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Decision Aids for Localized Prostate Cancer in Diverse Minority Men: Primary Outcome Results from a Multi-Centered Cancer Care Delivery Trial (Alliance A191402CD)

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Conflicts of Interest

Dr. Morris is a non-compensated consultant to Bayer, Novartis, Advanced Accelerator Applications, Janssen, Lantheus. Dr. Morris is a compensated consultant to ORIC, Curium, Athenex, NCCN, and Exelixis. Dr. Morris also receives institutional funding for clinical trials from: Bayer, Endocyte, Progenics, Corcept, Roche/Genentech, Celgene/BMS, and. Janssen. None of Dr. Morris's disclosures are related to this work. Dr. Paskett is the MPI on a grant to her institution form Merck Foundation and another from Pfizer. Dr. Paskett also receives grant funding to her institution form the Breast Cancer Research Foundation. None of Dr. Paskett's disclosures are related to this work.

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Abstract

Background: Decision aids (DAs) can improve knowledge for prostate cancer treatment. However, the relative effects of DAs delivered within the clinical encounter and in more diverse patient populations are unknown. We performed a multi-centered cluster randomized controlled trial (RCT) with a 2×2 factorial design to test the effectiveness of within-visit as well as pre-visit DAs for localized prostate cancer, oversampling minority men.

Methods: The interventions were delivered in urology practices affiliated with the NCI Community Oncology Research Program (NCORP) Alliance Research Base. The primary outcome was prostate cancer knowledge (% correct, 12-item measure) assessed immediately after urology consultation.

Results: Four sites administered the pre-visit DA (n=39 patients), 4 sites administered the within-visit DA (n=44 patients), 3 sites administered both pre- and within-visit DAs (n=25 patients), and 4 sites provided usual care (n=50 patients). Median % correct in prostate cancer knowledge based on the post-visit knowledge assessment after intervention delivery were as follows—the pre+within DA study arm was 75%, the pre-visit DA only arm was 67%, within-visit DA only arm was 58%, and usual care was 58%. Neither pre-visit nor within-visit DAs had a significant impact on patient knowledge of prostate cancer and its consequences at the pre-specified 2.5% significance level ($p = 0.132$ and 0.977, respectively).

Conclusions: Decision aids for localized prostate cancer treatment provided at two different points in the care continuum in a trial that oversampled minority men did not confer measurable gains in prostate cancer knowledge.

Precis:

This study oversampled minority men and evaluated the effect of two decision aids on prostate cancer patients' knowledge. Decision aids were not shown to impact knowledge about prostate cancer treatment options.

Keywords

Prostate cancer; decision aids; knowledge; shared decision making

INTRODUCTION

Prostate cancer remains the most common non-cutaneous malignancy in men with varying pathologic aggressiveness and outcomes. Clinical management of localized prostate cancer should include risk stratification derived from prostate-specific antigen (PSA) and Gleason score, incorporate life expectancy, and account for patients' quality of life, values, and preferences.[1] For instance, active surveillance may best serve patients with low-risk prostate cancer or life expectancy less than 10 years, whereas healthier patients diagnosed with clinically aggressive prostate cancer typically require surgery or radiation therapy. However, each form of primary therapy (radiation therapy or surgery) has been shown to have similar survival benefits but different quality of life implications for urinary incontinence and erectile dysfunction.

Complicating matters further, prostate cancer disproportionately affects Black or African American men and other minority populations in the United States with higher rates of aggressive disease and poorer quality of care associated with more progression and greater mortality.[2–5] Moreover, Black or African American men typically report making treatment decisions with less knowledge and experience. It is also well known that poor patient-provider communication and mistrust are adverse mediators of known disparities in cancer care delivery.[6]

Shared decision-making can facilitate a more deliberate treatment decision for patients diagnosed with localized prostate cancer by aiding in patients' understanding of the competing risks and quality of life considerations for all management options, and then applying those considerations to their own situation while incorporating the guidance of their cancer specialist.

Decision aids (DA) – tools to promote shared decision making – have been shown to improve patient knowledge, potentially reduce decisional conflict in prostate cancer treatment decisions, and thereby facilitate shared decision-making.[7,8] To date, trials have exclusively focused on DAs delivered and used by patients prior to treatment consultations and have not included sufficient numbers of minority men to ascertain whether observed decision aid effect sizes for improvement in knowledge are more broadly applicable for minority men facing a diagnosis of prostate cancer. In principle, improving patient knowledge about potential treatment consequences could help at least indirectly reduce the burden of prostate cancer treatments by calibrating expectations for some loss of bowel, bladder, and erectile function.[6] Determining whether DAs delivered within consultations work and whether DAs at all work in high-risk minority groups could help reduce racial disparities in prostate cancer.

In this context, we sought to test whether DAs delivered prior to and/or within a consultation for localized prostate cancer could improve immediate patient knowledge of prostate cancer

risks, features, and its treatment consequences as well as immediate decisional conflict. We hypothesized that pre-visit and within-visit decision aids would each independently improve patient knowledge in a diverse population that intentionally over-sampled minority men with localized prostate cancer facing an initial treatment decision.

