SUPPLEMENTARY INFORMATION

WISDOM Randomized Trial Comparing Risk-Based Versus Annual Breast Cancer Screening: Baseline Characteristics and Study Conduct

Fiscalini et al.

Table of Contents

Supplementary Table S1: Minority enrolment in WISDOM

Year-by-year rates of enrolment to WISDOM categorized by self-reported race/ethnicity

	White, NH	Black or African American	Native Hawaiian or Other Pac Islander/American Indian or Alaska Native, NH	Asian, NH	Two or More Race, NH	Hispanic or Latino	Unknown/Pref not to answer/other
Start-2019	81.4%	1.7%	0.3%	4.5%	2.7%	8.1%	1.2%
2020	74.9%	4.1%	0.4%	5.9%	3.3%	10.4%	1.0%
2021	73.4%	8.1%	0.5%	4.0%	3.1%	10.2%	0.7%
2022	67.4%	11.5%	0.6%	4.4%	3.9%	11.4%	0.7%
2023	59.4%	17.5%	0.8%	5.8%	3.1%	11.8%	1.5%
All Time	75.6%	5.6%	0.4%	4.6%	3.1%	9.6%	1.0%

Supplementary Table S2: List of clinical sites

List of WISDOM recruitment sites and years of enrolment in WISDOM 1.0

Site	Year Site Opened
Initial sites	
University of California San Francisco	2016
University of California San Diego	2016
University of California Los Angeles	2017
University of California Davis	2017
University of California Irvine	2017
Sanford Health	2017
Expansion sites	
University of Chicago	2019
University of Alabama at Birmingham	2020
Diagnostic Center of Miami	2020
Louisiana State University	2020
Veterans Affairs*	2021

*Recruitment only through select VA centers

Supplementary Table S3: Factors affecting patient participation choices

Multivariate Analysis Comparing Participant Choice of Randomized versus Self-Selection into Annual or Personalized. NH = Non-hispanic

