization group and included all variables represented in Tables 1-3, as well as participants' median ZIP code income (from 2000 census data). All parameter estimates, standard error estimates, and test statistics were calculated by combining results across the imputed data sets.[19, 20] Alpha equaled 0.05, two-tailed, throughout.

Results

A total of 1932 women were screened for eligibility; 635 did not meet inclusion criteria (Figure). Of the 1297 eligible women, 744 enrolled in the study, a 57.3% participation rate; 375 were randomized to the intervention group and 369 were randomized to the control

group. After randomization, 34 women experienced pregnancy losses before 11 weeks gestation. The 710 remaining women (357 allocated to the intervention group and 353 to the control group) comprised the mITT sample from which the data used in this analysis were obtained.

This sample constituted a sociodemographically diverse cohort of pregnant women; 15.8% of the participants self-identified as African American, 9.2% as Asian or Pacific Islander, 45.4% as Latina, and 25.6% as white. About a third (35.5%) opted to participate in the Spanish-language version of the study. Nearly half (45.9%) had no more than a high school education, a quarter (25.4%) had less-than-adequate literacy, and 44.5% had low numeracy (Table 1).

As hypothesized, significantly fewer women who were randomized to the intervention group underwent invasive diagnostic testing compared to women randomized to the control group (Table 2; 5.9% versus 12.3%, OR 0.45, 95% CI 0.25-0.80, *p*=.005). The overall prenatal testing strategy employed by the two groups also differed: women randomized to the intervention group were more likely to have no testing (OR 3.30, 95% CI 1.43-7.64, p =. 005) or screening alone (OR 2.67, 95% CI 1.19-5.97, p=.02; reference group screening followed by diagnostic testing).

Also as hypothesized, women randomized to the intervention group had significantly higher knowledge scores (Table 3; 9.4 versus 8.6 out of 15, b=0.82, 95% CI 0.34-1.31, p<.001), and were more likely to correctly report both the miscarriage risk of amniocentesis (73.8% versus 59.0% correct, OR 1.95, 95% CI 1.39-2.75, p<.001) and their age-adjusted likelihood of carrying a fetus with trisomy 21 (58.7% versus 46.1% correct, OR 1.66, 95% CI 1.22-2.28, p=.001). Although we had hypothesized that women randomized to the intervention group would have lower decisional conflict and decision regret, significant differences did not emerge on these outcomes.

We were able to access usage data from the decision support guide for 325 of the 357 women randomized to the intervention group. 309 of those women completed all sections of the program and had data on the testing strategy the program suggested might be most aligned with their values. For 72.2%, the suggested approach was to start with a screening test; 9.7% were told that going straight to invasive testing might be best for them. The rest (18.1%) were informed that their values indicated a preference for no testing. When we compared the recommended testing strategy to the strategy undergone among the 264 women who completed all sections of the program and for whom we had chart review data, we found that the majority (75.0%) underwent the recommended strategy.

Discussion

In this study of a diverse population of women receiving care in a variety of settings, we demonstrated that, after receiving complete prenatal testing information and the opportunity to explicitly consider their values and preferences via an interactive decision support tool, and having financial barriers to testing removed, participants were less likely to opt for invasive testing and more likely to forego testing for aneuploidy altogether, suggesting that

expanding coverage of amniocentesis and chorionic villus sampling to women of all risk levels may not result in increased use of these procedures. We also found that this approach improved patient knowledge regarding prenatal testing and understanding of amniocentesis-related miscarriage and age-adjusted Down-syndrome risk, suggesting that it resulted in more informed patient decision-making.

What do our findings suggest for patient counseling and decision making in an era of rapidly expanding options for prenatal testing, including cell free DNA testing and chromosomal microarray analysis?[21, 22] First, our study has generated evidence that using an interactive decision support guide that presents systematic information and an opportunity to engage in values clarification exercises can help women of varying literacy levels make informed prenatal decisions reflective of their own preferences and goals. In addition to providing an opportunity for women to consider the various options at their own pace, having such a decision guide available in clinical settings can provide a consistent and accurate message regarding the risks and benefits of testing.