METHODS

Our study (Alliance for Clinical Trials in Oncology A191402CD) was conceptualized in an investigator-initiated competitive grant application in response to a National Institute of Minority Health and Health Disparities announcement (RFA-MD-13–006). It was refined further in collaboration with the Health Disparities, Health Outcomes, Genitourinary and Cancer Care Delivery Committees of the NCI Community Oncology Research Program (NCORP) Alliance Research Base.[9] An advisory board comprised of community advocates knowledgeable about prostate cancer and with representation from minority populations was convened to advise investigators in trial planning, conduct, outreach and reporting. Details of our protocol were previously published[10] and are briefly summarized below. This study was reviewed and approved by the NCI Cancer Prevention and Control Central Institutional Review Board (CIRB).

Design

We used a cluster-randomized trial (CRT) with a 2×2 factorial design. With such a design, clinical practices were identified upfront and randomized with equal allocation to one of four arms receiving both a pre-visit and within-visit decision aid, a pre-visit decision aid only, a within-visit decision aid only, or no decision aid (usual care) (Figure 1). The factorial design enabled efficient ascertainment of individual DA effects, while also examining potential additive effects between the two decision aids.

Population

We recruited 21 urology practices affiliated with NCI-funded NCORP sites that received funding to conduct cancer care delivery research (CCDR), including several NCORP minority and underserved sites. We sought to approach individual patients with clinically localized prostate cancer within 4 months of diagnosis at those practices who were facing an initial treatment decision. Inclusion criteria included age ≥18 years, a positive prostate cancer biopsy within the previous 4 months (clinical T1–3), a prostate specific antigen (PSA) test < 50 ng/mL and ability to read and comprehend English or have access to translation/interpreter assistance. Exclusion criteria included known metastatic disease, a history of noncutaneous malignancy within the last 5 years, concurrent enrollment in another clinical trial for prostate cancer treatment, and impaired decision-making capacity (e.g., dementia). Additionally, patients were recruited only if they were seeking an initial opinion about their diagnosis and had not yet had an initial consultation about prostate cancer treatment options. Because our underlying scientific question included a desire to understand the effects of decision aids in minority men, particularly Black or African American men, we set aside half of all trial slots for Black or African American men to ensure pre-specified effect size analysis in this subgroup, while also hoping to attract a diverse overall demographic mix of participants.

Interventions

Prostate Cancer Choice Decision Aid (within-visit)—*Prostate Cancer Choice is* a within-visit decision aid, designed to be deployed by clinicians during an office visit on a tablet or computer to support discussion with patients about treatment choices. After focus groups with patients and urologists, the DA was developed with the educational content to primarily serve as a prompt for guideline concordant conversation with the clinician during the clinical encounter. It also provided individualized estimates of prostate cancer risk stratification (based on pre-treatment PSA, clinical T stage and Gleason score) and life expectancy, and queried current quality of life through a validated instrument.[11] Patients randomized to this arm also rated the importance of oncologic outcomes and quality of life. A summary page including prostate cancer risk stratification, life expectancy, existing quality of life and values was then provided at the end of the consultation. (http://prostatecancer.takethewind.com/web/index.php)

Knowing Your Options Decision Aid (pre-visit)—*Knowing Your Options* was designed to provide men with localized prostate cancer detailed information about their cancer and treatment options using video, images and risks communicated visually. The aid also prompts users to consider their values related to making a decision, and includes a summary document available for printing. Underlying the design of the aid was a desire to promote deliberation by patients and emphasize that a decision need not be made quickly. It can be used prior to a conversation with a cancer specialist and after a clinical encounter to allow patients ample time to consider their treatment options. It was developed under a contract from the Agency for Healthcare Research and Quality. (https://effectivehealthcare.ahrq.gov/decision-aids/prostate-cancer/)

Both *Prostate Cancer Choice* and *Knowing Your Options* presented the same scientific evidence, each conforming to international standards for decision aid development[12] and were nonproprietary products that could be disseminated widely if demonstrated to be effective. Patients were approached to participate prior to a scheduled first consultation for initial prostate cancer management but after having received their diagnosis. Consenting participants received the intervention corresponding to their clinic's randomization assignment. To limit the possible effects of each DA on the diverse clinical practices, the protocol allowed each site to administer the DA without specific requirements of patient expectations or time estimates. Details of how the DAs were applied are described in detail elsewhere.[10]

Outcome Measures

Our primary outcome measure was a one-time assessment of patient knowledge of prostate cancer risks, features, and implications for treatment assessed immediately after the index specialist consultation (Appendix A). To assess knowledge, we devised, pilot tested, and implemented a 12-item Yes/No questionnaire. After deliberating with experts, to assess knowledge, we elected to avoid possible learning affects associated with a baseline+repeat testing approach, a so called "difference in differences" approach to outcome comparison. Instead, we used a one-time assessment of individual knowledge assessed immediately after the index consultation using the 12-item measure. The number of correct responses were

converted to a proportion. Other secondary outcomes included clinical time (in minutes) for the consultation, decisional regret measured by the Decisional Regret Scale, and health-related quality of life measured by the Expanded Prostate Cancer Composite Index 26. The latter two secondary outcomes are not reported in this article, as they are planned for a subsequent article devoted to one-year outcomes.

Data Management and Analysis

This study was monitored twice annually by the Alliance Data and Safety Monitoring Board, a standing committee with members drawn from both within and outside of the Alliance. Data collection was conducted centrally by the Alliance Statistics and Data Management Center (SDMC) and data quality was ensured by review of data by the Alliance SDMC and by the study chairperson following Alliance policies. We implemented the analysis plan outlined in our previously published protocol; however, we provide a brief summary below.[10] The trial was registered with clinicaltrials.gov in advance (NCT03103321).

