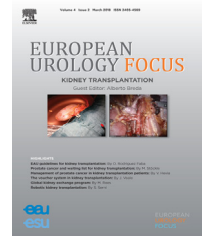


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## Clinical Studies Update

# Clinical Trial Protocol for a Randomized Trial of Community Health Worker-led Decision Coaching to Promote Shared Decision-making on Prostate Cancer Screening Among Black Male Patients and Their Providers

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## 1. Introduction

Prostate cancer is the second leading cause of cancer death among men in the USA and affects Black men disproportionately [1,2]. The US Preventive Services Task Force encourages prostate-specific antigen (PSA) testing decisions based on shared decision-making (SDM), in which patients are supported to make the best clinical decisions given their personal preferences [3]. However, studies suggest that SDM is rarely achieved in clinical practice, particularly during PSA screening consultations, owing to a lack of

balanced discussion of the pros and cons of screening and a lack of clarification of patient preference [4–7].

Decision coaching is the process by which a non-healthcare professional coach “provides a patient with individualized, nondirective guidance to meet decision making needs in preparation for consultation” with a healthcare provider [8]. Prior research has shown that community health worker (CHW)-led interventions can improve awareness, knowledge, support, and efficacy in reducing the impact of chronic disease and cancer in underserved populations [9–13]. We propose a randomized controlled trial to evaluate the effectiveness of a CHW-led decision-coaching program to facilitate SDM for prostate cancer screening decisions by Black men at a primary care federally qualified health center (FQHC).

## 2. Study details

We aim to recruit 143 Black male patients and all providers (up to 15) who care for them. Black men aged 40–69 yr attending an FQHC for a routine primary care appointment will be eligible to participate. All providers at the FQHC

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caring for men who fit the inclusion criteria will be eligible (Table 1).

Participants will be randomized to receive either (1) a decision aid along with decision coaching on PSA screening from a CHW or (2) a decision aid along with CHW-led interaction on dietary and lifestyle modifications to serve as an attention control (Fig. 1). The intervention arm will include review of the prostate cancer screening decision aid with the CHW and a structured decision counseling session for the patient to clarify preferences, consisting of (1) an organized interview to understand their prostate cancer risk, screening options, and goals and values related to their decision making, (2) role-playing exercises to improve SDM, and (3) attendance of the coach at the patient's appointment.

### 2.1. Key assessments

Quantitative data are collected from patients via surveys at four different time points: (1) clinic enrollment before the coaching session; (2) immediately after the coaching session but before encounter with the provider; (3) after the clinical appointment; and (4) at 3–6 mo after the clinic visit. Providers complete surveys at study initiation, after every study patient encounter, and at study completion or the time of their separation from the clinic.

Qualitative data are collected from all providers and a subset of patients, using in-depth, semi-structured interviews to identify and describe attitudes and perceptions of Black men and their providers in relation to PSA testing, the CHW-led decision coaching intervention, and SDM.

### 2.2. Primary outcomes

The primary outcomes are decision quality, patient knowledge, and PSA screening rates measured after administration of a CHW-led decision coaching intervention. Decision quality is objectively measured using two domains: (1) being informed (eg, accurate understanding of screening and its risks and benefits) and (2) making preference-concordant decisions (ie, treatment consistent with patient preferences as determined by responses to survey questions) [14–16]. Patient knowledge of prostate cancer and PSA screening is assessed using a survey we developed and piloted among Black men recruited from churches in Harlem, New York [17]. PSA screening data are collected 6 mo after the intervention using patient self-reports and electronic health record data.

### 2.3. Secondary and exploratory outcomes

Secondary outcomes include perception of the quality of care and experience with the decision coaching program assessed using domains that include communication, decisional self-efficacy, self-efficacy in communicating with the provider, satisfaction, and decisional conflict [18–26].

Exploratory outcomes include the net cost of the CHW-led decision coaching program for PSA screening, behaviors

**Table 1 – Inclusion and exclusion criteria for study participation**

#### Inclusion criteria

##### Patients:

- Age 40–69 yr
- Black
- Male
- Attending FQHC for routine primary care appointment

##### Providers:

- Provider at FQHC
- Caring for patients who fit the inclusion criteria

#### Exclusion criteria

##### Patients:

- Patients seen within 9 mo of other PSA test
- Patients seen within 180 d after primary diagnosis of urinary obstruction, prostatitis, hematuria, other disorders of the prostate, unexplained weight loss, or lumbar back pain
- Patients with a prior diagnosis of prostate cancer (ICD-10-CM C61)
- Patients visiting their provider for any indication other than a well-visit appointment

##### Providers:

- Providers who do not treat adult male patients (eg, obstetrics/gynecology, pediatrics)

FQHC = federally qualified health center; ICD-10-CM = International Classification of Diseases, 10th Revision, Clinical Modification.

and norms around PSA screening, and perceptions of the feasibility and acceptability of CHW-led decision coaching.

