



The Role of Androgen Deprivation Therapy in Cardiovascular Disease – A Longitudinal Prostate Cancer Study (RADICAL PC1)

A Randomized Intervention for Cardiovascular And Lifestyle Risk Factors in Prostate Cancer Patients (RADICAL PC2)

RADICAL PC
New prostate cancer (diagnosed within 1 year) or commencing ADT for the 1st time
N=4400

RADICAL PC1
Observational registry
N=1800

RADICAL PC2
Randomized, controlled trial
N=2600

Intervention:
Systematic CV risk factor
management
N=1300

Control:
Usual care
N= 1300

Clinical outcomes

RADICAL PC1 - Objectives

- To determine:
 - a) the prevalence of CVD risk factors and disease, and
 - b) the incidence of adverse CVD events
- To evaluate the relationship of ADT with adverse CVD events
- To identify factors (clinical factors and PC treatments) that are independently associated with the development of CVD in men with PC

RADICAL PC2 - Objectives

Primary

To determine whether a systematic CV and lifestyle risk factor modification strategy reduces the risk of CVD in men with a new diagnosis of PC

Secondary

To determine whether a systematic CV and lifestyle risk factor modification strategy improves the CV risk profile.

To estimate the incremental cost-effectiveness ratio of a systematic CV and lifestyle risk factor modification strategy

Inclusion Criteria

PC that is either:

- New (i.e. the diagnosis was made within 1 year), or
- Treated with ADT for the first time within 6 months prior to the baseline visit, or
- To be treated with ADT for the first time within 1 month after the baseline visit

Exclusion Criteria

- Unwilling to provide consent, or
- <45 years of age

Patients will be eligible for RADICAL PC1, but will not be eligible for RADICAL PC2 if:

- 1) they see a cardiologist every year;
or
- 2) both:
 - statin use and
 - systolic BP \leq 130mmHg

Intervention in RADICAL PC2

- Randomized in an open manner to usual care or
- Systematic risk factor management
 - Statin
 - Systolic BP ≤ 130 mmHg
 - Dietary counseling
 - Exercise advice
 - Support to quit smoking

Baseline Data Collected

- Demographics, SES, race
- Co-morbidities
- BP, anthropometrics, muscle strength, gait speed, 6-MWD
- Depression
- Cognitive function
- Activities of daily living
- Erectile function
- Routine lab tests

Follow-up

- Annually
- Baseline questionnaires and physical measures repeated every 2 years until close-out