We assumed that most patients would correctly answer 50% (standard deviation of 12%) of the 12 knowledge questions. We hypothesized that patients receiving any decision aid (either the pre-visit or within-visit decision aid) would have a 1-point difference in knowledge score, or 8% greater knowledge compared to usual care. The targeted accrual goal was calculated as 172 participants from all 20 sites. In the study design, we assumed an intra-cluster correlation coefficient (ICC) of 0.10, to account for clustering of patient outcomes by site, based on prior literature. Complete details of our power analysis are described elsewhere.[10]

For the primary analysis, we used a linear mixed-effects model to examine the effects of each decision aid on post-visit patient knowledge. Race/ethnicity (non-Hispanic White; Other), age (in years), clinical stage (T1; T2 or T3), PSA ng/mL, and Gleason Grade Group (≤ 6; 7 (3+4), 7 (4+3), and 8–10), were included in the model. To control the Type 1 error rate at 5% across the two simultaneous comparisons for testing the study's primary hypotheses, statistical significance for each comparison (pre-visit vs no pre-visit decision aid and within-visit vs no within-visit decision aid) was assessed at the 2.5% significance level. We report the parameter estimates for each effect, including the respective standard error, two-sided 97.5% confidence interval, and nominal P value. Additionally, we report the estimated ICC. Although the study was not prospectively powered to detect an interaction effect, as a supportive analysis, we evaluated any potential for synergy between the interventions by estimating an interaction effect in the linear mixed-effects model. Further, we repeated the primary analysis within the racial/ethnic subgroup comprising any-race/ethnicity other than non-Hispanic White. P values are two-sided. Statistical analyses were conducted using SAS® version 9.4 by the Alliance SDMC.

RESULTS

Characteristics of Participating Sites & Patient-Participants

Among the initial 21 sites randomized, 7 sites did not enroll any patients, and 14 enrolled a total of 147 patients. A replacement site for a non-accruing site joined after study commencement and accrued an additional 11 patients. In total, 15 sites accrued 158 patients between November 2017 and June 2019, though their distribution was asymmetric (Figure 1). Three sites in the combined pre+within visit decision aid arm accrued 25 participants; 4 sites in the pre-visit only decision aid arm accrued 39 patients; 4 sites in the within-visit decision aid arm accrued 44 patients; and 4 sites in the usual care arm accrued 50 patients.

Patient demographic and clinical characteristics were clinically balanced across the arms (Table 1). Mean age (SD) was 63.5 (7.7) years. Eighty-five (53.8%) were Black or African American. The median consultation time was 39.5 minutes (range: 13.0, 250.0). Three (1.9%) did not complete the 12-item knowledge questionnaire, and 7 (4.5%) left partial answers; omitted items were assumed to be incorrect. The primary analysis was based on 155 patients in whom at least partial outcomes were collected. The same 155 patients also completed the DCS.

Primary Outcome - Knowledge

Descriptive results according to the 2×2 factorial design of our cluster randomized trial for our primary outcome knowledge are tabulated in Table 2; furthermore, the distribution of the knowledge scores are visually shown as box plots in Figure 2 for each of the four factorial cells of the trial. The mean proportion correct within the group of patients who received the pre-visit decision aid (N=62) was 0.67 (SD=0.164; median = 0.67), while within the group who did not receive the pre-visit decision aid (N=93) the mean % correct was 0.57 (SD = 0.204; median = 0.58). The mean proportion correct within the group of patients who received the within-visit decision aid (N=67) was 0.62 (SD=0.174; Median = 0.67), while within the group who did not receive the within-visit decision aid (N=88) the mean proportion correct was 0.60 (SD = 0.209; median = 0.67). Results from the primary analysis is shown in Table 3. Compared to each intervention's respective control, and after controlling for race/ethnicity, age, clinical stage, PSA, and Gleason Grade Group, as well as allowing for between-site variability, the mean difference in post-visit knowledge was 0.094 (97.5% CI: −0.055, 0.242) and 0.002 (97.5% CI: −0.147, 0.150) for the pre-visit decision aid and for the within-visit decision aid, respectively. Neither decision aid intervention effect achieved statistical significance at the pre-specified 2.5% level ($P = 0.132$ and 0.977, respectively). As a supportive analysis, we evaluated any potential for synergy between the interventions by estimating an interaction effect. The coefficient associated with the interaction term was close to zero (0.005; 95% CI: −0.265, 0.274) providing a lack of evidence of any potential interaction effect.

In the primary analysis, the estimated ICC was high (ICC=0.23). As a post hoc analysis, we investigated what was driving such a high ICC. Figure 3 shows a vertical bar graph of the average knowledge score within each site, grouped according to the factorial cells of the trial. The average knowledge score calculated for each site ranged from 0.31 to 0.76, which

was the range within the usual care arm and is consistent with the large SD observed within the usual care arm reported in Table 2. The primary analysis was repeated with site GA020 excluded from the analysis. The ICC was substantially reduced (ICC = 0.08) and consistent with the assumed ICC applied in the study design (ICC = 0.10); however, with site GA020 excluded the effect of the pre-visit decision aid became attenuated and the conclusions remained unchanged.

The primary analysis was repeated within the racial/ethnic subgroup comprising any race/ethnicity other than non-Hispanic White (N=104). The pre-visit and within-visit intervention effects were similar in magnitude to the overall results with neither intervention effect achieving statistical significance at any reasonable level (data not shown).

