

# CALGB-70807

## The Men's Eating and Living (MEAL) Study: A Randomized Trial of Diet to Alter Disease Progression in Prostate Cancer Patients on Active Surveillance

ClinicalTrial.gov Identifier: NCT01238172

### Study Background

#### Trial Description

**RATIONALE:** Eating a diet high in vegetables may slow down disease progression in patients with prostate cancer.

**PURPOSE:** This randomized clinical trial is studying how well diet works in altering disease progression in patients with prostate cancer on active surveillance.

#### Arms:

Arm A - MEAL Program Intervention: (Experimental): Patients will receive dietary education and telephone counseling sessions over 24 months.

Arm B - Prostate Cancer Foundation Booklet: (Control): Patients receive information about diet, nutrition, exercise and cancer. Patients also receive regularly scheduled newsletters.

#### Objectives:

##### Primary

- To determine if a telephone-based dietary intervention compared to no intervention will decrease clinical progression in AS patients.

##### Secondary

- To compare the incidence of active treatment (surgery, irradiation, local ablation, or androgen deprivation) in AS patients receiving dietary intervention compared to no intervention.
- To compare prostate cancer-related anxiety in AS patients receiving dietary intervention compared to no intervention.
- To compare health-related quality of life in AS patients receiving dietary intervention compared to no intervention.

**OUTLINE:** This is a multicenter study. Patients are stratified according to age ( $\leq 70$  years vs  $> 70$  years), race (black or African American vs other), and baseline prostate

biopsy (0-12 months before registration vs > 12-24 months before registration).  
Patients are randomized to 1 of 2 treatment arms.

**Study Milestones:**

Primary Completion Date: November 18, 2017

## **Publication Information:**

Analysis Type: Primary

PubMed ID: 31935026

Citation: JK. Parsons. Effect of a Behavioral Intervention to Increase Vegetable Consumption on Cancer Progression Among Men With Early-Stage Prostate Cancer: The MEAL Randomized Clinical Trial. JAMA 2020. 140-148

Associated Datasets:

NCT01238172-D1-Dataset.csv (baseline),

NCT01238172-D2-Dataset.csv (consort\_out),

NCT01238172-D3-Dataset.csv (figout),

NCT01238172-D4-Dataset.csv (offtreat)

NCT01238172-D5-Dataset.csv (dietcomposition)

## **Dataset Information:**

Dataset Name: NCT01238172-D3-Dataset.csv (figout)

Description: Dataset NCT01238172-D3-Dataset.csv (figout) is one of 5 datasets associated with PubMed ID 31935026. This dataset contains information for the 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.

## **NCT01238172-D3-Dataset.csv (figout) Data Dictionary:**

LABEL	NAME	ELEMENTS	COMMENTS
De-identified patient ID	patid		
Patient's vital status	VITSTAT	Alive, Dead	
Arm	TREAT_ASSIGNED	PCF Book, MEAL	
Time to Progression (days)	progtime		
Progression Censor	censor	0=Censor, 1=Event	
Time to Gleason Only Progression (days)	gprogtime		
Gleason Only Progression Censor	gcensor	0=Censor, 1=Event	
Alternative Treatment Censor	txcensor	0=Censor, 1=Event	
Time to Alternative Treatment (days)	time2tx		
24-Month Follow-up Biopsy	biop24	0=No, 1=Yes	