Our finding that women who were randomized to the intervention group were less likely to undergo testing than those who received usual care adds support to the contention that women may not be receiving adequate counseling about their options. This underscores the need for clinicians to be clear that prenatal testing is not appropriate for everyone, and to present foregoing testing as a reasonable choice. In the era of cell free DNA testing for aneuploidy, it is particularly important that women understand the purpose and potential consequences of undergoing testing, as non-invasive prenatal testing may easily be routinized as simply another blood test in the large panel of routine prenatal labs.

While our study was strengthened by its use of a randomized design, its focus on outcomes obtained from medical records as well as those reported by patients, and participation of English- and Spanish-speaking women of varying literacy levels receiving care in a variety of settings, several limitations deserve comment. First, while we succeeded in recruiting a diverse sample, all participants resided in the San Francisco Bay area, and our participation rate was 57.3%, potentially limiting the study's generalizability. We did not measure participants' knowledge, attitudes and preferences until 24 weeks gestation because having women respond to those questions prior to making decisions about prenatal screening would, in itself, constitute an intervention. We therefore cannot assess mechanisms of action via those potential mediators. And while a significant difference in knowledge scores emerged at this time point, the clinical significance is unclear. Differences in knowledge scores have been shown to be strongest in the first two weeks after using decision tools and to dissipate over time, suggesting that the intergroup difference in this score may have heen higher at the time testing utilitization decisions were made.[11] Moreover, substantive differences in the percent of women who correctly reported their likelihood of carrying an affected fetus and experiencing a procedure-related miscarriage suggests that the tool improved knowledge in these domains.

In addition, because chromosomal disorders are relatively rare (we found 5 cases of trisomy, all of which were identified via prenatal testing and resulted in terminations), we did not have a sufficient sample to conduct a sub-analysis of women who were found to be carrying

an affected fetus. Finally, because of our interest in observing what women would do in the context of complete information about all prenatal testing options without financial barriers, participants were told they could undergo testing without out-of-pocket expense to them. How to effectively implement guides in clinical settings without such guaranteed access remains to be determined.

Importantly, this study was largely conducted before the introduction of cell-free DNA testing. As a result, no information on this new screening test was included in the decision support guide, and this option was not available to study participants. However, the general features of cell free DNA testing and the conditions for which it screens are similar to the tests covered in this study, and the implications for counseling and informed patient decision making remain the same.

Conclusions

Full implementation of prenatal testing guidelines using a computerized, interactive decision support guide in the absence of financial barriers to testing resulted in lesser prenatal test use and more informed choices. If validated in additional populations, this approach may result in more informed and preference-based prenatal testing decision making, and fewer women undergoing testing.

Supplementary Material

Refer to Web version on PubMed Central for supplementary material.

Acknowledgments

All authors certify that this manuscript represents original and valid work, that they have given final approval of the submitted manuscript, and that they have participated sufficiently in the work to take public responsibility for part or all of the content. Drs. Kuppermann, Gregorich, Vargas, Caughey and Norton participated designing and obtaining funding for the study. Statistical analysis was conducted by Dr. Gregorich and Ms. Nakagawa. All authors participated in data acquisition, interpretation of data analyses, and drafting or critical revising the manuscript. Dr. Kuppermann was responsible for supervising study staff. She and Dr. Gregorich had full access to all the data in the study and takes responsibility for the integrity of the data and the accuracy of the data analysis. Dr. Kuppermann was the UCSF site PI of a clinical study of cell free DNA testing funded by Ariosa Diagnostics, and she has received unrestricted research funding from Verinata Health and Natera. Dr. Caughey serves as a medical advisor to Ariosa and Cellscape and has received stock options in both companies. Dr. Norton was a site PI and lead co-PI of a clinical study of cell free DNA testing funded by Ariosa Diagnostics, and was site PI of a clinical study of noninvasive prenatal testing funded by Cellscape. She has received unrestricted research funding from Natera and is an unpaid clinical advisor to Natera. This study was funded by grants from the National Institutes of Health (R01HD049686) and the March of Dimes Foundation (Social and Behavioral Sciences Research Grant No. 12-FY09-213). The funding sources had no involvement in the design and conduct of the study; collection, management, analysis, and interpretation of the data; and preparation, review, or approval of the manuscript; and decision to submit the manuscript for publication. Preliminary findings from this study were presented at the annual meeting of the Society for Medical Decision Making in Baltimore, MD, on October 21, 2013 (abstract #TRA2-2).