DISCUSSION

This study, the first NCI-sponsored cancer care delivery research (CCDR) trial, originating from the Alliance-NCORP research base, a cluster-randomized trial with a 2×2 factorial design conducted in urology practices in a community oncology research base, investigated the effects of decision aids on patient knowledge delivered at two different points in the care trajectory and successfully oversampled minority men. Neither decision aid delivered pre-visit nor within the visit significantly improved patient-reported knowledge, based on a post-visit, 12-item, disease-specific knowledge questionnaire, after adjusting for site and patient differences.

Despite its null results, this study advances the science and literature on shared decision-making for localized prostate cancer in several ways. First, this study helps in describing the effects of decision aids for minority men with localized prostate cancer. It also begins to address the optimal timing of decision aid delivery in the clinical setting. Regarding the former, our study shows it is feasible to enroll large proportions of minority patients in practice-based cancer care delivery trials. To date, this is one of the largest DA trials (>150 patients), and arguably the most diverse study of its kind, using a clustered randomized trial design, and enrolling a majority of Black or African American men (54%) with newly diagnosed with prostate cancer to date, though it still was somewhat under-accrued. Our design aimed at addressing implementation modes of delivery and comparing them, thereby at least nudging the field from efficacy toward pragmatic effectiveness and an implementation mindset. That neither the pre-visit nor the in-visit modes had a demonstrable effect on prostate cancer knowledge does not negate these other contributions.

In explaining the null effects, several explanations come to mind. It is at least plausible that the prostate cancer knowledge questionnaire lacked the sensitivity to detect a difference. Moreover, one could argue that knowledge as an outcome measure is flawed; in fact most randomized clinical trials in a recent meta-analyses show little or no increase in knowledge, and none included enough Black or African American men to surmise their effect in that population. At the time the study was planned, it was the best outcome available.

The optimal timing of decision aid delivery remains an important unanswered question. To date, the timing of decision aid delivery in the pre- or in-visit clinical for prostate

cancer treatment decisions has not been critically examined. To our knowledge, all published studies examined pre-visit decision aids. Our null and somewhat underpowered data do not settle that question -- one that deserves future investigation. And in this respect heterogeneity of use in decision aid implementation – a question beyond effectiveness related to implementation-- applies equally to both DA modes we tested.

Testing two decision aids delivered at different times relative to the clinical encounter and incorporating a large number of underrepresented Black or African American men -- who are at higher risk of worse oncologic and functional outcomes than other racial groups -- creates a valuable baseline for similar comparisons of decision aid modes for future studies. Decisions aids used in the pre-visit and within-visit setting did not demonstrate a difference across arms in patient knowledge as measured by a post-visit, disease specific, 12-item questionnaire. These findings should be viewed in light of the notable variation in the effect of decision aid usage and outcome measurement and the mixed effects they have on prostate cancer knowledge and other outcomes.[13–20] A recent systematic review and meta-analysis of decision aids for treatment decisions in localized prostate cancer found no changes in patient knowledge in prostate cancer along with high heterogeneity across sites.[21] Most of the data on the impact of decision aids on patient knowledge about prostate cancer treatments comes from only two trials—one small clinical trial showing a large effect (n=61),[13] and a larger clinical trial, reporting marginal gains in patient knowledge (n=182).[22] A similar systematic review and meta-analysis of decision aids for prostate cancer screening, which had a large number of trials included and less heterogeneity, recently found at best modest impacts on patient knowledge as well.[23] In both cases, decision aid trials assessing impact on knowledge in treatment decisions for prostate cancer reported limited participation by Black or African American men. In this respect, our findings showing no demonstrable improvement in knowledge, are not surprising, and also prompt whether future studies should be using this measure at all.

This study has important limitations. First, several sites did not accrue patients, while others accrued excess, leading to overall asymmetric accrual, and perhaps contributing to the higher-than-expected inter-site heterogeneity. The ICC gauged the site-to-site heterogeneity in patient knowledge scores and the high ICC led to less precise estimates of the intervention effects. Because the ICC in the completed trial data was considerably higher than the value allowed for at the design stage, the trial was likely underpowered to identify a clinically important effect for each decision aid intervention. This degree of variability is rare and may justify further investigation beyond the scope of this report. It is also possible that the highest accruing sites in the control arm were especially motivated and effective at patient education at baseline, creating a challenge in ascertaining differences in knowledge outcomes from the interventions. These, when added to the diminished sample size (usable data on 155 of 172 target patients), leaves plenty of room for null results. Moreover, because we did not gather fidelity-to-intervention data, we do not know if the interventions, particularly the within-visit intervention, were used as intended. Absent this data, our inferences about potential inefficacy of that decision aid mode are further hampered. In addition, how we measured the knowledge outcome, though deliberate, may have exposed us to site-to-site heterogeneity in baseline education efforts and other vigorous patient engagement strategies. Second, another limitation is that, had we chosen a “change

in knowledge" as our outcome (a so called "difference in differences" approach), we may, in hindsight, have been able to account for baseline differences across sites in our cluster-randomized design. Third, we acknowledge that the cluster-randomization study design resulted in some imbalances by race and clinical characteristics of prostate cancer for risk stratification (PSA, T stage, and Gleason score) across sites. It is plausible that these imbalances may have contributed to lack of differences in our primary outcome, though our measure assessed general prostate cancer treatment knowledge rather than knowledge specific to details about prostate cancer risk stratification. Fourth, it is likely that additional patient-level factors which were not collected, in particular health literacy, would have modified the knowledge outcome measure. Lastly, several other key outcome measures are often used in shared decision-making trials, such as decisional conflict, patient satisfaction with the decision, and patient utilities and concordance with values and treatment decisions. Due to the constraints of study sites and patient burden with data collection, we recognize that our findings may have been constrained in demonstrating effectiveness with these other outcome measures. While DCS represented an ancillary outcome measure in this study, we focused this study on the primary outcome of patient knowledge recognizing that there were no differences in DCS for each arm of the DAs across sites compared to controls.

