

A191402CD

Testing Decision Aids to Improve Prostate Cancer Decisions for Minority Men

ClinicalTrials.gov Identifier: NCT03103321

Study Background

Trial Description

This randomized phase III trial studies how well decision aids work in improving knowledge in patients with newly diagnosed prostate cancer. Decision aids may improve patients' knowledge of their condition and options for treatment, and may also help when talking with their doctor.

Arms:

Arm A ("Knowing your Options", "Prostate Choice"): (Experimental): Patients receive decision aids "Knowing your Options" before and "Prostate Choice" during their consultation visit.

Arm B ("Knowing your Options"): (Experimental): Patients receive "Knowing your Options" decision aid before their consultation visit.

Arm C ("Prostate Choice"): (Experimental): Patients receive "Prostate Choice" decision aid during their consultation visit.

Arm D (usual care): (Active Comparator): Patients undergo usual care.

Objectives:

- PRIMARY OBJECTIVES:
 - I. To test the comparative effectiveness of decision aids (DA's) on patient knowledge.
- SECONDARY OBJECTIVES:
 - I. To test the impact of in-visit DA's alone compared to usual care on quality of life outcomes and treatment utilization.
 - II. To test the impact of out-of-visit DA's alone compared to usual care on quality of life outcomes and treatment utilization.
 - III. 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.
 - IV. To test the comparative effectiveness of DA's on minority men's knowledge.
 - V. To compare clinic time required to administer the DA's across arms.
- OUTLINE: Patients are randomized into 1 of 4 arms.

ARM A: Patients receive decision aids “Knowing your Options” before and “Prostate Choice” during their consultation visit.

ARM B: Patients receive “Knowing your Options” decision aid before their consultation visit.

ARM C: Patients receive “Prostate Choice” decision aid during their consultation visit.

ARM D: Patients undergo usual care. After completion of study, patients are followed up at 12 months.

Study Milestones:

Start date: July 14, 2017

Primary Completion Date: December 5, 2019

Publication Information:

Analysis Type: Primary

PubMed ID: 34890060

Citation: Cancer. 2022 Mar 15;128(6):1242-1251. doi: 10.1002/cncr.34062. Epub 2021 Dec 10.

Associated Datasets: NCT03103321-D1-Dataset.csv (manu_data)

Dataset Information:

Dataset Name: NCT03103321-D1-Dataset.csv (manu_data)

Description: Dataset NCT03103321-D1-Dataset.csv (manu_data) is one of 1 datasets associated with PubMed ID 34890060. This dataset contains data presented in the baseline characteristics table and primary analysis.

Data can be used to approximate published study findings, but exact reproduction of previous manuscripts may not be possible in some cases (e.g., when data must be modified for de-identification purposes or have undergone further data cleaning).

Blank values indicate data not applicable or missing, except where otherwise noted.

In order to protect the confidentiality of patients enrolled onto A191402CD, information regarding enrolling sites has been removed from the dataset.

NCT03103321-D1-Dataset.csv (manu_data) Data Dictionary:

LABEL	NAME	ELEMENTS	COMMENTS
Patient ID	PAT_ID		
Age (years)	AGE		
Arm	ARM	Both Decision Aids, During Consultation Aid, Pre-Consultation Aid, Usual Care	
Ethnicity	ETHNCTY1	Hispanic, Non-Hispanic, Not reported, Unknown	
Race	RACE1	American Indian or Alaska Native, Asian, Black or African American, Not reported: patient refused or not available, Unknown: Patient unsure, White	
Gender	SEX	Male	
Gleason Score	GLEASONC	6, 7, 8, 9	
PSA	psaon		
Clinical T Stage	TSTAGE	T1, T2, T3	
Gleason Risk	risk	Gleason <= 6, Gleason 7 (3+4), Gleason 7 (4+3), Gleason 8-10	
Start time of consultation	start_test		
Stop time of consultation	stop_test		
Question 1: Most prostate cancer spreads quickly to other parts of the body.	PCTQ1	False, True, Unsure	

LABEL	NAME	ELEMENTS	COMMENTS
Question 2: Other illnesses can make treating prostate cancer more difficult.	PCTQ2	False, True, Unsure	
Question 3: Some treatments are better than others at stopping cancer.	PCTQ3	False, True, Unsure	
Question 4: Radiation therapy from a machine for prostate cancer requires weeks of daily treatments.	PCTQ4	False, True, Unsure	
Question 5: Radiation seed therapy for prostate cancer requires weeks of daily treatments.	PCTQ5	False, True, Unsure	
Question 6: Radiation for prostate cancer can cause rectal pain.	PCTQ6	False, True, Unsure	
Question 7: Surgery for prostate cancer can cause urine leakage.	PCTQ7	False, True, Unsure	
Question 8: For most men, radiation therapy for prostate cancer has no affect on urinary control.	PCTQ8	False, True, Unsure	
Question 9: Both surgery and radiation can decrease sexual function.	PCTQ9	False, True, Unsure	
Question 10: Low-risk prostate cancer can be safely monitored.	PCTQ10	False, True, Unsure	
Question 11: After prostate cancer surgery, a man will go home with a catheter.	PCTQ11	False, True, Unsure	
Question 12: Hot flashes is a side-effect of hormone treatment.	PCTQ12	False, True, Unsure	
Proportion correct on the 12-item Prostate Cancer Treatment Questionnaire	pctq_percent	0, 0.5, 0.25, 0.75, 0.08333, 0.16667, 0.33333, 0.41667, 0.58333, 0.66667, 0.83333, 0.91667	
Total consultation time. (minutes)	totaltime		
Decision aid pre-consultation (planned)	pre	No, Yes	

LABEL	NAME	ELEMENTS	COMMENTS
Decision aid during-consultation (planned)	during	No, Yes	
Race/Ethnicity Subgroup	raceth	Non-Hispanic White, Other Race and Ethnicity	
Patient received the wrong treatment intervention	wrongtx	1 = Yes Blank (" ") = No	
T-stage	tstag	T1, T2 & T3	