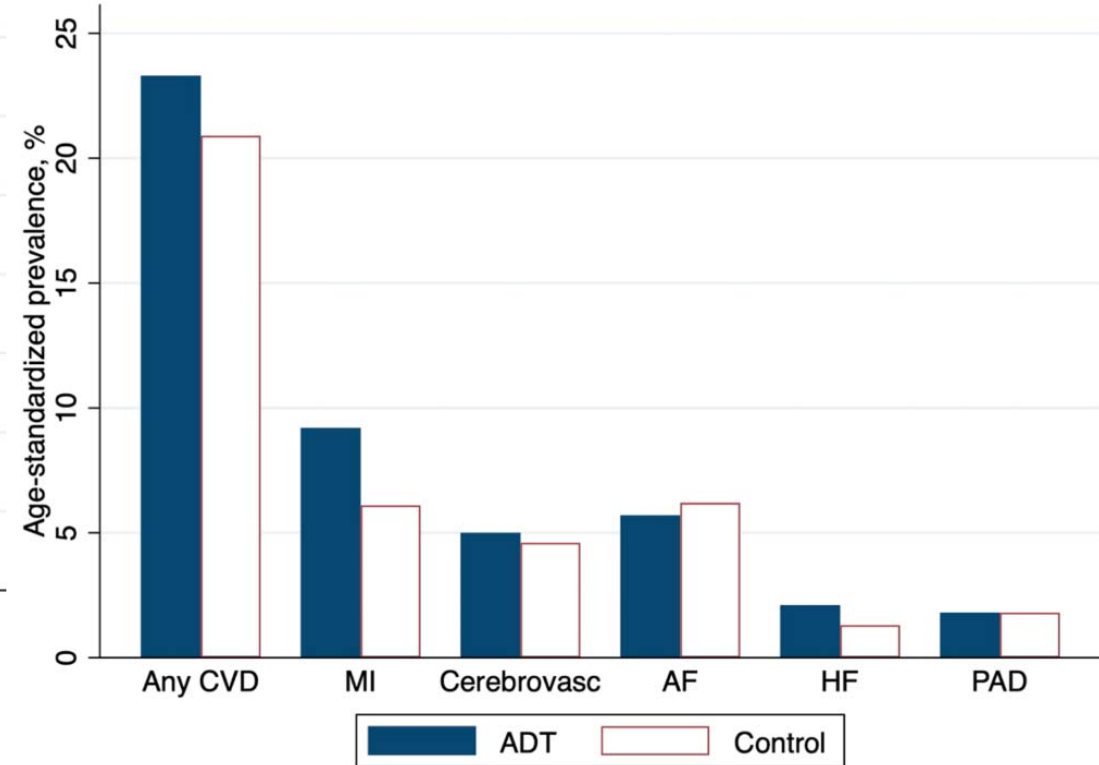
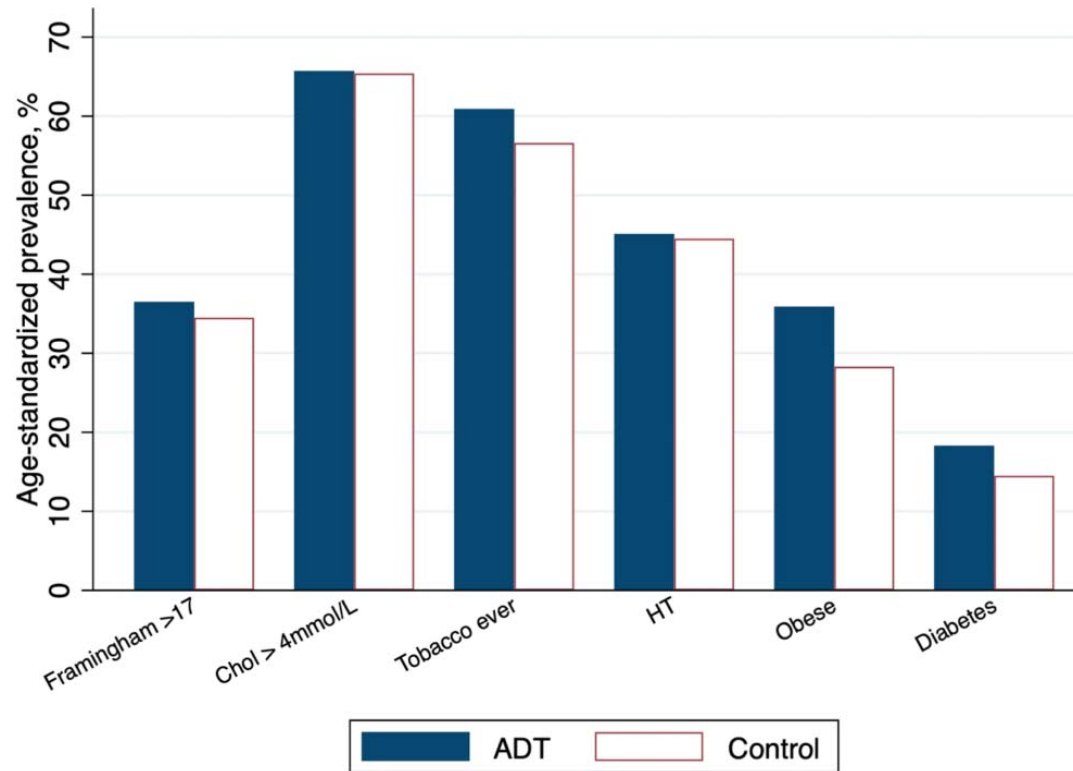
Progress – Feb 9, 2023

- 3249 participants
 - 1873 randomized in PC2
- 48 sites
- 6 countries (Canada, USA, Brazil, Australia, Israel, Türkiye)