These results, when considered along with recent systematic reviews, demonstrate the necessity of better measures for prostate cancer treatment decision support. It also raises broader questions of how best to support newly diagnosed prostate cancer patients. Particularly among the disproportionate number from minority Black or African American communities affected by prostate cancer, patients need sustainable system-level supports for their treatment decisions in the predicament this disease presents.

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Appendix

Appendix A.

12-item knowledge about prostate cancer treatments questionnaire.

Please check the TRUE or FALSE box for each statement based on your knowledge of prostate cancer treatme
are not completely sure, mark 'Unsure'.

	True	False
Most prostate cancer spreads quickly to other parts of the body	☐	☐
Other illnesses can make treating prostate cancer more difficult	☐	☐
Some treatments are better than others at stopping prostate cancer	☐	☐
Radiation therapy from a machine for prostate cancer requires weeks of daily treatments	☐	☐
Radiation seed therapy for prostate cancer requires weeks of daily treatments	☐	☐
Radiation for prostate cancer can cause rectal pain	☐	☐
Surgery for prostate cancer can cause urine leakage	☐	☐
For most men, radiation therapy for prostate cancer has no effect on urinary control	☐	☐
Both surgery and radiation can decrease sexual function	☐	☐
Low-risk prostate cancer can be safely monitored	☐	☐
After prostate cancer surgery, a man will go home with a catheter	☐	☐
Hot flashes is a side-effect of hormone treatment	☐	☐

Investigator developed.

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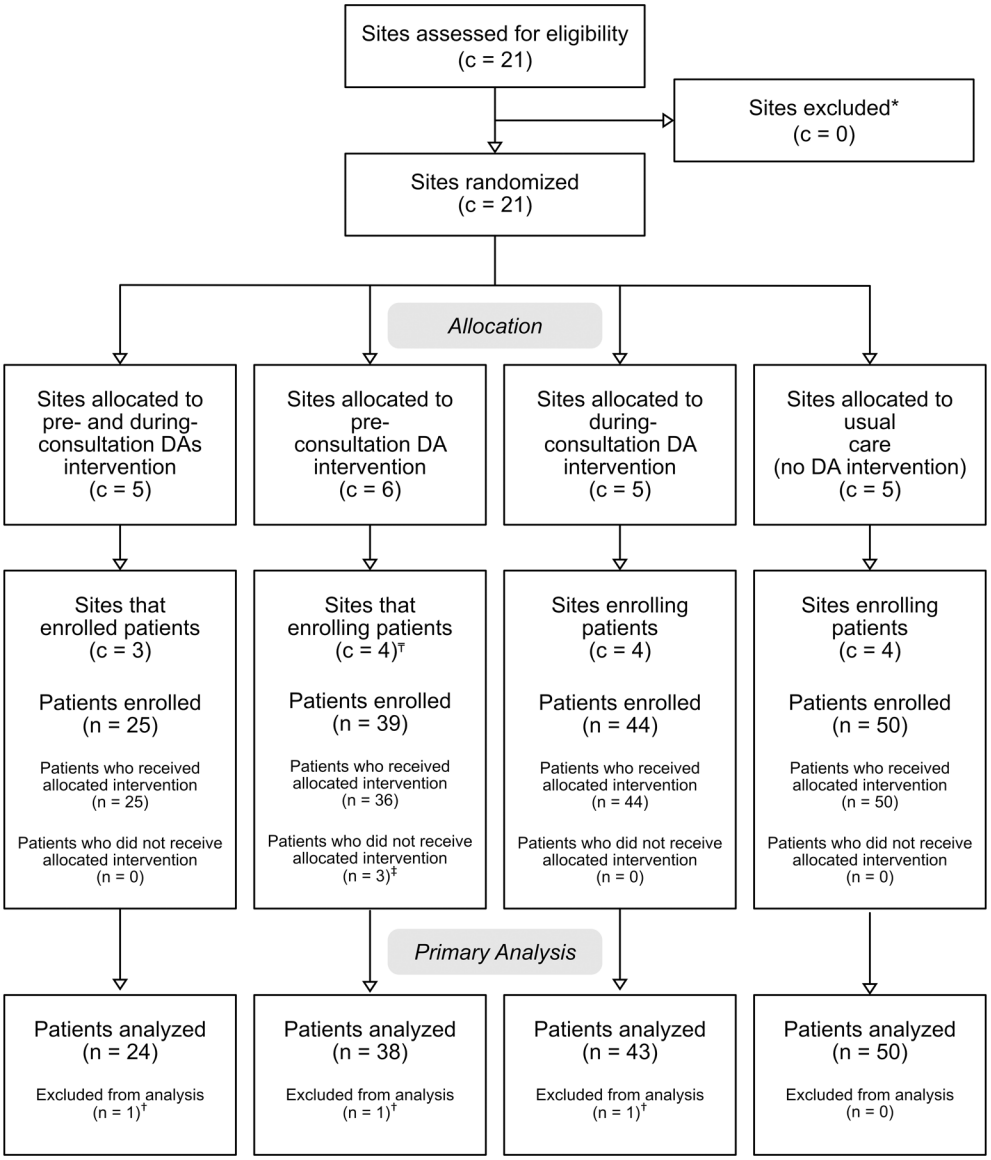

Figure 1.