	Self-Select Risk-based vs Randomized				Self-Select Annual vs Randomized			
	RR	Lower CI: 2.5%	Upper CI: 97.5%	p-value	RR	Lower CI: 2.5%	Upper CI: 97.5%	p-value
Age (years) at Group Selected Date								
40-49	ref	ref	ref	ref	ref	ref	ref	ref
50-59	0.93	0.89	0.97	0.0002	1.27	1.09	1.48	0.0018
60-69	0.88	0.84	0.92	<0.0001	1.54	1.29	1.84	<0.0001
70-74	0.79	0.73	0.84	<0.0001	2.01	1.64	2.47	<0.0001
Race, Ethnicity								
NH White	ref	ref	ref	ref	ref	ref	ref	ref
Hispanic	1.15	1.11	1.20	<0.0001	1.22	1.04	1.41	0.0118
NH Asian	1.20	1.14	1.27	<0.0001	1.41	1.17	1.71	0.0004
NH Black or African American	1.03	0.97	1.09	0.3825	1.58	1.33	1.88	<0.0001
NH More than one race	1.14	1.07	1.21	<0.0001	0.75	0.55	1.04	0.0886
NH Native Hawaiian or Other Pac Islander/Am Indian or Alaska Native	087	0.71	1.08	0.2124	0.89	0.41	1.93	0.7654
Other/Unknown	1.34	1.22	1.48	<0.0001	1.46	1.00	2.13	0.0521
Family History at Baseline								
No First or Second Degree Relative	ref	ref	ref	ref	ref	ref	ref	ref
First Degree Relative	1.48	1.42	1.53	<0.0001	0.98	0.86	1.11	0.7066
Second Degree Relative	1.23	1.19	1.28	<0.0001	0.93	0.84	1.04	0.2168
First and Second Degree Relative	1.60	1.54	1.66	<0.0001	0.96	0.82	1.12	0.5673
Don't Know	1.21	1.15	1.26	<0.0001	0.79	0.67	0.94	0.0077
No Response/Missing	1.27	1.15	1.40	<0.0001	0.97	0.67	1.40	0.8705
Any Atypia Biopsies†								
Not Biopsied	ref	ref	ref	ref	ref	ref	ref	ref
Biopsied - No ADH	1.09	1.06	1.12	<0.0001	1.11	1.01	1.23	0.0336
Biopsied - Yes ADH	1.45	1.35	1.56	<0.0001	1.27	0.87	1.86	0.2069
Hormone Replacement Therapy Use Ever†								
None	ref	ref	ref	ref	ref	ref	ref	ref
One or More	1.11	1.07	1.14	<0.0001	1.16	1.05	1.29	0.0043
Age (years) at Menarche†								
12 to 13	ref	ref	ref	ref	ref	ref	ref	ref
Under age 12	0.97	0.94	1.00	0.0769	0.93	0.82	1.06	0.2940
14 or above	1.00	0.97	1.03	0.9317	0.99	0.89	1.10	0.8273
Age (years) at first live birth†								
Nulliparous	ref	ref	ref	ref	ref	ref	ref	ref
<20 years	0.95	0.90	1.00	0.0637	0.92	0.75	1.12	0.3950
20-24 years	0.94	0.90	0.98	0.0085	0.94	0.82	1.09	0.4467
25-29 years	0.96	0.92	1.00	0.0391	1.03	0.90	1.18	0.6621
30-34 years	1.02	0.99	1.07	0.2246	0.94	0.80	1.09	0.3860
>34 years	1.05	1.00	1.10	0.0412	0.96	0.81	1.14	0.6679
Baseline Area Deprivation Index[1] (ADI)								
Least Disadvantaged (1 to 3)	ref	ref	ref	ref	ref	ref	ref	ref
Middle Disadvantaged (4 to 6)	1.00	0.97	1.03	0.8976	0.96	0.87	1.07	0.4578
Most Disadvantaged (7 to 10)	0.94	0.91	0.98	0.0018	0.94	0.83	1.06	0.3016
Data suppressed/Not geocoded	1.08	1.02	1.15	0.0131	1.18	0.96	1.46	0.1236

† denotes imputed variable

[1] Kind & Buckingham, N. Engl. J. Med. 378, 2456–2458 (2018).

Deleted: ¶

Supplementary Table S4. Risk assessment and screening recommendations

Risk:	Highest Risk	Elevated Risk	Average Risk	Lowest Risk
Criteria/ Threshold	BRCA1/2, TP53, PTEN, STK11, CDH1 mutation carrier OR ATM, PALB2 or CHEK2 mutation carrier with positive family history of breast cancer OR Women with a ≥6% 5-year risk (risk of an average BRCA carrier) OR Women with a history of mantle radiation between ages 10-30 years	Women aged 40-49 with extremely dense breasts OR Women at a ≥1% 5-year risk of developing ER- breast cancer based on susceptibility SNPs OR Women in top 2.5th percentile of risk by 1-year age category OR ATM, PALB2 or CHEK2 mutation carrier without a positive family history** of breast cancer	Women aged 50-74 OR Women aged 40-49 with a ≥1.3% 5-year risk (risk of an average 50 year-old woman)	Women aged 40-49 with a <1.3% 5-year risk of developing breast cancer
Screening Rec:	Annual mammogram Adjunct MRI BHS active outreach Risk reduction consultation	Annual mammogram* BHS active outreach Risk reduction consultation	Biennial mammogram†	No screening until age 50

* If individual does not meet criteria for annual mammogram + MRI
† If individual does not meet criteria for annual mammogram or annual mammogram + MRI
** Family history is defined as a first degree relative with breast cancer, two second-degree relatives with breast cancer, or one second-degree relative diagnosed prior to age 45.
(previously published in Esserman et al. NPJ Breast Cancer. 2017;3(1):34. doi:10.1038/s41523-017-0035-5)