References

1. Nadler HL, Gerbie A. Present status of amniocentesis in intrauterine diagnosis of genetic defects. Obstet Gynecol. 1971; 38(5):789–799. [PubMed: 5114231]
2. Antenatal Diagnosis. NIH Consensus Statement. 1979 Mar 5-7; 2(2):11–15.

3. Haddow JE, Palomaki GE, Knight GJ, Cunningham GC, Lustig LS, Boyd PA. Reducing the need for amniocentesis in women 35 years of age or older with serum markers for screening. N Engl J Med. 1994; 330(16):1114–1118.10.1056/NEJM199404213301603 [PubMed: 7510852]
4. van den Heuvel A, Chitty L, Dormandy E, Newson A, Deans Z, Attwood S, et al. Will the introduction of non-invasive prenatal diagnostic testing erode informed choices? An experimental study of health care professionals. Patient Educ Couns. 2010; 78(1):24–28. doi:10.1016/j.pec.2009.05.014 [doi]. [PubMed: 19560305]
5. Press N, Browner CH. Why women say yes to prenatal diagnosis. Soc Sci Med. 1997; 45(7):979–989. doi:S0277953697000117 [pii]. [PubMed: 9257391]
6. Kuppermann M, Nease RF, Learman LA, Gates E, Blumberg B, Washington AE. Procedure-related miscarriages and Down syndrome-affected births: implications for prenatal testing based on women's preferences. Obstet Gynecol. 2000; 96(4):511–516. [PubMed: 11004350]
7. Grobman WA, Dooley SL, Welshman EE, Pergament E, Calhoun EA. Preference assessment of prenatal diagnosis for Down syndrome: is 35 years a rational cutoff? Prenat Diagn. 2002; 22(13):1195–1200.10.1002/pd.494 [PubMed: 12478632]
8. Jaques AM, Collins VR, Muggli EE, Amor DJ, Francis I, Sheffield LJ, et al. Uptake of prenatal diagnostic testing and the effectiveness of prenatal screening for Down syndrome. Prenat Diagn. 2010; 30(6):522–530. doi:10.1002/pd.2509 [doi]. [PubMed: 20509151]
9. Roter DL, Erby L, Larson S, Ellington L. Oral literacy demand of prenatal genetic counseling dialogue: Predictors of learning. Patient Educ Couns. 2009; 75(3):392–397. doi:10.1016/j.pec.2009.01.005; 10.1016/j.pec.2009.01.005. [PubMed: 19250792]
10. Driscoll DA, Morgan MA, Schulkin J. Screening for Down syndrome: Changing practice of obstetricians. Am J Obstet Gynecol. 2009; 200(4):459.e1–459.e9. doi:10.1016/j.ajog.2008.12.027; 10.1016/j.ajog.2008.12.027. [PubMed: 19318157]
11. Kuppermann M, Norton ME, Gates E, Gregorich SE, Learman LA, Nakagawa S, et al. Computerized prenatal genetic testing decision-assisting tool: a randomized controlled trial. Obstet Gynecol. 2009; 113(1):53–63.10.1097/AOG.0b013e31818e7ec4 [PubMed: 19104360]
12. American College of Obstetricians and Gynecologists. ACOG Practice Bulletin No. 88: Invasive prenatal testing for aneuploidy. Obstet Gynecol. 2007; 110(6):1459–1467.10.1097/01.AOG.0000291570.63450.44 [PubMed: 18055749]
13. American College of Obstetricians and Gynecologists. ACOG Practice Bulletin No. 77: Screening for fetal chromosomal abnormalities. Obstet Gynecol. 2007; 109(1):217–227. [PubMed: 17197615]
14. Goel V, Glazier R, Holzapfel S, Pugh P, Summers A. Evaluating patient's knowledge of maternal serum screening. Prenat Diagn. 1996; 16(5):425–430. doi:2-2. [PubMed: 8844000]
15. O'Connor AM. Validation of a decisional conflict scale. Med Decis Making. 1995; 15(1):25–30. [PubMed: 7898294]
16. Brehaut JC, O'Connor AM, Wood TJ, Hack TF, Siminoff L, Gordon E, et al. Validation of a decision regret scale. Med Decis Making. 2003; 23(4):281–292. [PubMed: 12926578]
17. Norton ME, Nakagawa S, Norem C, Gregorich SE, Kuppermann M. Effects of changes in prenatal aneuploidy screening policies in an integrated health care system. Obstet Gynecol. 2013; 121(2 Pt 1):265–271. doi: http://10.1097/AOG.0b013e31827e5c85; http://10.1097/AOG.0b013e31827e5c85. [PubMed: 23344275]
18. Schafer, J. Analysis of Incomplete Multivariate Data. London: Chapman & Hall; 1997.
19. Rubin, D. Multiple Imputation for Nonresponse in Surveys. New York: John Wiley & Sons; 1987.
20. Li K, Meng X, Raghunathan TE, Rubin DB. Significance levels from repeated p-values with multiply imputed data. Statistica Sinca. 1991; 1:65–92.
21. American College of Obstetricians and Gynecologists Committee on Genetics. Committee Opinion No. 545: Noninvasive prenatal testing for fetal aneuploidy. Obstet Gynecol. 2012; 120(6):1532–1534. doi:10.1097/01.AOG.0000423819.85283.f4; 10.1097/01.AOG.0000423819.85283.f4. [PubMed: 23168792]
22. American College of Obstetricians and Gynecologists Committee on Genetics. Committee Opinion No. 581: The use of chromosomal microarray analysis in prenatal diagnosis. Obstet Gynecol.