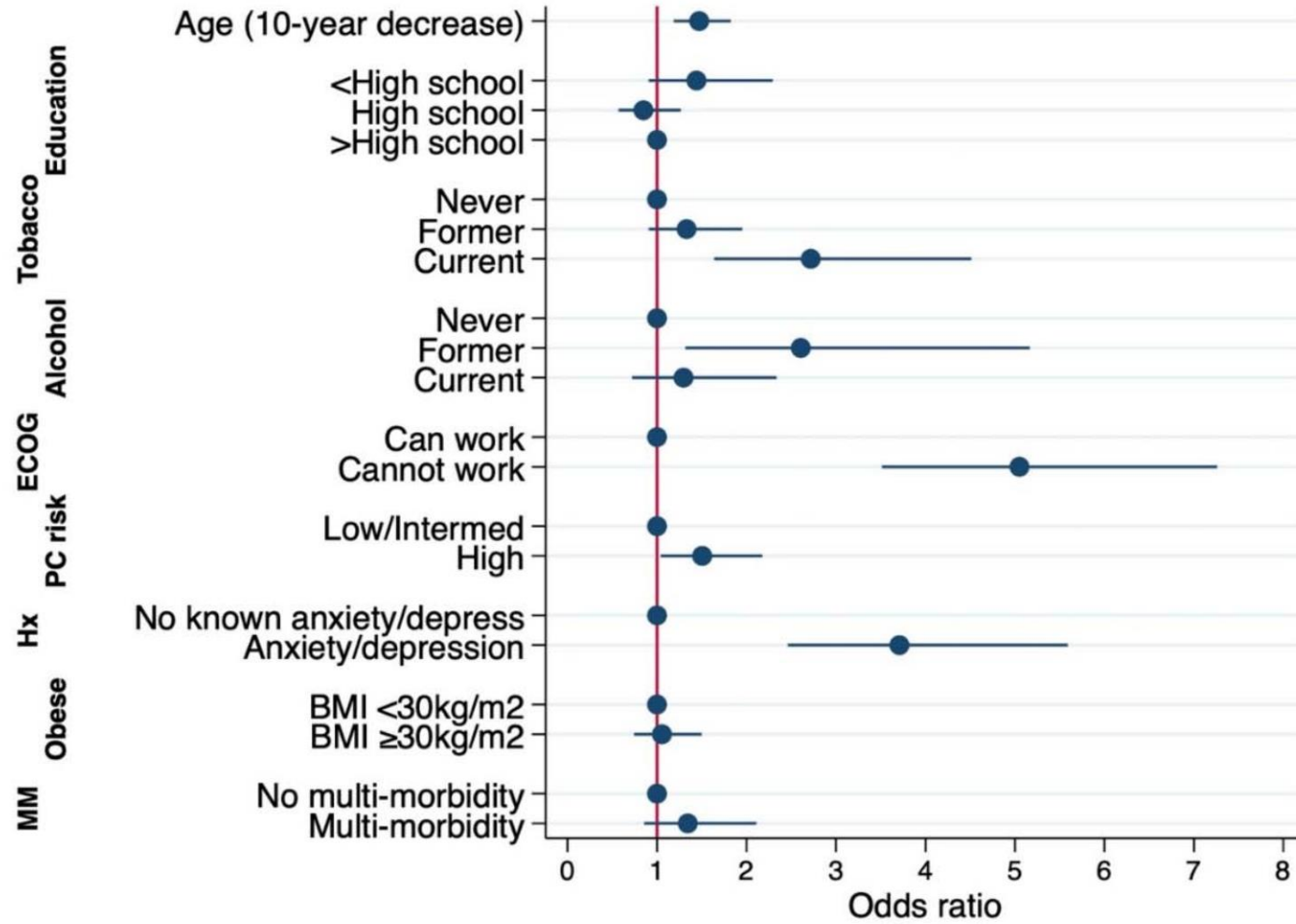
Baseline characteristics

- Age 68±8
- 225 (7%) metastatic disease
- PC risk
 - 8% low
 - 38% intermediate
 - 53% high (including metastatic disease)
- PC management
 - 42% prostatectomy
 - 38% radiotherapy
 - 9% observation
 - 43% on ADT
 - 1% on chemotherapy