Site- and Patient-level Recruitment, Randomization, and Flow for Cancer Care Delivery Research, 2×2 Factorial, Cluster-randomized Trial (Alliance A141902CD). c = Number of sites (clusters; n = Number of patients; DA = Decision AID

* Reasons for why a site did not meet the eligibility criteria were not captured as part of the protocol.

▫ A replacement site for a non-accruing site joined after study commencement.

‡ Three patientes received both pre- and during-consultation decision aids.

† Patient did not complete the 12-item knowledge about prostate cancer treatments questionnaire.

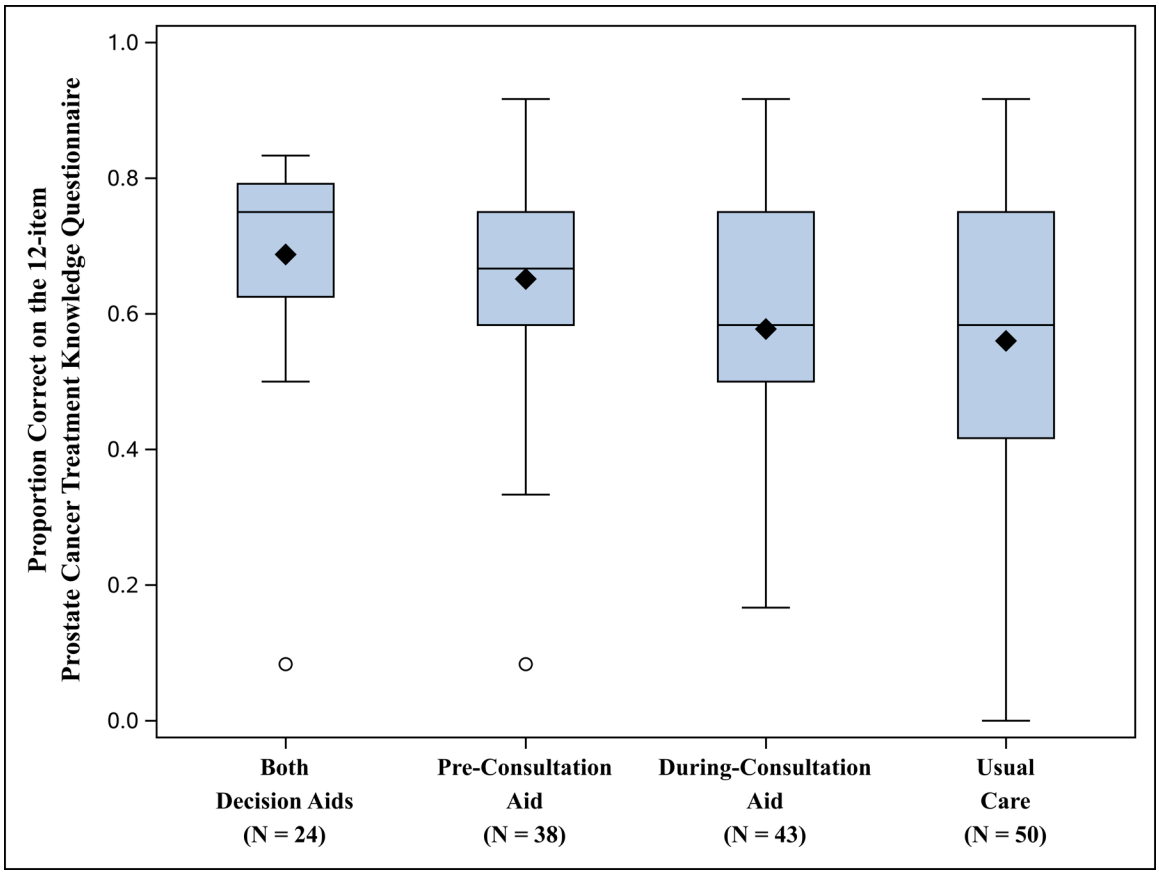

Figure 2.
Distribution of knowledge scores by study arm among 155 patient-participants at 15 sites who completed (or partially completed) the 12-item questionnaire.