2013; 122(6):1374–1377. doi:10.1097/01.AOG.0000438962.16108.d1; 10.1097/01.AOG.0000438962.16108.d1. [PubMed: 24264715]

23. Bass PF, Wilson JF, Griffith CH. A shortened instrument for literacy screening. J Gen Intern Med. 2003; 18(12):1036–1038. [PubMed: 14687263]
24. Lipkus IM, Samsa G, Rimer BK. General performance on a numeracy scale among highly educated samples. Med Decis Making. 2001; 21(1):37–44. [PubMed: 11206945]

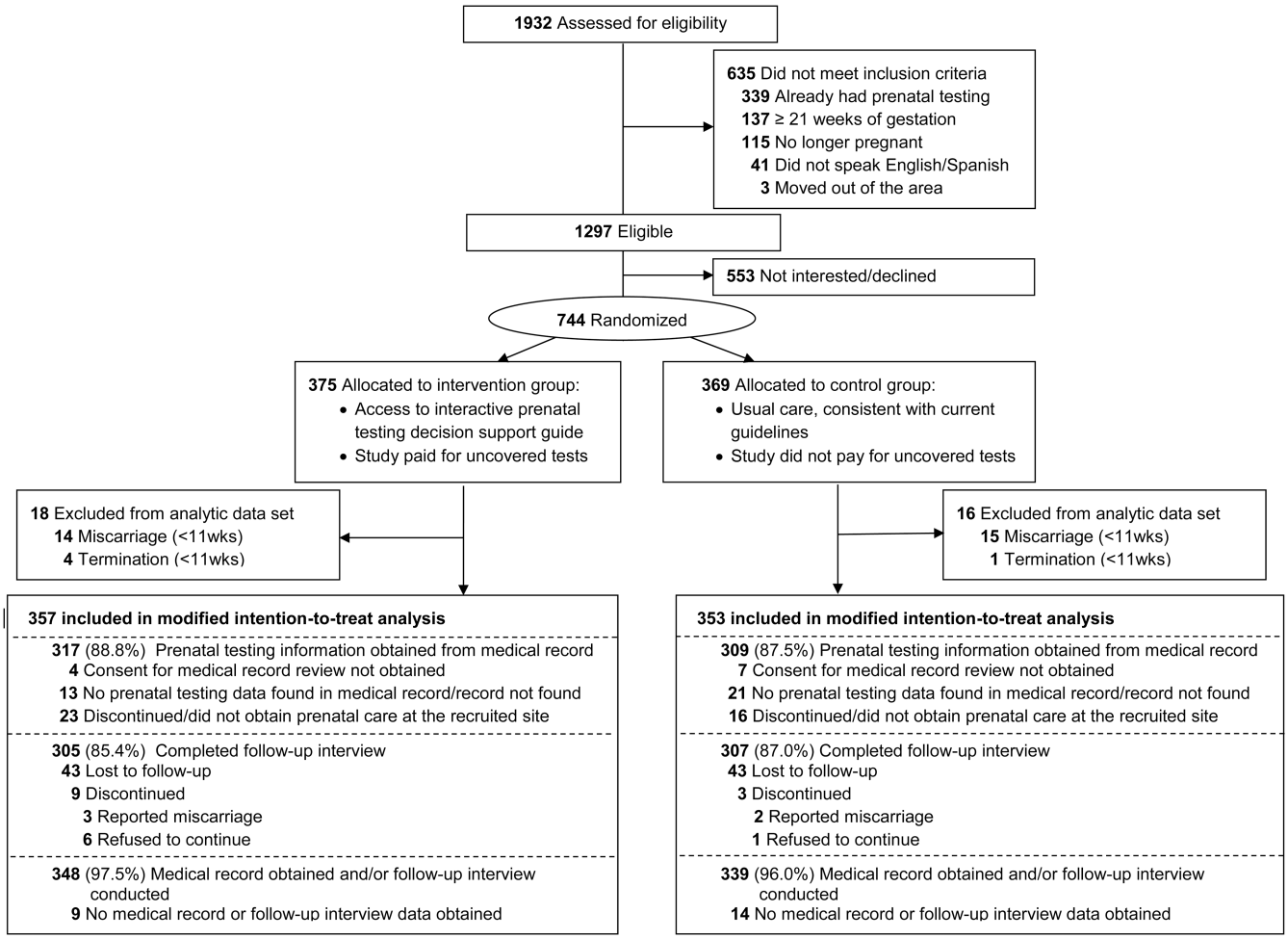

Figure.

Table 1
Baseline characteristics of study participants by randomization group (N=710)

	Intervention group n=357	Control group n=353
Sociodemographic characteristics		
Age		
Mean age in years	29.2 ± 6.0	29.3 ± 6.3
≥ 35 years old	77 (21.6%)	75 (21.2%)
Married/living with partner	267 (74.8%)	253 (71.6%)
Race/ethnicity		
African American, Black	54 (15.1%)	58 (16.4%)
Asian	27 (7.6%)	38 (10.8%)
Latina, Latin American	174 (48.7%)	148 (41.9%)
White	93 (26.1%)	89 (25.2%)
Other*	9 (2.5%)	20 (5.7%)
Spanish-language interview	136 (38.1%)	116 (32.9%)
Educational attainment		