Baseline Characteristics



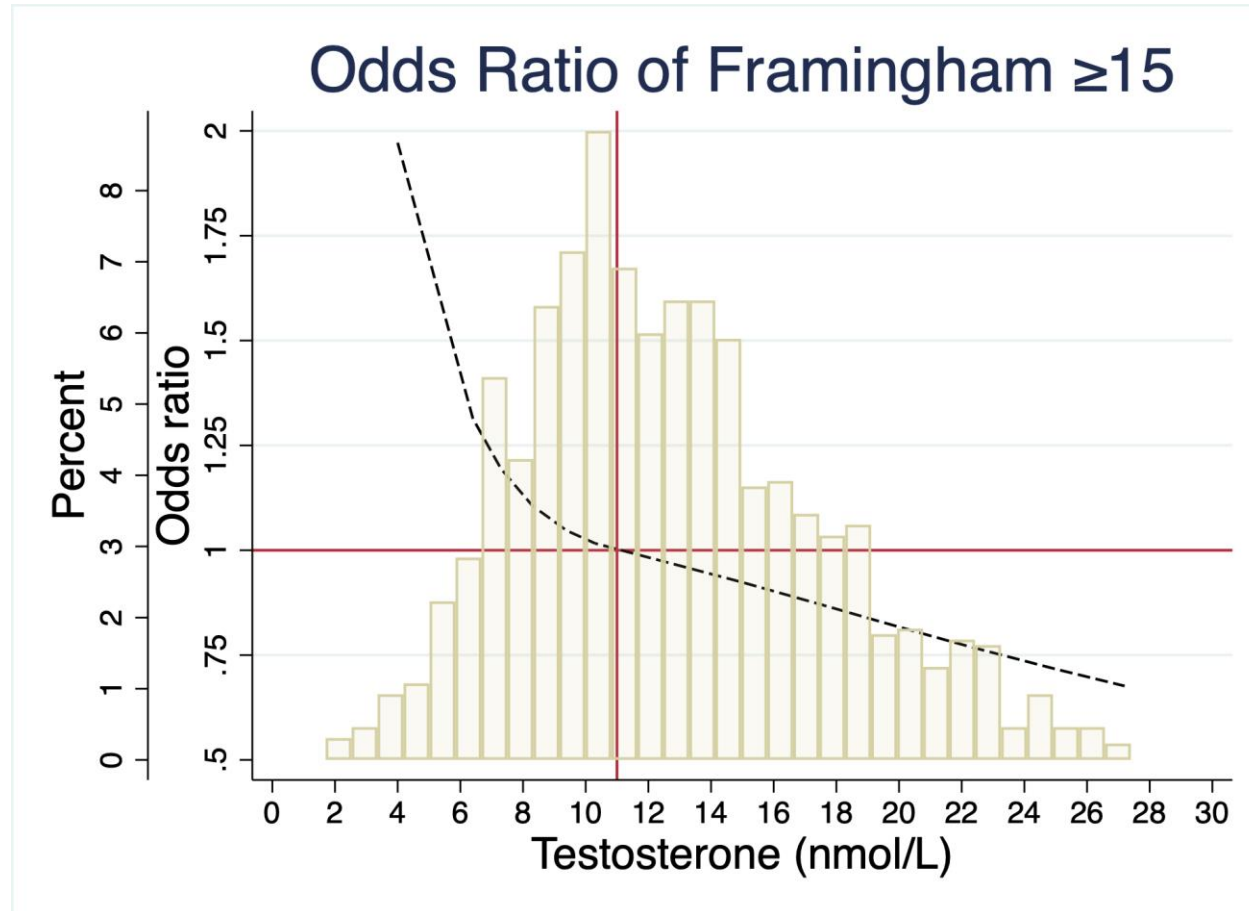
Inability to work is strongest predictor of prevalent depression



Development and Comparability of a Short Food-Frequency Questionnaire to Assess Diet in Prostate Cancer Patients: The Role of Androgen Deprivation Therapy in Cardiovascular Disease – A Longitudinal Prostate Cancer Study (RADICAL PC) Substudy

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T and CV Risk in Men with PC Naïve to ADT



CV Risk Factor Control in 2618 Men with PC from 4 Countries – RADICAL PC