### 2.4. Statistical considerations

We use linear mixed models for continuous outcomes, logistic generalized linear mixed models for binary outcomes, and random-effects multinomial models for outcomes with more than two levels, such as adherence.

## 3. Results and discussion

The first patient was recruited on October 15, 2019. Recruitment was temporarily suspended because of the COVID-19 pandemic from March 2020 to July 2020. The expected recruitment period is 3 yr.

PSA screening decisions should be based on SDM, clinician professional judgment, and patient preferences, but the process is rarely accomplished in current clinical practice. Decision coaching is an evidence-based approach providing individualized, nondirective guidance in preparing patients for SDM [8]. Our trial will evaluate the efficacy, cost-effectiveness, and sustainability of a CHW-led decision coaching program to facilitate SDM for prostate cancer screening by Black men and their providers at a primary care FQHC.

The CHW model provides culturally sensitive health promotion to diverse patient populations [27,28]. CHWs can effectively support cancer decisions in the Black community [29,30]. CHW interventions are viewed as a cost-effective approach to bridge cultural and social barriers between health care systems and underserved communities to improve overall community health and wellbeing [28,31–33]. A CHW-led decision-coaching program has high

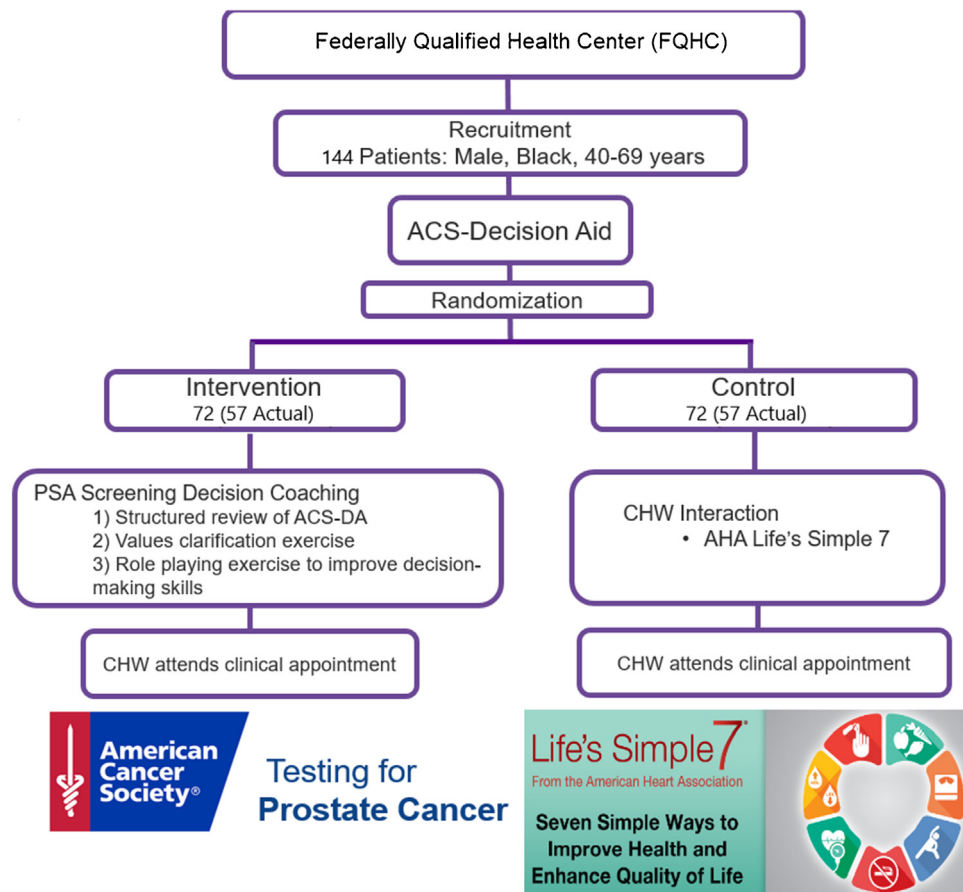


Fig. 1 – Schema of the study methods. CHW = community health worker; ACS = American Cancer Society; PSA = prostate-specific antigen; DA = decision aid; AHA = American Heart Association.

potential for generalizability and public health impact for PSA screening and chronic conditions in diverse populations.

**Conflicts of interest:** The authors have nothing to disclose.

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