Some high school or less	105 (29.4%)	94 (26.8%)
High school graduate	65 (18.2%)	61 (17.4%)
Some college	69 (19.3%)	84 (23.7%)
College graduate	59 (16.5%)	55 (15.6%)
Graduate degree	59 (16.5%)	58 (16.5%)
Literacy/numeracy		
Less than adequate literacy†	94 (26.4%)	86 (24.4%)
Low numeracy‡	161 (45.0%)	155 (43.9%)
Annual household income		
Less than or equal to $25,000	160 (44.9%)	178 (50.3%)
$25,001-$50,000	60 (16.9%)	51 (14.6%)
$50,001-$100,000	62 (17.4%)	47 (13.2%)
$100,001-$150,000	39 (11.1%)	40 (11.3%)
Greater than $150,000	35 (9.8%)	38 (10.7%)
Recruitment site		
Sites serving primarily women of lower socioeconomic status		
San Francisco General Hospital	113 (31.7%)	111 (31.4%)
Santa Clara Valley Medical Center (San Jose)	57 (16.0%)	60 (17.0%)
Alameda County Medical Center-Highland Hospital (Oakland)	14 (3.9%)	16 (4.5%)
La Clínica de la Raza (Oakland)	24 (6.7%)	23 (6.5%)
Other sites		
University of California, San Francisco	81 (22.7%)	78 (22.1%)
Kaiser Permanente Northern California (San Francisco, Oakland, Richmond)	68 (19.0%)	65 (18.4%)

