



The COcoa Supplement and Multivitamin Outcomes Study (COSMOS)

JoAnn E. Manson, MD, DrPH

Howard D. Sesso, ScD, MPH

**Brigham and Women's Hospital
Harvard Medical School**

Garnet L. Anderson, PhD

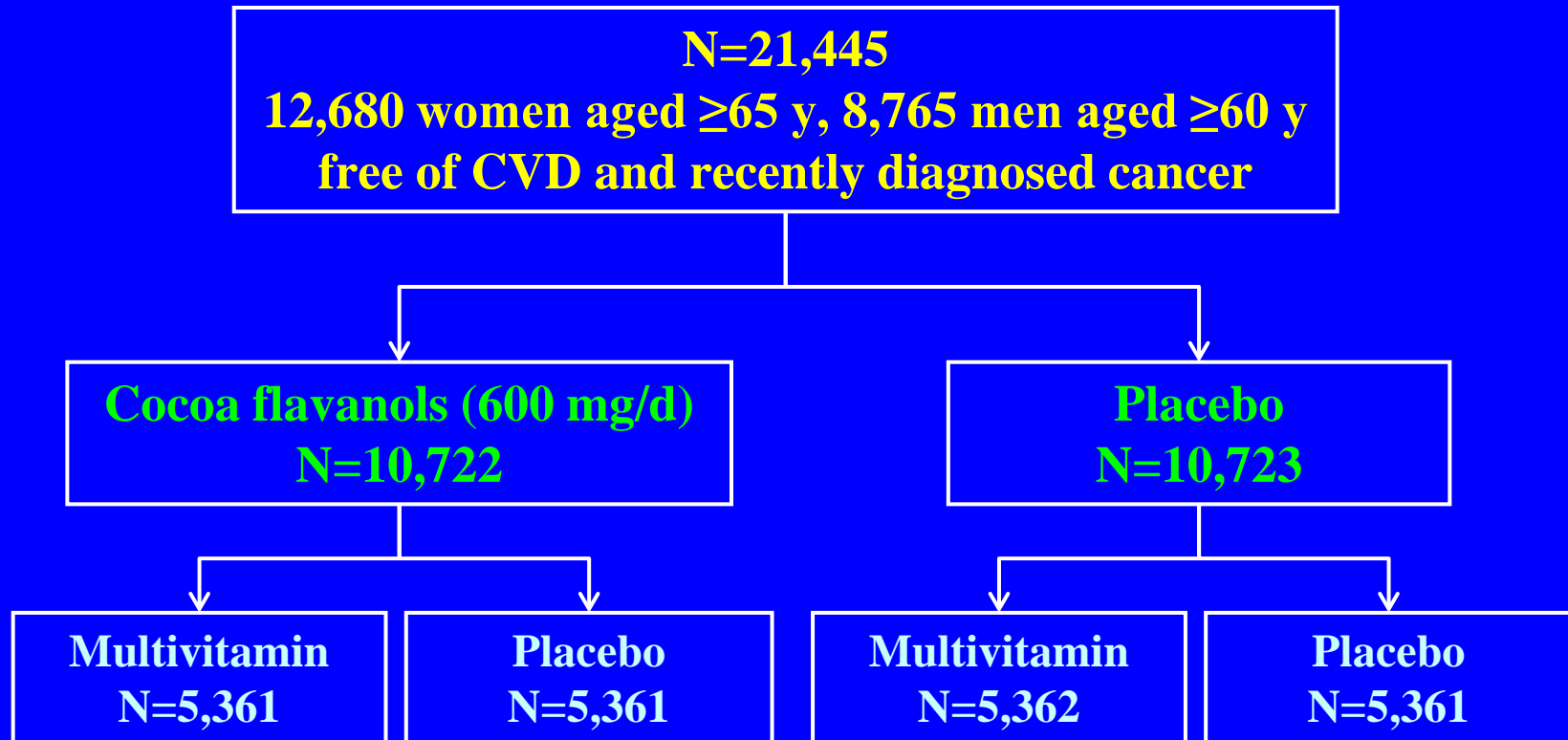
Fred Hutchinson Cancer Research Center

WHI Investigators Meeting

May 3, 2018



COcoa Supplement and Multivitamin Outcomes Study (COSMOS)



Median Treatment Period = 4.0 years

Primary Outcomes: Major cardiovascular events (MI, stroke, CVD death, and coronary revascularization) and total cancer (excluding non-melanoma skin cancer)

Baseline Blood/Urine Collection: >6800 participants; follow-up samples in a subgroup

Baseline Clinic Visit: Subcohort of ~600 Boston-based participants with follow-up at 2 years

COSMOS Blood (Biospecimen Collection)

- *Timeline and sample size of blood and urine collections*

Time	Actual to Date
Baseline (April 2016-March 2018)	~7,000
Year 1 (began August 2017)	1,200
Year 2	1000 (planned), mid-late 2018
Year 4	1000 (planned), mid-late 2020

- *Home visit via Examination Management Services Inc (EMSI)*
 - Fasting blood and spot urine collection
 - Seated BP, height, weight, waist and hip circumference
 - Participants can also collect blood and urine on their own or by visiting a Quest Diagnostics center around the U.S.
-

COSMOS Clinic Visits

- ***Timeline and sample size of clinic visits at BWH, Boston:***
 - **Baseline and 2-year follow-up** in ~600 women and men
- ***In-depth assessments at clinical visits:***
 - **Fasting blood, spot urine, anthropometry**
 - **Cognitive (including ModBent) and physical function**
 - **Vascular studies, 24-hour ABP, fecal samples, and MRI**

Time	Completed to Date
Baseline (Sept 2016 - March 2018)	603 (297 women, 306 men)
Vascular: Pulse Wave Velocity	~550
24-hour Ambulatory BP	~500
Fecal samples	~400
Brain MRI	105
Year 2 (same studies)	To begin in mid 2018

COSMOS Mind

- Supported through an NIH (NIA) grant.
- Led by Wake Forest University (Laura Baker, PI).
- *Telephone-based cognitive assessments:*
 - No dementia at baseline
 - ~45 minutes long
 - Telephone interview for cognitive status-modified (TICS_m) and other tests

Time	Completed to Date
Baseline (began July 2016)	2,249
Year 1 (began September 2017)	Ongoing (n~2000)
Year 2	To begin in mid 2018
Year 3	To begin in mid 2019

COSMOS Web (ModBent)

- Supported through Mars Symbioscience.
- In collaboration with Columbia University.
- *Web-based cognitive assessments:*
 - ~30 minutes long
 - Conducted at baseline, 1, 2, and 3 years
 - ModBent (novel pattern recognition task)
 - Flanker and Spatial Memory Tests

Time	Completed to Date
Baseline (began July 2016)	3,958
Year 1 (began October 2017)	Ongoing (n~3000)
Year 2	To begin in mid 2018
Year 3	To begin in mid 2019

COSMOS Eye

- Supported through an NIH (NEI) grant.
 - Led by Dr. Bill Christen at BWH.
 - Addition of cataract and age-related macular degeneration (AMD) as confirmed endpoints in COSMOS.
-

Conclusions

- **COSMOS provides exciting opportunities for biomarker, microbiome, ambulatory BP, vascular, cognitive, and vision studies.**
- **We encourage manuscript proposals and ancillary study applications leveraging this resource.**



Thank you!