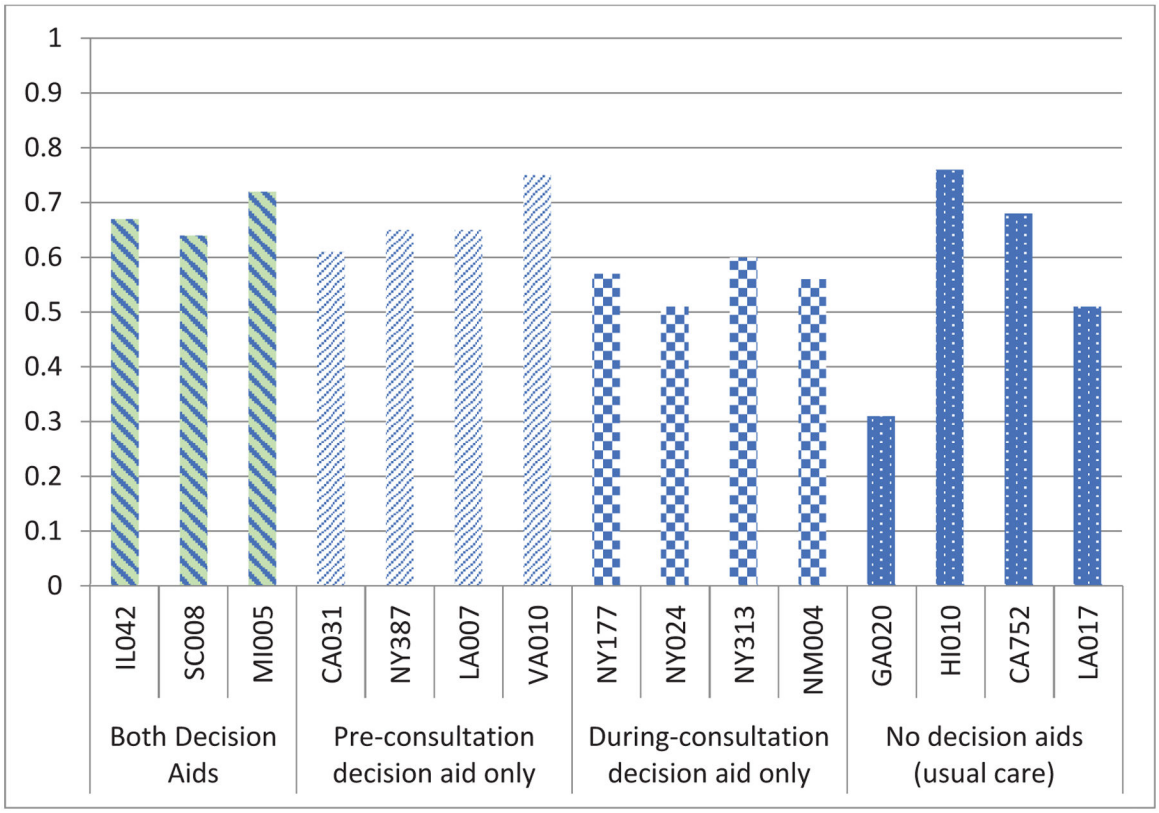

Figure 3.
Average knowledge scores (proportion correct) for each site and according to the factorial cells of the trial.

Table 1.

Baseline characteristics 158 Patients at 15 Participating Practices by Study Arm

	Both Decision Aids N=25 at 3 Centers	Pre-visit Decision Aid N=39 at 4 Centers	Within-visit Decision Aid N=44 at 4 Centers	Usual Care N=50 at 4 Centers	Total (N=158)
Age (years)					
N	25	39	44	50	158
Mean (SD)	62.5 (7.33)	63.1 (8.09)	64.6 (7.46)	63.4 (7.87)	63.5 (7.69)
Median	65.0	64.0	64.5	62.5	63.0
Range	41.0, 72.0	40.0, 83.0	50.0, 86.0	50.0, 88.0	40.0, 88.0
Race, n (%)					
White	13 (52.0)	16 (41.0)	10 (22.7)	20 (40.0)	59 (37.3)
Black or African American	12 (48.0)	19 (48.7)	28 (63.6)	26 (52.0)	85 (53.8)
Asian	0 (0.0)	1 (2.6)	1 (2.3)	3 (6.0)	5 (3.2)
American Indian/Alaska Native	0 (0.0)	0 (0.0)	1 (2.3)	0 (0.0)	1 (0.6)
Not reported or available	0 (0.0)	0 (0.0)	2 (4.5)	1 (2.0)	3 (1.9)
Unknown: Patient unsure	0 (0.0)	3 (7.7)	2 (4.5)	0 (0.0)	5 (3.2)
Ethnicity, n (%)					
Hispanic	0 (0.0)	1 (2.6)	2 (4.5)	0 (0.0)	3 (1.9)
Non-Hispanic	25 (100.0)	37 (94.9)	38 (86.4)	47 (94.0)	147 (93.0)
Not reported	0 (0.0)	0 (0.0)	2 (4.5)	2 (4.0)	4 (2.5)
Unknown	0 (0.0)	1 (2.6)	2 (4.5)	1 (2.0)	4 (2.5)
Race/Ethnicity, n (%)					
Non-Hispanic White	13 (52.0)	15 (38.5)	7 (15.9)	17 (34.0)	52 (32.9)
Other	12 (48.0)	24 (61.5)	37 (84.1)	33 (66.0)	106 (67.1)
Clinical T Stage, n (%)					
T1	15 (60.0)	31 (79.5)	36 (81.8)	34 (68.0)	116 (73.4)
T2	10 (40.0)	6 (15.4)	8 (18.2)	14 (28.0)	38 (24.1)
T3	0 (0.0)	2 (5.1)	0 (0.0)	2 (4.0)	4 (2.5)
Gleason Grade Group					
≤ 6	8 (32.0%)	19 (48.7%)	17 (38.6%)	17 (34.0%)	61 (38.6%)
7 (3+4)	9 (36.0%)	14 (35.9%)	13 (29.5%)	12 (24.0%)	48 (30.4%)
7 (4+3)	3 (12.0%)	3 (7.7%)	6 (13.6%)	9 (18.0%)	21 (13.3%)
8	2 (8.0%)	3 (7.7%)	4 (9.1%)	8 (16.0%)	17 (10.8%)
9–10	3 (12.0%)	0 (0.0%)	4 (9.1%)	4 (8.0%)	11 (7.0%)
PSA					
N	25	39	44	50	158
Mean (SD)	7.7 (6.17)	9.9 (6.18)	10.8 (8.43)	12.2 (10.41)	10.5 (8.40)
Median	5.0	8.0	7.5	8.0	7.0
Range	3.0, 34.0	4.0, 33.0	1.0, 44.0	1.0, 47.0	1.0, 47.0