	Intervention group n=357	Control group n=353
Reproductive history		
Prior pregnancy	253 (70.9%)	247 (70.0%)
Prior live birth	203 (56.9%)	202 (57.2%)
Had prenatal testing in a previous pregnancy	109 (30.5%)	122 (34.5%)
Had genetic counseling in a previous pregnancy	49 (13.7%)	53 (15.1%)
Gestational age at first prenatal visit (weeks)[§]	9.4 ± 3.3	9.3 ± 3.1

Data are n (%) or mean ± standard deviation.

[*] Includes Native American and “mixed.”

[†] Rapid Estimate of Adult Literacy in Medicine-Revised (REALM-R) score of ≤6 on a 0-to-8 scale, which is considered as being at risk for poor literacy.[23]

[‡] ≤2 correct responses on a 5-item numeracy scale.[24]

[§] Estimated from self-reported first prenatal visit date and last menstrual period.

Table 2

Prenatal tests and testing strategies undergone by randomization group (N=710)

	Intervention group n=357	Control group n=353	OR (95% CI)	*p*-value*
Had invasive diagnostic testing				
Amniocentesis	14 (3.9%)	29 (8.2%)	0.45 (0.22-0.92)	.02
CVS	9 (2.4%)	15 (4.1%)	0.57 (0.23-1.42)	.22
Any diagnostic testing†	21 (5.9%)	43 (12.3%)	0.45 (0.25-0.80)	.005
Testing strategy undergone				.03‡
No testing	92 (25.6%)	72 (20.4%)	3.30 (1.43-7.64)	.005
Screening test only	244 (68.5%)	238 (67.3%)	2.67 (1.19-5.97)	.02
Straight to invasive diagnostic test	11 (3.0%)	16 (4.6%)	1.67 (0.54-5.21)	.37
Screening test followed by invasive diagnostic test	10 (2.9%)	27 (7.7%)	Reference	

CVS, chorionic villus sampling, OR, odds ratio; CI, confidence interval

**P*-value for corresponding odds ratio.

†Two women had both CVS and amniocentesis.

‡*P*-value from omnibus 3-degree of freedom test from multinomial logistic regression.

Table 3

Knowledge about prenatal testing, risk comprehension, decisional conflict and decision regret at 24-36 weeks gestation

	Intervention group n=357	Control group n=353		*p*-value
Continuous outcomes			**b (95% CI)**	
Knowledge*	9.4 ± 3.2	8.6 ± 3.2	0.82 (0.34,1.31)	<.001
Decisional conflict†	12.9 ± 14.1	13.8 ± 15.6	-0.89 (-3.27,1.50)	.47
Decision regret‡	8.29 ± 12.5	6.83 ±10.8	1.46 (-0.36,3.29)	.12
Categorical outcomes			**OR (95% CI)**	
Correct estimate of amniocentesis miscarriage risk§	263 (73.8%)	208 (59.0%)	1.95 (1.39-2.75)	<.001
Correct estimate of Down syndrome risk**	210 (58.7%)	163 (46.1%)	1.66 (1.22-2.28)	.001

Note. tabled values include means ± standard deviations for continuous outcomes or *n* (%) for categorical outcomes; point estimates of the intervention effect representing unstandardized linear regression coefficients (b) or odds ratios (OR); 95% confidence intervals of point estimates (95% CI); and *p*-values of point estimates

*Number of correct responses on 15-item knowledge questionnaire adapted from the Maternal Serum Knowledge Questionnaire."[14] Possible scores range from 0 (no correct answers) to 15 (all answers correct).

†15-items from the 16-item Decisional Conflict Scale;[15] possible scores range from 0 to 100, with higher scores indicating more conflict.

‡Mean score on Decision Regret Scale;[16] possible scores range from 0 to 100, with higher scores indicating more regret.

§Replies in "Greater than zero but less than 10 in 1000" were considered correct. Replies in "zero" and "greater than 10 in 1000" were considered incorrect and combined as referent group in logistic regression modeling on the correct replies.

**Replies were considered correct if the estimate provided was within the age-specific range for the participant.