Women’s Health Initiative (WHI) Database & Opportunities – Stefanick

WHI Components and Primary Outcomes

Hormone Therapy Trials:
- E+P: 16,608 with uterus*
- E-Alone: 10,739 post-HysX
  
  Primary: CHD; 2nd Hip Fx, Colorectal CA, *Uterine CA
  
  Primary Safety: Breast Cancer

Calcium/Vitamin D Trial
  
  [1 or 2 yr, DM +/- or HT Trial]
  
  Primary: Hip Fractures
  Secondary: Colorectal Cancer

Dietary Modification Trial
  
  Primary: Breast and Colorectal Cancers 2nd: CHD
  (Diet Intervention: N=19,541; Comparison: N=29,294)

Observational Study
  
  CT + OS: 161,808 total (1993-2005)
  Extension 2005-2010 (39 sites): 115,407
  2010-2015 (4 Regional Centers): 93,567
  Extension – 2020 (Stanford QSU)

WHI Components:

- 27,347
- 36,282
- 48,835
- 93,676

Controlled Trials

Observational Study

3 Controlled Trials

Observational Study
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**93,567** (87% of eligible)  
*Consented to Extension in 2010*  
*Baseline: 1993-1998 (mean ~20 yrs)*

<table>
<thead>
<tr>
<th>Baseline* Age</th>
<th>N: CT+ OS</th>
</tr>
</thead>
<tbody>
<tr>
<td>50-54</td>
<td>14,474</td>
</tr>
<tr>
<td>55-59</td>
<td>21,536</td>
</tr>
<tr>
<td>60-69</td>
<td>43,358</td>
</tr>
<tr>
<td>70-79</td>
<td>14,199</td>
</tr>
</tbody>
</table>

**Race/Ethnicity**

<table>
<thead>
<tr>
<th>Race/Ethnicity</th>
<th>N</th>
<th>Percentage</th>
</tr>
</thead>
<tbody>
<tr>
<td>White (HT: MRC*)</td>
<td>81,659</td>
<td>87%</td>
</tr>
<tr>
<td>Black (MRC*)</td>
<td>6,136</td>
<td>6.6%</td>
</tr>
<tr>
<td>Hispanic (MRC*)</td>
<td>2,472</td>
<td>2.6%</td>
</tr>
<tr>
<td>Asian/Pacific Islnd</td>
<td>1,880</td>
<td>0.5%</td>
</tr>
<tr>
<td>Native American</td>
<td>318</td>
<td></td>
</tr>
<tr>
<td>unknown</td>
<td>1,102</td>
<td></td>
</tr>
</tbody>
</table>

**National Geographic Diversity**  
(GPS-Coded WHI Participant Addresses & Centers*)

- *40 original sites* (10 minority recruitment sites)
- 3 DXA bone & body composition sites

**Map dates from 2009, courtesy of Eric Whitsel (UNC).**
Plotted locations represent sum total of ppt addresses that had already been processed & geocoded at that point in time. **Restricted to 48 contiguous states, despite Hawaii WHI site and fact that many participants lived (& now live) elsewhere**

*MRC: GWAS, CV biomarkers*

[https://www.whi.org/SitePages/WHI%20Home.aspx](https://www.whi.org/SitePages/WHI%20Home.aspx)
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https://www.whi.org/researchers/SitePages/Home.aspx

Life and Longevity After Cancer (LILAC)
Women's Health Initiative Strong & Healthy (WHISH) Trial

Randomized Consent Study Design - based on Zelen. N Eng J Med 1979

Eligible based on existing data

- Yes
  - Randomize
  - Control
  - Follow, per original protocol

- No
  - Follow, per original protocol

Key Inclusion criteria:
- Alive
- WHI Medical Record Cohort
- or linked to CMS (Medicare)

Opt Out: no

- Consent
  - Follow, per original protocol

- Intervention
  - Follow, per original protocol

Primary Outcome: Major CV events (MI, Stroke, CV Death)

*Exclusions:
- Dementia
- Living in a nursing home
- Self-reported inability to walk

Accelerometer Sub-study

Physical Activity Go4Life. Intervention
Mailings ± IVR* (automated phone system)
Website, etc. + live advisor, PRN

** Interactive Voice Response System (Consent)

http://go4life.nia.nih.gov/