	Both Decision Aids N=25 at 3 Centers	Pre-visit Decision Aid N=39 at 4 Centers	Within-visit Decision Aid N=44 at 4 Centers	Usual Care N=50 at 4 Centers	Total (N=158)
Consultation Time (minutes)					
N	25	39	32	50	146
Mean (SD)	29.2 (9.23)	43.2 (29.42)	56.7 (20.23)	59.0 (54.37)	49.1 (38.10)
Median	27.0	38.0	52.5	39.0	39.5
Range	17.0, 48.0	13.0, 150.0	20.0, 116.0	13.0, 250.0	13.0, 250.0

SD = standard deviation; PSA = prostate specific antigen.

Table 2.

Descriptive Results for the primary outcome knowledge within each factorial cell of the 2 × 2 factorial trial and according to receipt of the pre-visit and within-visit decision aids among the 155 patient-participants at 15 sites.

			Within-visit Decision Aid		
			Yes	**No**	**TOTAL**
Pre-visit Decision Aid	**Yes**	N	24	38	62
		Mean (SD)	0.69 (0.165)	0.65 (0.164)	0.67 (0.164)
		Median	0.75	0.67	0.67
		Range	0.08, 0.83	0.08, 0.92	0.08, 0.92
	No	N	43	50	93
		Mean (SD)	0.58 (0.167)	0.56 (0.232)	0.57 (0.204)
		Median	0.58	0.58	0.58
		Range	0.17, 0.92	0.00, 0.92	0.00, 0.92
	TOTAL	N	67	88	
		Mean (SD)	0.62 (0.174)	0.60 (0.209)	
		Median	0.67	0.67	
		Range	0.08, 0.92	0.00, 0.92	

SD = standard deviation. Based on the 155 participants who completed (or partially completed) the 12-item questionnaire for the primary outcome knowledge.

Table 3.

Differences in knowledge scores between each intervention and its respective control.

	Pre-visit Decision Aid N = 62	No pre-visit Decision Aid N = 93	Within-visit Decision Aid N = 67	No Within-visit Decision Aid N = 88
Knowledge of prostate cancer treatment:				
Adjusted mean	0.684	0.590	0.638	0.636
(SE)	(0.045)	(0.039)	(0.045)	(0.039)
Adjusted difference	0.094		0.002	
[97.5% CI]	[−0.055, 0.242]		[−0.147, 0.150]	
p-value	0.132		0.977	

Note: Results were obtained from a mixed effects regression model, which contained a fixed intercept, a fixed effect for having received the pre-consultation decision aid (main effect), a fixed effect for having received during-consultation decision aid (main effect), and a random, site-specific intercept to allow patients within the same site to be correlated as well as the following explanatory variables: race/ethnicity (non-Hispanic White; Other), age (in years) at baseline, baseline clinical stage (T1; T2 or T3), baseline PSA ng/mL, and baseline Gleason (≤ 6 [reference]; 7 (3+4), 7 (4+3), and 8–10). Both comparisons are for the intervention compared with its respective control. Positive differences represent a favorable outcome (increase knowledge) for the relevant intervention. To control the Type 1 error rate at 0.05 across the two simultaneous comparisons for testing the study's primary hypotheses, the confidence coefficient applied to each of the two-sided confidence intervals was (1 – [0.05 / 2]) × 100%. However, we report the actual (unadjusted) *P* value; the threshold for determining statistical significance would be 0.05 / 2 = 0.025 (a Bonferroni correction). The estimated intra-cluster correlation was 0.23. The interaction between the interventions was investigated as a supportive analysis and was found not to be significant at any reasonable level of significance (interaction coefficient = 0.005; [95% CI: −0.265, 0.274]; *P* value = 0.971).

Table 4.

Descriptive Results for the secondary outcome decisional conflict total score within each factorial cell of the 2 × 2 factorial trial and according to receipt of the pre-visit and within-visit decision aids among the 155 patient-participants at 15 sites.

			Within-visit Decision Aid		
			Yes	**No**	**TOTAL**
Pre-visit Decision Aid	**Yes**	N	24	38	62
		Mean (SD)	12.29 (21.263)	14.34 (18.533)	13.55 (19.489)
		Median	0.00	10.00	7.50
		Range	0.00, 85.00	0.00, 80.00	0.00, 85.00
	No	N	43	50	93
		Mean (SD)	11.16 (19.452)	13.00 (23.474)	12.15 (21.612)
		Median	0.00	0.00	0.00
		Range	0.00, 70.00	0.00, 90.00	0.00, 90.00
	TOTAL	N	67	88	
		Mean (SD)	11.57 (19.966)	13.58 (21.374)	
		Median	0.00	0.00	
		Range	0.00, 85.00	0.00, 90.00	

SD = standard deviation. Based on the 155 participants who completed the Decisional Conflict Scale (DCS) for the secondary outcome DCS total score.