



Alliance A191402CD: Testing Decision Aids to Improve Prostate Cancer Decisions for Minority Men (A Limited Access Study)

Jon C. Tilburt, MD

Mayo Clinic

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Rationale

Rationale

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Follow Up

Decision aids can improve patient knowledge and patient-provider communication by presenting risk information and helping elicit patient preferences. They improve knowledge and reduce treatment regret in prostate cancer treatment.[1-4] Decision aids can mitigate low literacy effects in disparities by decreasing the demands required for patients to make an informed treatment decision. They better align the task of decision making with the skills and abilities of patients.[5,6] In other clinical conditions, decision aids have been successfully used to reduce disparities in self-reported symptoms and patient knowledge.[7] Recent educational interventions seem to have greater effect in men with less than a college education, thereby neutralizing disparities associated with education and literacy.[8] Thus, decision aids are a plausible health system intervention that could be delivered in the specialty care context to reduce disparities in knowledge and functional outcomes potentially mediated by poor communication, that will work even in patients with low health literacy.

References: 1. Fagerlin A, Rovner D, Stableford S, Jentoft C, Wei JT, Holmes-Rovner M. Patient education materials about the treatment of early-stage prostate cancer: a critical review. Ann Intern Med. May 4 2004;140(9):721-728. 2. Lin GA, Aaronson DS, Knight SJ, Carroll PR, Dudley RA. Patient decision aids for prostate cancer treatment: a systematic review of the literature. CA Cancer J Clin. Nov-Dec 2009;59(6):379-390. 3. O'Brien MA, Whelan TJ, Villasis-Keever M, et al. Are cancer-related decision aids effective? A systematic review and meta-analysis. J Clin Oncol. Feb 20 2009;27(6):974-985. 4. Wei JT, Uzzo RG. Shared decision-making strategies for early prostate cancer. Semin Urol Oncol. Feb 2002;20(1):74-78. 5. Paasche-Orlow MK, Wolf MS. Promoting health literacy research to reduce health disparities. J Health Commun. 2010;15 Suppl 2:34-41. 6. Ratzan SC, Parker RM. Health literacy - identification and response. J Health Commun. Dec 2006;11(8):713-715. 7. Weng HH, Kaplan RM, Boscardin WJ, et al. Development of a decision aid to address racial disparities in utilization of knee replacement surgery. Arthritis Rheum. May 15 2007;57(4):568-575. 8. Lepore SJ, Helgeson VS, Eton DT, Schulz R. Improving quality of life in men with prostate cancer: a randomized controlled trial of group education interventions. Health Psychol. Sep 2003;22(5):443-452.

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Primary

- To test the comparative effectiveness of decision aids (DA's) on patient knowledge.

Secondary

- To test the impact of in-visit DA's alone compared to usual care on quality of life outcomes and treatment utilization.
- To test the impact of out-of-visit DA's alone compared to usual care on quality of life outcomes and treatment utilization.
- To test the impact of combined in-visit and out-of-visit DA's compared to both usual care and individual DAs on quality of life outcomes and treatment utilization.
- To test the comparative effectiveness of DA's on minority men's knowledge.
- To compare clinic time required to administer the DA's across arms

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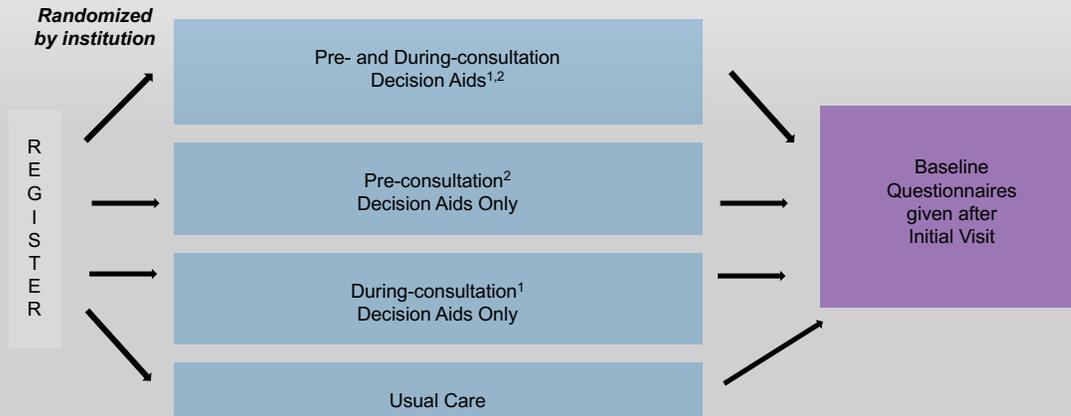
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Study Schema



- 1. "Prostate Choice" Decision Aid
- 2. "Knowing Your Options" Decision Aid

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Site personnel will be trained on the delivery of the intervention prior to the enrollment of any patients. This will consist of either video training and telephone conferencing or on-site training.



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Intervention To Be Tested and Randomization

In-Visit Tool

Prostate Choice, is a decision aid for PCa treatment that incorporates the best available evidence in a literacy-sensitive, easy to use format for patients and providers delivered on a tablet device. Prostate Choice has a modular format that covers the key components critical to a high quality treatment decision for localized PCa. It is a touch-based interactive user experience that focuses on categories "Your Diagnosis," "Your Situation," "Your Priorities," "Your Treatments," and culminates in a summary combining all the categories. Each of the elements of Prostate Choice can be selected by patient or clinician.

Pre-visit Tool

Knowing Your Options: A Decision Aid for Clinically Localized Prostate Cancer is designed to lay out the basic facts of treatment choices for patients prior to their appointment with their doctor with more extensive written explanation. In this trial, the Knowing Your Options tool will be administered prior to initial consultations with urologists when eligible patients are presenting to discuss treatment options in the days leading up to/on the day of that consultation. Similar to Prostate Choice, Knowing Your Options also allows for personalization for PCa severity in risk of cancer-specific mortality.

Randomization

To facilitate decision aid administration, enhance patient compliance, and avoid treatment arm contamination; a cluster randomized four-arm clinical trial will be performed. Researchers intend to test both during-consultation, pre-consultation and the combination of both during-consultation and pre-consultation evidence-based decision aids using a novel 2x2 factorial design in two key populations. A 2x2 factorial design breaks the combinations of during-consultation and pre-consultation decision aids into four treatment arms (cells): A) Prostate Choice in-visit combined with Knowing Your Options pre-consultation decision aid; B) Usual during-consultation care and Knowing Your Options decision aid prior to the consultation; C) Prostate Choice within specialty consultations and usual pre-consultation care; and D) Usual during-consultation care and Usual pre-consultation care. This approach allows inferences about effects with less concern about baseline imbalances between groups, confounding, or chance.



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Eligibility Criteria

- Patients must have prostate biopsy within 4 months prior to registration showing newly diagnosed prostate cancer, stage T1- 3N0M0. Patients must have: Gleason score 6-10
- PSA < 50 ng/mL
- Patients who have had a history of non-cutaneous malignancy in the previous 5 years are not eligible.
- Scheduled prostate cancer consultation to be the first consultation after diagnosis
- Patients may not be concurrently enrolled to another clinical trial for the treatment of cancer.
- Patients with impaired decision-making capacity (such as with a diagnosis of dementia or memory loss) are not eligible for this study.
- Patients must be able to read and comprehend English. *Non-English-speaking patients may participate so long as an interpreter (e.g., family member, clinic staff, etc.) is present for consent, for the Decision Aid administration, and gathering of baseline and follow-up measures.*
- Age \geq 18 years

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